



VERMONT JOURNAL
of ENVIRONMENTAL LAW

Volume 20 • Issue 1

VERMONT JOURNAL OF ENVIRONMENTAL LAW
VERMONT LAW SCHOOL

Volume 20, Issue 1

Spring 2019

ARTICLES

An Analysis of Establishing Regional Environmental Governance
Through a Mega Regional Trade Agreement: The Asia-Pacific
Practice

I-Ju Chen..... 1

From Un-Coordinated to Efficient: A Proposal for Regulating
GE Products in a Way That Meets the Needs of Consumers,
Producers, and Innovators

Sarah Luther 32

NOTES

A Current Affair: Ensuring Sustainable Aquaculture in the U.S.
Exclusive Economic Zone

Colby Stewart..... 70

FERC Compliance with NEPA: Upstream and Downstream
Impacts

Ata Akiner 95

VERMONT JOURNAL OF ENVIRONMENTAL LAW

VERMONT LAW SCHOOL

Volume 20, Issue 1

Spring 2019

EDITORIAL BOARD

EDITOR-IN-CHIEF

Dillon Post

ADMINISTRATIVE EDITOR

Rasheta Butler

SENIOR MANAGING EDITOR

Bodie Waldrop

SENIOR ARTICLES EDITOR

Amanda Carrington

SENIOR NOTES EDITOR

Kyle Sasser

SYMPOSIUM EDITORS

Hannah Dean

Margaret Shugart

WEB EDITOR

Nicholas Lansfeldt

SOCIAL MEDIA EDITOR

Andrea Moreno

SYMPOSIUM EDITORS

Aaron Kelly

Daphneyse Marcelin

Nicole Webbert

EVENTS EDITOR

Ethan Story

PRODUCTION EDITORS

Michael Brown

Mandy Jaggarsal

NOTES EDITORS

Eli Ancharski

Tabitha Bouchard

Victoria Santry

Mia Schiappi

ARTICLES EDITORS

Eddie Kim

Luckie Milad

Janious Steed

ENVIRONMENTAL

JUSTICE EDITOR

Nico Lustig

EDITORIAL STAFF

Twisha Balasubramanian

Dan Brown

Sedona Chavez

Olivia Deans

Philip Deatherage

Andrew Dinwoodie

Lizzie Fainberg

Lewis Grove

Chester Harper

Alyson Hehr

Marisa Heiling

Abby Hogan

Andrew Hulett

Noah Jalloes-Prufer

Charles Kuo

Gabriela McMurtry

Sarah Mooradian

William Northrop

Yasmin Perez Ortiz

Nicha Rakpanichmanee

Savannah Rose

Dayna Smith

Justin Somelofske

Alex Steinbach

Therese Wilkerson

FACULTY ADVISOR

John Echeverria

VERMONT JOURNAL OF ENVIRONMENTAL LAW

Vermont Law School
P.O. Box 96
South Royalton, Vermont 05068
(802) 831-1024
vjel@vermontlaw.edu

vjel.vermontlaw.edu

Cite to this *Journal* as: 20 VT. J. ENVTL. L. (2019).

The views expressed in this issue are those of the authors and do not represent the position or views of VJEL or Vermont Law School.

Submissions: VJEL welcomes the submission of unsolicited articles, comments, essays, and book reviews. Manuscripts can be submitted to the above addresses.

Subscriptions: You can subscribe directly to our Journal online at vjel.vermontlaw.edu.

Copyright: © Copyright 2019 by Vermont Law School. All rights reserved. Except as otherwise provided, the author of each article in this issue has granted permission for copies of that article to be made for classroom use, provided that: (1) the author and *Vermont Journal of Environmental Law* are identified on the copied materials; (2) each copy bears the proper notice of copyright; and (3) *Vermont Journal of Environmental Law* is notified in writing of the use of the material(s).



This Journal is available exclusively in electronic format.

AN ANALYSIS OF ESTABLISHING REGIONAL ENVIRONMENTAL GOVERNANCE THROUGH A MEGA REGIONAL TRADE AGREEMENT: THE ASIA-PACIFIC PRACTICE

*I-Ju Chen**

Introduction.....	2
I. The Linkage Between Trade and the Environment	4
A. The Debate Between Trade Liberalization and Environmental Protection	4
B. WTO Agreements and Case Law Concerning Environmental Protection	6
II. The Role of Free Trade Agreements in Environmental Protection in Asia-Pacific	7
III. An Overview of APEC	11
A. APEC's Function in Protecting the Environment.....	15
B. Future Goals and Limitations.....	16
IV. RTA's Significance in Protecting the Environment: The Case Study of CPTPP's Environmental Chapter	18
A. RTA's Significance in Protecting the Environment	18
B. Theory of Regional Environmental Governance	20
C. An Analysis of the CPTPP's Environmental Chapter.....	22
D. Improving the CPTPP for Better Environmental Governance in Asia-Pacific.....	27
Conclusion	29

* Ph.D. candidate in law at the University of Birmingham in the UK (ixc495@bham.ac.uk). Author appreciates Luca Rubini, Rilka Dragneva-Lewers and Yao-Ming Hsu for their feedback on an earlier draft of this article. Author also appreciates the editors of the *Vermont Journal of Environmental Law* for their editing help and insightful comments on this article. All errors and omissions are the author's.

INTRODUCTION

Regional environmental governance is essential to remediate transboundary environmental harm.¹ Establishing regional environmental governance abrogates tensions and complexities of harm arising from diverse economic development in Asia-Pacific countries.² Additionally, Asia-Pacific countries have unequal environmental standards stipulated in their domestic laws and regulations. Their confusing environmental standards likely result in conflicts across the region. These inconsistent environmental standards, along with potential disputes—such a sensitive field and confrontational phenomenon—further complicate the process to establish regional environmental governance in Asia-Pacific. On a multilateral level, the debate on the linkage of trade liberalization and environmental protection at the World Trade Organization (WTO) continues. In particular, four out of the total nine environmental disputes in the WTO and the General Agreement on Tariffs and Trade (GATT) occurred in Asia-Pacific.³ These disputes indicate the significance of establishing regional environmental governance in Asia-Pacific, not only to handle transboundary environmental harm but also to prevent environmentally-related trade disputes.

The Asia Pacific Economic Cooperation (APEC) is a regional forum that focuses on trade and economic issues and carries out regional environmental governance. APEC member economies operate on open regionalism. This voluntary and non-binding scheme, however, has caused obstacles for APEC to protect the environment. The main factor underlying this difficulty is the complicated geopolitics in Asia-Pacific. APEC's environmental protection objective derives from the nature of transboundary environmental matters,

1. Koh Kheng Lian & Nicholas A. Robinson, *Regional Environmental Governance: Examining the Association of Southeast Asian Nations (ASEAN) Model*, in GLOBAL ENVTL. GOVERNANCE: OPTIONS & OPPORTUNITIES 101, 102 (Daniel C. Esty & Maria H. Ivanova ed., 2002).

2. John Davis, *Regional Economic Integration, the Environment and Community: East Asia and APEC*, 17 INT'L REV. OF APPL. ECON. 69, 71 (2003) (listing an array of common transboundary environmental problems including water quality and quantity problems from solid and toxic wastes from industrial, agricultural, and domestic sectors).

3. See, e.g., Appellate Body Report, *United States—Import Prohibition of Certain Shrimp and Shrimp Products*, WTO Doc. WT/DS/58 (adopted Nov. 6, 1998) (citing the *Shrimp-Turtle* case brought by India, Malaysia, Pakistan, and Thailand against the U.S.); see also Report of the Panel, *United States—Restrictions on Imports of Tuna*, WTO/DS/21 (circulated Sept. 3, 1991) (citing the *Tuna-Dolphin* case brought by Mexico against the U.S.); Report of the Panel, *Canada—Measures Affecting Exports of Unprocessed Herring and Salmon*, L/6268 (adopted Mar. 22, 1988) (citing the case concerning measures affecting exports of unprocessed herring and salmon brought by U.S. against Canada.); Report of the Panel, *United States—Prohibition on Imports of Tuna and Tuna Products from Canada*, L/5198 (adopted Feb. 22, 1982) (citing the case concerning prohibition of imports of tuna and tuna products brought by Canada against U.S.).

which requires a regional approach to deal with such matters.⁴ As APEC is considered the hub of trade on environmental goods, it recognizes the significant development of trade measures aimed towards environmental protection in Asia-Pacific.⁵

Based on the linkage between trade and the environment in Asia-Pacific, this article argues for the necessity of creating regional environmental governance by a mega-regional trade agreement (RTA).⁶ In this article, the countries in Asia-Pacific are those twenty-one member economies in APEC.⁷ Besides analyzing the regional environmental governance of APEC, this article explains why environmental governance in other Asia Pacific regional economic forums do not function well. The identified regional economic forums include: Asian Development Bank (ADB), Inter-American Development Bank (IDB), and Asian Infrastructure Investment Bank (AIIB). These members overlap with those in APEC. These regional forums lack sufficient institutional capacity and arrangements, technical expertise, and financial support. Therefore, a mega-RTA is a significant tool to establish regional environmental governance.

This rest of the article is structured as follows. The second section examines the linkage between trade and the environment globally and regionally in Asia-Pacific. The third section analyzes how APEC implements environmental protection. The fourth section evaluates why the environmental chapter in the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP)—the successor of Trans-Pacific Partnership Agreement (TPP)—appears to introduce more effective regional environmental governance than APEC. However, the CPTPP environmental chapter faces rectifiable criticisms. Finally, the article concludes with the contemporary challenges and opportunities in international trade and environmental law, along with the associated policies and governance in Asia-Pacific.

4. Davis, *supra* note **Error! Bookmark not defined.**, at 74.

5. Patricia M. Goff, *The Environmental Goods Agreement: A Piece of the Puzzle*, No. 72 CIGI PAPERS 2, 2 (June 2015), https://www.cigionline.org/sites/default/files/cigi_paper_no.72.pdf (last visited Mar. 9, 2019).

6. See *Regional trade agreements and the WTO*, WTO, https://www.wto.org/english/tratop_e/region_e/rta_pta_e.htm (last visited Mar. 9, 2019) (adopting regional trade agreements (RTAs) to describe free trade agreements between more than two signing parties in a specific geographical area. WTO defines RTAs as reciprocal trade agreements between two or more partners, including free trade agreements and customs unions).

7. *Member Economies*, ASIA-PACIFIC ECON. COOPERATION, <https://www.apec.org/about-us/about-apec/member-economies.aspx> (last visited Mar. 9, 2019) (consisting of Australia, Brunei Darussalam, Canada, China, Chile, Hong Kong, Indonesia, Japan, Malaysia, Mexico, New Zealand, Papua New Guinea, Peru, Philippine, Russia, South Korea, Singapore, Chinese Taipei, Thailand, US, and Vietnam).

I. THE LINKAGE BETWEEN TRADE AND THE ENVIRONMENT

A. The Debate Between Trade Liberalization and Environmental Protection

Since the 1990s, the WTO has been criticized for giving little concern to social issues related to non-tariff barriers to trade,⁸ including environmental protection.⁹ The World Commission on the Social Dimension of Globalization, however, indicated that trade liberalization can improve social protections. Increased trade profits can bring general efficiencies with benefits to the environment.¹⁰

The WTO's chief objective is to substantially reduce tariffs and non-tariff barriers to promote trade liberalization at a multilateral level.¹¹ During the final period of the Uruguay Round, between 1986 and 1994, certain member states within the WTO sought to expose numerous environmental issues. However, the linkage between free trade and the environment is complicated. The debate on whether they are mutually beneficial has revolved around particular issues.¹² While one could advocate free trade as a source of economic development, it can also damage the environment through increased pollution.¹³ If states focus solely on promoting trade interests, there is a high possibility that their environmental regulatory autonomy could be negatively affected.¹⁴ Moreover, trade-supportive policy can often lead to environmental harms, such as the examples in Hong Kong and the Pearl River Delta during the 1980s and 1990s.¹⁵ The Global

8. LORAND BARTELS, SOCIAL ISSUES IN REGIONAL TRADE AGREEMENTS LABOUR, ENVIRONMENT AND HUMAN RIGHTS, in LEGAL STUDIES RESEARCH PAPER SERIES 1, 2–5 (2014), reprinted in BILATERAL AND REG'L TRADE AGREEMENTS: COMMENTARY, ANALYSIS AND CASE STUDIES 364 (Simon Lester, Bryan Mercurio and Lorand Bartels eds., 2nd ed. 2015).

9. *Id.* at 3.

10. WORLD COMMISSION ON THE SOCIAL DIMENSION OF GLOBALIZATION, A FAIR GLOBALIZATION: CREATING OPPORTUNITIES FOR ALL, 57–58 (2004), <http://www.ilo.org/public/english/wcsdg/docs/report.pdf> (last visited Mar. 9, 2019).

11. Marrakesh Agreement Establishing the World Trade Organization, Preamble, Apr. 15, 1994, 1867 U.N.T.S. 154, 154 [hereinafter Marrakesh Agreement] (“Recognizing that their relations in the field of trade and economic endeavor should be conducted with a view to ... while allowing for the optimal use of the world's resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment . . .”).

12. Goff, *supra* note 5, at 2.

13. *Id.*

14. S. Thomas, The Necessity of Trade-Restrictive Measures Aimed at Protecting the Environment 3 (2004) (unpublished master thesis, University of Groningen) (on file with author), cited in Firehiwot Wujira, *Non-Trade Concerns in Interpreting General Exception Clauses of WTO Agreements*, 4 MIZAN L. REV. 164, 164 (2010).

15. See Christine Loh, *Tackling Cross-border Air Quality in Southern China*, China Environment Series, WOODROW WILSON INT'L CTR. FOR SCHOLARS, 64 (2007), <https://www.wilsoncenter.org/sites/default/files/ces9.pdf> (last visited Mar. 9, 2019) (describing how Hong Kong and the Pearl River Delta region experienced environmental issues as industrialization grew).

Commission on the Economy and Climate Change (Commission), a major international initiative, also reported increased pollution after the economic development. In 2014, the Commission asserted that globalization has resulted in both high- and low-carbon growths over the last 25 years. These carbon growths were important economic stimuli for developed and developing countries, including emerging economies. Still, carbon growths have significantly changed production in countries that have coal-based energy systems and less powerful pollution controls. Thus, the trade boom has likely increased the amount of global greenhouse gas emissions.¹⁶

Nonetheless, free trade can achieve objectives of environmental protection. The “Environmental Kuznets Curve” supports this claim. Kuznets hypothesized that a turning point exists in the relationship between environmental pollution and trade liberalization when economic profits increase to a certain margin.¹⁷ Trade liberalization can also help achieve environmental goals in other ways. For instance, a positive correlation exists between economic development and the responsibility with which states pursue environmental protections. Sallie James argues that because trade leads to wealth with an increased desire and ability to protect the environment, these two areas—trade and environmental protection—are complementary.¹⁸ According to the Commission, trade is important to accelerate the transmission of low-carbon technologies to countries with low-cost manufacturing. Trade both reduces cost and increases the geographic range, within which these technologies circulate.¹⁹ Fundamental economic theories, such as comparative advantage, help explain the role that trade has played in facilitating low-carbon technologies.²⁰ Economic efficiency gained through liberal economic practices can indeed generate positive environmental results.²¹

16. THE GLOB. COMM’N ON THE ECON. AND CLIMATE CHANGE, BETTER GROWTH BETTER CLIMATE: THE NEW CLIMATE ECONOMY REPORT 49 (2014), http://static.newclimateeconomy.report/wp-content/uploads/2014/08/NCE_SynthesisReport.pdf (last visited Mar. 9, 2019).

17. Simon Kuznets, *Economic Growth and Income Inequality*, 45 AM. ECON. REV. 1, 20 (1955) (describing other trends also, like inequality, that change with economic growth).

18. Sallie James, *Free Trade is a Boon to the Environment*, CATO INST. (Oct. 8, 2009), <https://www.cato.org/publications/commentary/free-trade-is-boon-environment> (last visited Mar. 9, 2019).

19. See GLOB. COMM’N ON THE ECON. AND CLIMATE CHANGE, *supra* note 16, at 49 (increasing global supply chains for solar and wind technology has reduced cost).

20. See ALAN PROFESSOR WINTERS, INTERNATIONAL ECONOMICS 13, 21–26 (4th ed. 1991) (evaluating the Ricardian model of comparative advantage).

21. See generally JENNIFER CLAPP & PETER DAUVERGNE, PATHS TO A GREEN WORLD: THE POLITICAL ECONOMY OF THE GLOBAL ENVIRONMENT 177 (The MIT Press 2005) (showing that companies become more efficient with less waste created, which, in turn, allows for less environmental issues).

Likewise, carefully considering the environment can spur economic profits and trade opportunities.²² For developing countries, however, green protectionism can prove burdensome. Developing countries must meet higher environmental standards, which makes development gains more difficult to achieve. Thus, the relationship between trade and the environment is complicated, but a positive correlation between these two areas can exist.²³

Tangible institutional efforts to make this relationship work might come in the form of international environmental treaties and WTO disputes. Whether the WTO retains its bias towards trade liberalization or moves to adopt greater environmental responsibility and justice frames the current debate about the future of this complex linkage between trade and the environment.

B. WTO Agreements and Case Law Concerning Environmental Protection

WTO Agreements are not merely focus on trade liberalization, they also consider environmental protection. Environmental considerations are incorporated into: the preamble of the WTO Agreement;²⁴ Article 20(b)(g) of the GATT;²⁵ Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement);²⁶ and Agreement on Technical Barriers to Trade (TBT Agreement).²⁷ Like other WTO rulings, the Appellate Body Report in *Shrimp-Turtle* affirmed that the WTO Agreement explicitly recognizes the objective of sustainable development.²⁸ The Appellate Body Report also recognized the important social dimension of sustainable development.²⁹ In the *EC-Tariff Preferences*, the WTO Appellate Body Report referred to its report in *Shrimp-Turtle* and affirmed that sustainable development is a goal of the WTO.³⁰

22. Goff, *supra* note 5, at 2.

23. *Id.*

24. Marrakesh Agreement, *supra* note 11, at 154.

25. See General Agreement on Tariffs and Trade art. 20, Oct. 30, 1947, 60 Stat. A-11, 55 U.N.T.S. 194, (stipulating exceptions for measures that are: “(b) necessary to protect human, animal or plant life or health; (g) relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption.”).

26. See WTO, *Understanding the WTO Agreement on Sanitary and Phytosanitary Measures*, (May 1998), https://www.wto.org/english/tratop_e/sps_e/spsund_e.htm (last visited Mar. 9, 2019) (dealing with the sanitary and phytosanitary measures to ensure food safety and to protect human, animal, and plant health based on the scientific principles and sufficient scientific evidence).

27. Agreement on Technical Barriers to Trade Art 2, Jan. 1, 1995, 1869 U.N.T.S. 299. (serving to consider environmental protection).

28. Appellate Body Report, *United States—Import Prohibition of Certain Shrimp and Shrimp Products*, ¶ 129, WTO Doc. WT/DS58/AB/R (adopted Nov. 6, 1998).

29. *Id.*

30. Appellate Body Report, *European Communities—Conditions for the Granting of Tariff Preferences to Developing Countries*, ¶ 94, WTO Doc. WT/DS246/AB/R (Apr. 7, 2004).

When the WTO interpreted its agreements to settle environmentally-related trade disputes, the WTO panels and Appellate Body illustrated the controversy of free trade and the environment. *Shrimp–Turtle* is the most recognized case to interpret Article 20 of the GATT. The Appellate Body Report explained that, although the contested measure aimed for environmental protection under Article 20(g) of the GATT, the measure unjustifiably discriminated between WTO members. Thus, the US environmental measures in the *Shrimp Turtle* case contradicted the criteria of the chapeau of Article 20 of the GATT.³¹

According to WTO case law, the WTO Appellate Body should not apply Article 20 exceptions to the GATT's substantive rules. Specifically, these exceptions would frustrate or defeat a person's GATT rights. However, the WTO Appellate Body requires reasonable application of trade measures to qualify for an exception. The chapeau—the terms of the headnote—of Article 20 is key to determine whether a measure qualifies. WTO case law implies environment-related trade measures that arbitrarily or unjustifiably discriminate between WTO members will not comply with the WTO rules.³²

II. THE ROLE OF FREE TRADE AGREEMENTS IN ENVIRONMENTAL PROTECTION IN ASIA-PACIFIC

The Doha Round in 2001 represented a milestone in reconciling trade liberalization and the environment within the WTO. Doha announced the declaration to support environmental protection in multilateral trade liberalization.³³ Paragraph 31 of the Doha Ministerial Declaration explicitly states how this declaration is a significant step towards a positive relationship between free trade and environmental concerns.³⁴ Nevertheless, the Doha

31. Appellate Body Report, *United States—Import Prohibition of Certain Shrimp and Shrimp Products*, *supra* note 28, at ¶ 186.

32. Appellate Body Report, *Canada—Certain Measures Affecting the Renewable Energy Generation Sector*, 1, 141–43, WT/DS412/AB/R (May 6, 2013) (holding that Canada's Micro Feed-In Tariff Program is inconsistent with WTO principles).

33. World Trade Organization, Ministerial Declaration of 20 November 2001, WTO Doc. WT/MIN(01)/DEC/1 (2001).

34. *See id.* ¶31 (“With a view to enhancing the mutual supportiveness of trade and environment, we agree to negotiations, without prejudging their outcome, on:

- (i) the relationship between existing WTO rules and specific trade obligations set out in multilateral environmental agreements (MEAs). The negotiations shall be limited in scope to the applicability of such existing WTO rules as among parties to the MEA in question. The negotiations shall not prejudice the WTO rights of any Member that is not a party to the MEA in question;
- (ii) procedures for regular information exchange between MEA Secretariats and the relevant WTO committees, and the criteria for the granting of observer status;

Round did not resolve environmental issues with trade liberalization.³⁵ The obstacle resulted from WTO members' attempts to reconcile the interests of developed and developing countries. To solve this deadlock, members in the WTO negotiated bilateral and regional trade agreements.³⁶

Article 24 of the GATT, Article 5 of the GATS, and the enabling clause stipulate the legal basis to establish customs unions or free trade areas outside of the WTO.³⁷ The impact of regional economic integration schemes outside of the WTO is widely debated. "Friends of the WTO" view these schemes as complementary building blocks of multilateral free trade. However, "foes of the WTO" claim that these types of preferential trade arrangements form exclusive trade blocs that will eventually impair trade multilateralism and become "stumbling blocks."³⁸

(iii) the reduction or, as appropriate, elimination of tariff and non-tariff barriers to environmental goods and services.

We note that fisheries subsidies form part of the negotiations provided for in paragraph 28.”).

35. Mark Halle, *Trade and Environment: Looking Beneath the Sands of Doha?*, 3 J. EUR. ENVTL. & PLAN. L. 107, 109 (2006); see generally WTO Secretariat, *Developmental Aspects of the Doha Round of Negotiations*, WTO Doc. WT/COMTD/W/143 (Nov. 22, 2005) (including the Doha Round objectives, such as trade and intellectual property, trade and development, and trade and investment).

36. See generally *Regional Trade Agreements*, WTO, https://www.wto.org/english/tratop_e/region_e/region_e.htm#facts (last visited Mar. 9, 2019) (evolving RTAs in the world showed a significant growth of RTAs in force after 2008. In 2008, 35 RTAs were in force).

37. See The General Agreement on Tariffs and Trade art. 24, July 1986 https://www.wto.org/english/docs_e/legal_e/gatt47.pdf (last visited Mar. 9, 2019) (“[T]he provisions of this Agreement shall not prevent . . . the formation of a customs union or of a free-trade area . . . : (a) with respect to a customs union, or an interim agreement leading to a formation of a customs union, the duties and other regulations of commerce imposed at the institution of any such union or interim agreement in respect of trade with contracting parties not parties to such union or agreement shall not on the whole be higher or more restrictive than the general incidence of the duties and regulations of commerce applicable in the constituent territories prior to the formation of such union or the adoption of such interim agreement, as the case may be; (b) with respect to a free-trade area, or an interim agreement leading to the formation of a free trade area, the duties and other regulations of commerce maintained in each of the constituent territories and applicable at the formation of such free-trade area or the adoption of such interim agreement to the trade of contracting parties not included in such area or not parties to such agreement shall not be higher or more restrictive than the corresponding duties and other regulations of commerce existing in the same constituent territories prior to the formation of the free-trade area, or interim agreement as the case may be.”); see also General Agreement on Trade In Services, art. 5, Jan. 1995, (“This Agreement shall not prevent any of its Members from being a party to or entering into an agreement liberalizing trade in services between or among the parties to such an agreement. . . .”); see also *Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries*, WTO, https://www.wto.org/english/docs_e/legal_e/enabling1979_e.htm (last visited Mar. 9, 2019) (“Regional or global arrangements entered into amongst less-developed contracting parties for the mutual reduction or elimination of tariffs and, in accordance with criteria or conditions which may be prescribed by the CONTRACTING PARTIES, for the mutual reduction or elimination of non-tariff measures, on products imported from one another.”).

38. SUN-TAIK HAN, *EUROPEAN INTEGRATION: THE IMPACT ON ASIAN NEWLY INDUSTRIALISING ECONOMIES* 29 (OECD 1992).

The factors supporting regional economic integration are as follows.³⁹ First, regional preferential arrangements could help sustain intra-regional momentum for multilateral trade liberalization.⁴⁰ Moreover, regional preferential arrangements could act as a model for the initial processes of significant trade liberalization. Second, regional economic integration will increase the opportunity cost if countries maintain trade barriers vis-à-vis third parties. To the extent that integration arrangements make the partner countries more competitive, regional economic integration could reduce green protectionism between partner countries. This may open partner countries' markets to external producers and drive access to non-partner countries.⁴¹ Last, third parties will try to negotiate bilateral reduction of trade barriers to gain access to the regional market. Third parties will put greater force behind multilateralism to undercut the partner countries' preferences. Additionally, countries might resort to second-best preferential trade arrangements for practical reasons. For instance, the free-rider, least-common-denominator, and "convoy" problems have been stressed in the Uruguay Round negotiations.⁴² Despite the constraints that the most-favored-nation clause and a multilaterally-negotiated-trade agenda imposes on the scope, depth, and pace of the negotiations, there are benefits to regional economic integration.

Counter arguments against regional economic integration claim that regional preferential trade arrangements may result in trade blocs without further benefiting multilateral free trade.⁴³ First, regional preferential trade arrangements may help generate regional champions.⁴⁴ This can create problems concerning interventionist policies associated with the standard concepts of strategic trade policy. Moreover, regional economic integration may cripple the free trade coalitions. Multilateral liberalization will eventually disintegrate member countries' preferential trade treatment because advances from further liberalization will be marginal and will leave

39. *Id.* at 30.

40. See, e.g., Robert L. Birmingham, *Integration and Economic Development*, 1965 U. Ill. L. F. 781, 811 (1965) (supporting integration of economic co-operation for developing countries to expand intra-regional and extra-regional trade).

41. Lolette Kritzinger-van Niekerk, *Regional Integration: Concepts, Advantages, Disadvantages and Lessons of Experience 2*, <http://siteresources.worldbank.org/EXTAFRREGINICOO/Resources/Kritzinger.pdf> (last visited Mar. 9, 2019).

42. See generally RICHARD G. LIPSEY & MURRAY SMITH, MULTILATERAL VERSUS REGIONAL TRADING ARRANGEMENTS: SUBSTITUTES OR COMPLIMENTS 10 (Simon Fraser Univ. Dep't of Econ. Working Paper No. 10-03, 2010) (arguing that developed countries's negotiations are slow moving because of the free-rider problem, non-tariff barriers to trade, and the "convoy" problem).

43. Anne O. Krueger, *Are Preferential Trading Arrangements Trade-Liberalizing or Protectionist?*, 13 J. ON ECON. PERSPECTIVES 105, 119-120 (1999).

44. *Id.* at 119.

regional groups with less impetus for multilateral free trade.⁴⁵ Last, recent efforts to formulate regional preferential trade arrangements are partly motivated from frustration with GATT's multilateral trade negotiations. These negotiations can be interpreted to mean that regional economic integration arrangements are not complementary, but rather substitutive for the multilateral approach to trade liberalization.⁴⁶

Free trade agreements (FTAs)⁴⁷ in the Asia-Pacific proliferated after the financial crisis of 1997.⁴⁸ In response to the crisis, affected states adopted FTAs to stimulate their economies and recover from financial loss. Professor and economist, Jagdish Bhagwati, argues that a "Spaghetti Bowl Effect" occurred when FTAs proliferated in Asia-Pacific.⁴⁹ The "Spaghetti Bowl Effect" describes when products are discriminated against based on respective "nationality," which Bhagwati asserts tarnishes trade. Trade experts have long noted these unpreventable costs.⁵⁰

The "Spaghetti Bowl Effect" has both benefits and disadvantages. Benefits include cooperation and competition of market access among states. Economists, including Krugman, Frankel, Stein, and Wei, concur that the incremental FTAs can create trade flows.⁵¹ Disadvantages include trade diversion and increased business transaction costs.⁵² Since early FTAs in Asia-Pacific did not focus on economic growth, business costs in turn increased in subsequent FTAs.⁵³ These disadvantages threaten to complicate

45. *See id.* (arguing that previous experiences show that regional economic integration entities rarely initiated further multilateral free trade policies.)

46. HAN, *supra* note 38, at 29.

47. Please note that FTAs in this article directly mean and are restricted to bilateral FTAs.

48. *See* APEC FTAs Database, APEC SECRETARIAT (2016), <http://fta.apec.org> (last visited Mar. 9, 2019) (showing that only four FTAs were signed before 1997, the majority came after).

49. *See* Jagdish Bhagwati, *U.S. Trade Policy: The Infatuation with FTAs*, 726 COLUM. U. DISCUSSION PAPER SERIES, 1,4-5, 20 (Apr. 1995) (discussing the negative effects on trade from preferential trading agreements).

50. *Id.* at 4.

51. *See generally* Paul Krugman, *Is Bilateralism bad?* 1, 2-4, 12, 14-15, 17-18 (Nat'l Bureau Econ. Research, Working Paper No. 2972, 1989) (noting how internalizing trade within a country can devastate global trade overall, so incremental FTAs will avoid this situation); Paul Krugman, *The move toward free trade zones*, in Policy Implications of Trade and Currency Zones 7-42, Symposium (The Federal Reserve Bank of Kansas City, Jackson Hole, WY, Aug. 1991); *see also* Jeffrey A. Frankel, REGIONAL TRADING BLOCS IN THE WORLD ECONOMIC SYSTEM 229 (1997) (discussing that regional FTAs are preferable but more needs to be done so that outside members get the benefit of the trading bloc); *see also* Shang-Jin Wei & Jeffery A. Frankel, *Open Regionalism in a World of Continental Trade Blocs*, 45 IMF Staff Papers 440, 441 (1998) (noting that continental trade blocs are more adapted to be welfare improving).

52. *See State of the Region Report 2006, Section 2: Regional Dynamics: Challenges for Asia Pacific Cooperation*, PAC. ECON. COOPERATION COUNCIL, <https://www.pecc.org/state-of-the-region-report-2006/224-state-of-the-region/2006-2007/393-section-2-regional-dynamics-challenges-for-asia-pacific-cooperation> (last visited Mar. 9, 2019) (describing positives and negatives of regional integration).

53. Deborah Elms, *The Trans-Pacific Partnership: The Challenges of Unraveling the Noodle Bowl*, 18 INT'L NEGOT. 25, 29 (2013).

the international trade system and fracture WTO law. Its preamble designates trade liberalization and a non-discriminatory, multilateral trading regime as its principle objectives.⁵⁴ According to one analysis, RTAs demonstrate a broad range of environmental provisions in comparison to WTO agreements.⁵⁵ For example, many RTA preambles recognize the necessity of protecting the environment, as such they emphasize the importance of sustainable development during trade liberalization.⁵⁶

One of the major differences between WTO agreements and RTAs are their institutional structures. Environmental measures are incorporated into various WTO agreements. These measures and discussions are also addressed in the Committee on Trade and Environment. Nevertheless, in several RTAs, environmental provisions can only be found in a separate environmental agreement on cooperation.⁵⁷ Several RTAs that did not originally contain specific environmental provisions created separate protocols or instruments to deal with environmental issues and problems in general.⁵⁸

III. AN OVERVIEW OF APEC

Over the past decade, countries in the Asia Pacific region liberalized their trade policies by unilateral, regional, and multilateral approaches. In practice, countries have also undertaken trade liberalization through regional forums, such as APEC, and prospects remain positive for continued trade liberalization in the region.⁵⁹

Asia Pacific regionalism is an intricate phenomenon. It entails regional integration, which leads to considerable interdependence across the region. Regionalism may be market-driven or policy-led, whereas regional integration features interaction through economic activities *and* non-economic channels. Regional integration also involves regional cooperation through official activities. These activities are conducive to regional integration because they contribute to cross-border coordination, plans, and

54. *Sustainable Development*, WTO, https://www.wto.org/english/tratop_e/envir_e/sust_dev_e.htm (last visited Mar. 9, 2019).

55. Ronald Steenblik & Cristina Tebar Less, *Chapter 9: Environment*, in *REGIONALISM AND THE MULTILATERAL TRADING SYSTEM* 139 (OECD 2003).

56. *See generally* North American Free Trade Agreement (NAFTA) Jan. 1, 1994; *see* European Economic Area (EEA) Jan. 1, 1994; *see* Trans-Pacific Strategic Economic Partnership Agreement (P4), July 18, 2005.

57. *See* North American Agreement on Environmental Cooperation, U.S.-Can.-Mex., Sept. 14, 1993, 32 I.L.M. 1480; *see also* Environment Cooperation Agreement Among the Parties to the Trans-Pacific Strategic Economic Partnership Agreement (P4), July 18, 2005.

58. Steenblik & Less, *supra* note 55, at 139.

59. EAST ASIA: RECOVERY AND BEYOND, WBG, 53–55 (May 2000).

response to problems. Such activities include “intergovernmental dialogue, information exchanges, provision of regional public goods, and regional institution building.”⁶⁰

Market force has been considered the most important drive in the regional development in Asia-Pacific.⁶¹ The essence of the Asia Pacific market might lie in trade, and particularly depend on the export-led industrialization strategy in the region.⁶² Regional economic integration in Asia-Pacific is determined by the nature of legal and institutional frameworks through the coordination among countries. APEC is the current regional institution in the Asia Pacific rim. It was established in 1989, just five years before the WTO was established in 1994. APEC has twenty-one members operating based on their voluntary scheme. APEC is an emerging regional economic integration and consists of most countries in the Pacific Rim, including dominant and emerging economic powers.⁶³ The map of APEC-member economies is in figure 1.

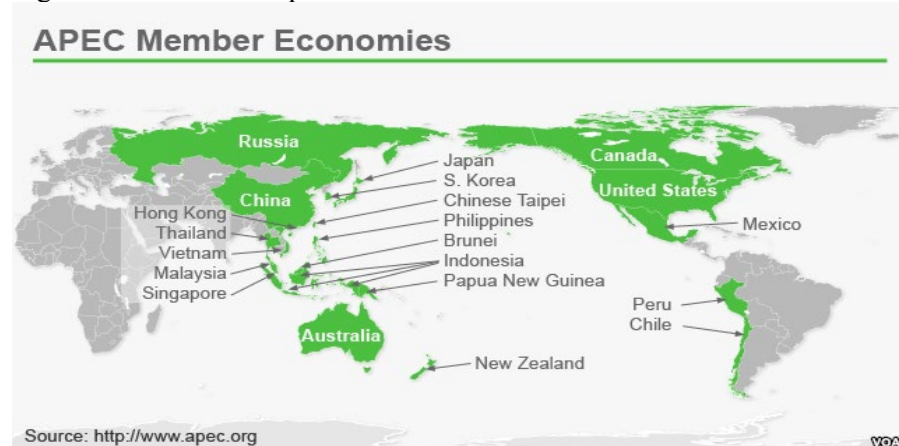
60. Roda Mushkat, *Creating Regional Environmental Governance Regimes: Implications of Southeast Asian Responses to Transboundary Haze Pollution*, 4 WASH. & LEE J. ENERGY, CLIMATE & ENV'T. 103, 111 (2013) (citing ASIAN DEVELOPMENT BANK, ASIAN REGIONALISM: A PARTNERSHIP FOR SHARED PROSPERITY XIL (2008) (discussing Asia's regionalism and specifically ASEAN's framework for regional cooperation)).

61. See Zhang Zhiyoung, *Economic Integration in East Asia: The Path of Law*, 4 PEKING U. J. LEGAL STUD. 262, 264–265 (2013) (discussing market forces driving economic cooperation).

62. See *South-East Asia Regional Economic Integration and Cooperation*, UNDP (Aug. 2006), http://www.asia-pacific.undp.org/content/dam/rbap/docs/Research%20&%20Publications/human_development/RBAP-HDR-2006-SEA-Regional-Economic-Integration.pdf (last visited Mar. 9, 2019) (discussing that governmental intervention by the Republic of Korea and Taiwan succeeded in stimulating economic benefits).

63. See *Member Economies*, *supra* note 7 (listing the participating countries in the Pacific Rim).

Figure 1: Map of APEC Member Economies



Different from the North American Free Trade Agreement (NAFTA), a formal FTA with binding effects on the signing parties, and the EU, a common market carrying regulatory measures and legal institutions and orders, APEC was established as a less rigid forum and was more a grouping of diverse economies. APEC was established in 1989 in Canberra, Australia with twelve members;⁶⁴ there was a risk that it would be viewed as a “vacuous talk-shop.”⁶⁵ Yet, APEC pursues the concept of open regionalism⁶⁶ and possesses unique features that make it economically and geopolitically significant. For instance, APEC offers a transregional dialogue platform for East and Southeast Asia, North and South America, and the Pacific.

APEC started with a modest program of sectoral and trade negotiations. Its objectives reflect the desire of its founding members: to promote economic growth, foster and strengthen trade, counter terrorism, and improve

64. See *Our Work With APEC*, N.Z. FOREIGN AFF. AND TRADE, <https://www.mfat.govt.nz/en/trade/our-work-with-apec/> (last visited Mar. 9, 2019) (listing the founding members: Australia, Brunei Darussalam, Canada, Indonesia, Japan, Korea, Malaysia, New Zealand, the Philippines, Singapore, Thailand and the United States).

65. JEFFREY A. FRANKEL ET AL., *APEC AND REGIONAL TRADING ARRANGEMENTS IN THE PACIFIC* 1 (1994).

66. Despite the various arguments of open regionalism, whether the proliferation of regional economic integration schemes will lead to closed or open regionalism may be influenced by the levels of microeconomic or macroeconomic. Regarding the microeconomic level, it will be influenced by the success in coping with structural adjustment problems with the blocs, and the commitment and willingness of the participating countries to confront the demands for protection and to seek multilateral trade liberalization. On the macroeconomic level, it is determined by the restoration of trade balances among the major trading partners and economic growth of the regions as well as the world. The micro and macroeconomic factors have a linkage about that protectionist demands tend to increase when the regional economy is suffering from inactive growth and increasing trade loss. HAN, *supra* note 38, at 30.

living standards.⁶⁷ “While APEC has been criticized for its talk-shop nature, its high-profile dialogue has strengthen APEC’s relevance in global governance.”⁶⁸ With regard to its institutional structure, APEC does not contain an organizational structure or a large bureaucracy supporting it. There is only the APEC Secretariat located in Singapore, which includes twenty-three diplomats seconded from APEC-member economies.

APEC consists of three main pillars: (1) trade and investment liberalization; (2) trade facilitation; and (3) economic and technical cooperation.⁶⁹ The annual meeting of APEC leaders, held in the U.S.A. since 1993, became a significant feature of APEC. Only one year after the 1993 meeting, APEC leaders created another historic step at their meeting in Bogor, Indonesia. The Bogor declaration set a goal of creating the world’s largest area of free trade and investment by 2020.⁷⁰ Under this plan, developed economies would achieve free trade by the year 2010 and developing economies would follow in 2020.⁷¹ The Bogor goals have influenced APEC’s Economic Leaders’ Meeting as well as the domestic economic policies of the member economies. But APEC has functioned as a *de facto* institution, lacking an establishment treaty conferring international legal personality. Therefore, it has suffered a severe credibility crisis because of “its failure to achieve ‘Early Voluntary Sectoral Liberalization (EVSL),’ compounded by its inability to assist member economies during the Asian financial crisis in the 1990s.”⁷²

This failure has been attributed to several reasons. One major reason was the diverse economic scales of the APEC’s twenty-one member economies. These created obstacles for economic integration.⁷³ The developed countries—U.S., Canada, Australia and New Zealand—believed EVSL was another scheme aimed at reducing tariffs.⁷⁴ However, the developing countries, including China and a few members of ASEAN, claimed that EVSL should include measures of trade facilitation, technical assistance, and

67. *Mission Statement*, ASIA-PACIFIC ECON. COOPERATION <http://www.apec.org/About-Us/About-APEC/Mission-Statement> (last visited Mar. 9, 2019).

68. Pasha Hsieh, *Reassessing APEC’s Role as A Trans-Regional Economic Architecture: Legal and Policy Dimensions*, 16 J. INT’L ECON. L. 119 (2013).

69. *Id.*

70. Bogor Declaration, Nov. 15, 1994, APEC Economic Leaders’ Declaration of Common Resolve, http://thetechnocratietyranny.com/PDFS/1994_Declaration_Bogor_Goals.pdf (last visited Mar. 9, 2019).

71. *1994 Leaders’ Declaration*, ASIA-PACIFIC ECON. COOPERATION (Nov. 16, 1994), https://www.apec.org/Meeting-Papers/Leaders-Declarations/1994/1994_aelm.aspx (last visited Mar. 9, 2019).

72. Hsieh, *supra* note 68.

73. *Id.*

74. *See Id.* (discussing how developed countries initiated EVSL to lower tariffs).

economic cooperation.⁷⁵ This conflicting understanding and support regarding the EVSL brought about difficulties in the process of deciding which sectors the EVSL should implement.⁷⁶

A. APEC's Function in Protecting the Environment

John Davis believed that regional economic organizations could create a forum for countries that lack a shared rule of law for cross-border issues, and thus make it possible for the countries in the region to address the severe environmental problems that they face together.⁷⁷ In fact, the APEC has been criticized for neither effectively promoting the agenda of trade nor that of the environment and for failing to deal with the environmental problems.⁷⁸ It functions as an open and voluntary forum with a shortage of strong political will; “[b]ecause of the difficulty in mobilizing political will to develop norms, APEC’s environmental activities in this period tended to focus on information and capacity building.”⁷⁹ Without the solid political power and talk, it is difficult to efficiently solve the environmental problems through international trade.⁸⁰ Additionally, many issues involve just as many environmental disputes as scientific controversies. Some issues at stake within environmental disputes are irreversible effects of indeterminate activities, boundaries, and costs. The notion and definition of public interest is also difficult to answer. Consequently, environmental disputes are complicated to resolve.⁸¹

Theory indicates that “institutions for managing transboundary environmental resources are more effective with their focus on the promotion

75. *Id.*; Mushkat, *supra* note 60, at 111.

76. *Glossary*, ASIAN-PACIFIC ECON. COOPERATION (2018) <http://www.apec.org/Glossary> (last visited Mar. 9, 2019) (“EVSL was based on the principle of voluntarism and the establishment of mutually beneficial packages. In 1997, APEC discussed the implementation of the EVSL in 15 potential sectors to positively influence trade, investment and economic growth in both of the individual APEC members and the region. However, EVSL failed because of major conflicts between the participants. The two essential factors – financial crisis of 1997-1998 in East Asia and domestic resistance and lobbying – both decelerated trade liberalization in the affected economies. Currently, Chemicals and Automotive in the EVSL are still being promoted under the APEC Industrial Dialogues.”).

77. Davis, *supra* note 2, at 80.

78. See Lyuba Zarsky, *APEC, Globalization and the “Sustainable Development Agenda”*, NAUTILUS INST. FOR SEC. AND SUSTAINABILITY (1998) (discussing APEC’s dismal record in negotiating environmental treaties alongside trade).

79. NATHAN BADENOCH, *TRANSBOUNDARY ENVIRONMENTAL GOVERNANCE: PRINCIPLES AND PRACTICE IN MAINLAND SOUTHEAST ASIA 19* (World Resources Institute 2002).

80. Astrid Fritz Carrapatoso, *Environmental Aspects in Free Trade Agreements in the Asia-Pacific Region*, 6 AEJ 229, 241 (2008).

81. Lawrence Susskind & Alan Weinstein, *Towards a Theory of Environmental Dispute Resolution*, 9 B.C. ENVTL. AFF. L. REV. 311, 333–334 (1980).

of principles rather than enforcement.”⁸² In the 1990s, APEC attempted to enhance environmental protection results by adopting non-binding norms of environmental governance.⁸³ The non-binding governing scheme, however, failed in such a sensitive area as environmental protection.⁸⁴ Apart from APEC, other methods of regional environmental governance in Asia-Pacific, such as ADB, IDB, and AIIB, all carry limited institutional capacity (lack of technical expertise, insufficient funding, and fragmented institutional arrangements).⁸⁵ Moreover, critics observe that these institutions can be “frustratingly bureaucratic,” which may prevent them from successfully integrating environmental standards into institution policies.⁸⁶

Further analysis of this experience suggests four main tasks for regional institutions in improving the interface between the environment and economic development: (1) developing a shared vision of norms and goals; (2) building capacity at the regional level to monitor implementation and raise performance; (3) policy coordinating; and (4) developing effective institutions to implement policy.⁸⁷ Additionally, Karapinar proposed alternatives that could achieve objectives of environmental protection, such as regulatory mechanisms that impose stricter environmental standards on production, pollution charges directly based on the polluter pays principle, and promotion of cleaner and more efficient technologies.⁸⁸

B. Future Goals and Limitations

There are many factors affecting the development of environmental protection in Asia-Pacific. One major factor is the backgrounds of countries

82. BADENNOCH, *supra* note 79, at 19 (citing Jutta Brunnee & Stephen J. Toope, *Environmental Security and Freshwater Resources: Ecosystem Regime Building*, 91(1) AME. J. OF INT’L L. 26–59 (1997)).

83. *Id.*

84. *Id.*

85. See Hongying Wang, *New Multilateral Development Banks: Opportunities and Challenges for Global Governance*, 8 GLOBAL POL’Y 113, 116 (2017) (“The leniency of the new [regional banks] toward infrastructure projects that may have negative social and environmental consequences could make them more attractive to some borrowers, who prioritize faster and lower-cost financing. This could undermine the ability of other [regional banks], including the World Bank, to uphold their standards.”).

86. Jisan Kim, *Regulating Economic Development: Environmental and Social Standards of the AIIB and the IFC*, HARV. INT’L L. J., (Apr. 21, 2016), <http://www.harvardilj.org/2016/04/regulating-economic-development-environmental-and-social-standards-of-the-aiib-and-the-ifc/> (last visited Mar. 9, 2019).

87. BADENNOCH, *supra* note 79, at 19 (citing Lyuba Zarsky, *Environmental Norms in the Asia-Pacific Economic Cooperation Forum*, in *Commitment and Compliance* 310 (D. Shelton ed., 2000)).

88. Baris Karapinar, *Export Restrictions and Sustainable Management of Natural Resources*, SWISS NAT’L CTR. OF COMPETENCE IN RES., (June 19, 2012), https://www.wti.org/media/filer_public/c0/43/c0435cce-7f87-4a17-a78f-8b94bd7450d1/karapinar-export_restrictions-190612-fin.pdf (last visited Mar. 9, 2019).

within Asia-Pacific are extremely diverse, i.e. from developed countries, including globally-dominant economic powers, to developing countries. Due partly to this, there was a resulting gap among the countries in implementing environmental policies. For example, while Western countries such as Australia, New Zealand, and the U.S. intensively regulate environmental policy in international trade law, Asian countries appear to only passively consider the green impacts of the FTAs they negotiated.⁸⁹ Such an outcome might be due to various considerations ranging from socio-economic to cultural and political perspectives.⁹⁰ For instance, issues of trade and environmental linkage are generally incorporated into the agenda only when Western countries—rather than Asian countries—lead FTA negotiations.⁹¹

Another significant reason preventing the Asia-Pacific from moving towards a better integration of trade and environmental protection is the Asian countries' fear of green protectionism.⁹² In other words, the Asian countries are concerned that environmental policy would become a trade barrier and a legal justification for the trade protection of the developed countries.⁹³

Given this fear of green protectionism, it is likely that the adoption of environmental policy as a legal ground for prohibiting trade imports will result in a cautious approach to the issue of environmental exceptions from trade restrictions in a number of Asia-Pacific countries.⁹⁴ This cautious approach ultimately will influence the process of how environmental policy is dealt with in the FTAs in Asia-Pacific.⁹⁵

Practically, for instance, New Zealand has successfully incorporated environmental issues in its trade negotiation agenda and made solutions that are acceptable to all its trade negotiating members.⁹⁶

As a result, there is a gap amongst the countries in Asia-Pacific in implementing environmental policies.⁹⁷ While developed countries typically have greater environmental regulations, developing countries fear that such regulations would impede their development of trade because developed countries would use the environmental regulations as trade protectionism. Important legal questions arise from this situation: would all the solutions

89. Carrapatoso, *supra* note 80, at 230.

90. *Id.*

91. *Id.*

92. DOUGLAS H. BROOKS, CHALLENGES FOR ASIA'S TRADE AND ENVIRONMENT 18 (1998).

93. Gueye Kamal & Kenichi Imai, *Harmonizing Trade and Environment in Recent Free Trade Agreements in the Asia-Pacific Region*, 4 INT'L REV. FOR ENVL. STRAT. 265, 272 (2003).

94. *Id.* at 274.

95. *Id.*

96. Carrapatoso, *supra* note 80, at 237.

97. *Id.* at 230.

that aim to tackle the deadlock of trade and the environment turn out to be mere rhetoric?⁹⁸ Do they have a real impact on the trade scheme concerning the environmental protection policy?⁹⁹ FTAs represent the opportunity to bridge these difficulties and to strengthen cooperation for environmental protection through trade schemes.¹⁰⁰ The next section focuses on why FTAs are needed as a tool to protect the environment. Furthermore, in Asia-Pacific, an RTA is, and will be, significant in the protection of the environment.

IV. RTA'S SIGNIFICANCE IN PROTECTING THE ENVIRONMENT: THE CASE STUDY OF CPTPP'S ENVIRONMENTAL CHAPTER

A. RTA's Significance in Protecting the Environment

Since environmental problems have transboundary effects, unilateral trade measures responding to the common failure to protect the environment are not adequate solutions.¹⁰¹ FTAs are recognized as an important economic instrument to connect trade and the environment because of their inter-reliance and cooperation between countries.¹⁰² FTAs deal extensively with non-tariff barriers to trade as well.¹⁰³ According to the 2012 report from the United Nations Conference on Development and Trade, "non-tariff measures contribute much more than tariffs to overall trade restrictiveness."¹⁰⁴ However, since FTAs reduce border barriers among signing states, there will be increased substitution, by means of compensation, to non-tariff barriers to trade.¹⁰⁵ Pursuing deeper integration among FTA members is, therefore,

98. *Id.*

99. *Id.*

100. Panel Report, *United States—Import Prohibition of Certain Shrimp and Shrimp Products* ¶ 9.1, WTO Doc. WT/DS58/R (adopted May 15, 1998) (arguing that the best way for parties to contribute to achieving WTO objectives is through cooperative agreements that account for the specific conditions in the geographical areas concerned).

101. Robert Howse, *The Appellate Body Rulings in the Shrimp/Turtle Case: A New Legal Baseline for the Trade and Environment Debate*, 37 COLUM. J. ENVTL. L. 491, 491 (2002).

102. Appellate Body Report, *United States—Import Prohibition of Certain Shrimp and Shrimp Products*, *supra* note 30, at footnote 107. *See also*, JACQUES BOURGEOIS ET AL., A COMPARATIVE ANALYSIS OF SELECTED PROVISIONS IN FREE TRADE AGREEMENTS, 4 (2007), http://trade.ec.europa.eu/doclib/docs/2008/march/tradoc_138103.pdf (last visited Mar. 9, 2019) (analyzing empirical evidence how FTAs relate to, among other things, trade and the environment).

103. KENNETH HEYDON & STEPHEN WOOLCOCK, THE RISE OF BILATERALISM: COMPARING AMERICAN, EUROPEAN, AND ASIAN APPROACHES TO PREFERENTIAL TRADE AGREEMENTS 47 (United Nations University Press 2009) (analogizing free trade agreements with preferential trade agreements).

104. MARC BACCHETTA ET AL., WORLD TRADE REPORT 2012, 135, 138, https://www.wto.org/english/res_e/booksp_e/anrep_e/world_trade_report12_e.pdf (last visited Mar. 9, 2019).

105. HEYDON & WOOLCOCK, *supra* note 103, at 47.

likely to reduce reliance on non-tariff barriers to trade.¹⁰⁶ Hence, regional integration is the utmost goal among signing parties of FTAs.

The harmonization of environmental standards and regulations in the regional integration tends to differ based on whether the region's members expect economic integration or merely trade facilitation.¹⁰⁷ A few RTAs include areas that have gone beyond the WTO, consisting of provisions preventing relaxation of domestic environmental laws and enforcement of those laws, which define the relationship between multilateral environmental agreements (MEAs) and the RTAs, and require each party to periodically prepare (and make publicly available) a report on the state of its environment.¹⁰⁸

Author, Wen-chen Shih, argues that the Asia-Pacific's broad position on environmental protection issues is "unsatisfactory and conservative."¹⁰⁹ Shih, therefore, emphasizes the role of a regional institution in establishing regional environmental laws and regulations, which would promote harmonization.¹¹⁰ However, we have not seen a binding regional environmental regulation system in Asia-Pacific.¹¹¹ In theory, an effective approach for "addressing transboundary environmental harm would establish a system that connects international policymaking with national implementation."¹¹² The advantages of a regional environmental institution include a harmonized standard that can be predicted and then contribute to a stable development of environmental law. Furthermore, having regional environmental governance would lead to a secured agreement for, and implementation of, an action for coping with environmental problems.¹¹³

After the Trump administration's decision to withdraw from the TPP on January 23, 2017, the most recent development of a mega RTA in the region is the CPTPP.¹¹⁴ Its predecessor was the TPP signed on February 6, 2016, and had, in effect, enlarged the Trans-Pacific Strategic Economic Partnership Agreement (SEP) that concluded in 2006 among four countries: Brunei

106. *Id.*

107. Steenblik and Less, *supra* note 55, at 139.

108. *Id.*

109. Wen-chen Shih, *Trade and Environment Linkages and Challenges Facing East Asian WTO Members*, 1 *ASIAN J. WTO & INT'L HEALTH L. & POL'Y* 157, 187 (2006).

110. *Id.*

111. *Id.* at 170.

112. Lian & Robinson, *supra* note 1, at 102.

113. *Id.*

114. Memorandum from the U.S. Trade Representative on Withdrawal of the U.S. from the Trans-Pacific Partnership Negotiations and Agreement (Jan. 23, 2017), <https://www.whitehouse.gov/the-press-office/2017/01/23/presidential-memorandum-regarding-withdrawal-united-states-trans-pacific> (last visited Mar. 9, 2019); see also *What is the Trans-Pacific Partnership (TPP)?*, COUNCIL ON FOREIGN REL., (last updated May 15, 2018), <https://www.cfr.org/trans-pacific-partnership-tpp> (last visited Mar. 9, 2019).

Darussalam, Chile, New Zealand, and Singapore.¹¹⁵ In 2008, the U.S. led TPP “trade talks” after its accession to the SEP.¹¹⁶ Since then, this mega RTA has drawn a lot of attention and is topical both in the WTO law scholarship and in the public.¹¹⁷ Compared to the existing FTAs in the region, the CPTPP includes an unprecedented range and scope of chapters in its agreement. The environmental chapter in the CPTPP is considered a golden standard among trade deals.¹¹⁸

B. Theory of Regional Environmental Governance

Regardless of the deadlock of the linkage between trade liberalization and environmental protection at a multilateral level,¹¹⁹ an RTA pertaining to regional environmental governance is essential for dealing with transboundary environmental harm.¹²⁰ Two of the most noticeable advantages from connected governance are minimized complexity and hierarchy, as well as facilitating boot-up and delivery times.¹²¹ As a result, well-functioning regional environmental governance is necessary for Asia-Pacific.

Since national-level institutions normally have failures in these particular areas¹²² and fail to integrate environmental issues, the environment has suffered. Therefore, the need is pressing for establishing regional governance that maintains a sufficiently wide perspective. Yet, even though others would argue for autonomy of national governments, the impact of regional governance over politics, economics, and the environment has occurred at a striking pace.¹²³

With regard to creating regional environmental governance, some suggest that regional institutions that directly represent national governments and interests (e.g. the ASEAN) operate more effectively due to their direct link with national processes shaping governmental interactions.¹²⁴ Yet,

115. *Id.*

116. *Id.*

117. Elms, *supra* note 53, at 29.

118. Jay Chittooran, *TPP in Brief: Environmental Standards* (Apr. 15, 2016), <http://www.thirdway.org/memo/tpp-in-brief-environmental-standards> (last visited Mar. 9, 2019).

119. *See* discussion *infra* Section II.

120. *See* Lian & Robinson, *supra* note 1, at 102 (discussing the regional level is where states can collaborate to solve ecosystem problems).

121. Daniel C. Esty & Maria H. Ivanova, *Revitalizing Global Environmental Governance: A Function-Driven Approach*, 3 INDIAN. J. ENVL L. 38, 50 (2002).

122. *See id.* (recognizing networked governance and not national-level institutions have strength in boot-up and delivery times).

123. BADENOCH, *supra* note 79, at 9.

124. *See* Le Thac Can et al., *Environmental Governance in Vietnam in a Regional Context*, http://pdf.wri.org/mekong_governance_mreg_canphanan.pdf (last visited Mar. 9, 2019) (discussing

others argue that the interaction of such institutions, along with the specific integration associated with each national actor, offers a large forum on which environmental governance reform can be addressed.¹²⁵

Therefore, intensive institutional components may result in more effective governance of transboundary environmental issues.¹²⁶ A good example is the wide range of institutions with overlapping, complementary mandates and multiple channels of communication and accountability. Moreover, the direction this institutional interplay takes is largely determined by the structures and practices of governance and the decision-making process.¹²⁷ The principles of the Rio Declaration considerably defined the conditions and principles for multilateral environmental governance.¹²⁸ These principles include access to information, participation in decision-making, and accountability in environmental matters.¹²⁹ Other principles in international environmental law, such as the precautionary principle, are also important components of environmental governance.¹³⁰ “Implementation of these principles will require a thorough rethinking of the ways government interacts with society at large.”¹³¹ These three fundamental principles can provide guidance to analyze regional environmental governance because it can be suggested that these principles are important foundations for good governance. In addition, these principles can serve as catalysts for implementing other principles.

regional governments adopting environmental protection through public awareness and including decision makers).

125. See generally Kao Kim Hourn, *The Impact of Regional Integration on the Governance Process in Cambodia: The Environmental Perspective*, in Mekong Regional Environmental Governance Project: Perspectives on Opportunities and Challenges 5 (Nathan Badenoch, 2001) (arguing regional integration occurs in Cambodia and will continue to do so).

126. See BADENOCH, *supra* note 79, at 9 (citing Ronnie D. Lipschutz, *Damming Troubled Waters*, 1 Intermarium (1997)) (discussing how institutional overlap that mandates communication and accountability will result in more effective governance).

127. BADENOCH, *supra* note 79, at 9.

128. See Report of the U.N. Conf. on Env'tl. Dev., *Rio Declaration on Environment and Development*, U.N. Doc. A/CONF.151/26 (Vol. I) (Aug. 12, 1992) [hereinafter *Rio Declaration*] (identifying the goal of establishing international agreements for environmental protection).

129. See *id.* at 2-3 (discussing the role of the government in establishing accountability, public participation, and access to information).

130. See U.N. General Assembly, *Report of the United Nations Conference on Environment and Development*, ¶ 15, U.N. Doc. A/CONF.151/26 (Vol. I) (Aug. 12, 1992) (discussing how states should use the precautionary approach to protect the environment and not delay environmental protection because of lack of scientific information or serious environmental threats).

131. BADENOCH, *supra* note 79, at 15 (citing ELENA PETKOVA & PETER VEIT, ENVIRONMENTAL ACCOUNTABILITY BEYOND THE NATION-STATE: THE IMPLICATIONS OF THE AARHUS CONVENTION (World Resources Institute 2000)).

The first principle is transparency and access to information.¹³² This principle evaluates whether an institution provides the public with reliable, timely information concerning their operational policies and procedures. Additionally, this principle requires access to information concerning environmental status, trends for society, and potential environmental impacts assessments. Second, public participation is necessary regarding the representation and participation of the various interests in their decisions.¹³³ The final principle examines accountability. This principle examines whether there are mechanisms for institutions to be accountable to affected stakeholders across boundaries.¹³⁴

C. An Analysis of the CPTPP's Environmental Chapter

CPTPP's environmental chapter is considered the high environmental standard in RTAs in the 21st century. The CPTPP is evaluated in this article to explore whether it is more advanced than the existing bilateral FTAs reinforcing environmental protection.¹³⁵ This article aims to provide the public with a thorough assessment of the positive and negative effects that CPTPP will have on the environment. Further, this article evaluates whether the CPTPP is a beneficial RTA in Asia-Pacific for environmental protection and governance.

Because of the scope of environmental protection it covers, CPTPP's environmental chapter is particularly novel in regional environmental governance in Asia-Pacific. Its environmental chapter covers and reflects the obligation derived from major Multilateral Economic Agreements (MEAs). Additionally, it provides original policies that aim to protect the oceans by an RTA. Moreover, the chapter has an environmental dispute settlement mechanism.

Specifically, the issues focused on environmental obligations in the CPTPP's chapter can be divided into four areas: maritime protection,

132. Michael Johnston, *Good Governance: Rule of Law, Transparency, and Accountability*, <http://unpan1.un.org/intradoc/groups/public/documents/un/unpan010193.pdf> (last visited Mar. 9, 2019).

133. *See id.* at 5 (discussing the emphasis on participation in liberalized economies after transitions).

134. *See* BADENOCH, *supra* note 79, at 20 (discussing mechanisms to hold the government accountable to the public interest).

135. *See generally* Trans-Pacific Partnership, annex 20--A, Office of the U.S. Trade Representative, Feb. 4, 2016 (listing the 12 countries that signed the TPP in 2016—Australia, Brunei, Canada, Chile, Japan, Mexico, Malaysia, New Zealand, Peru, Singapore, U.S., and Vietnam). *See also* Letter from Maria Pagan, Acting United States Trade Representative, Executive Office of the President (Jan. 30, 2017) (on file at the Office of the United States Trade Representative) (announcing that the U.S. will not be legally bound to the agreement because they do not intend to become a party to the agreement).

reinforcing MEAs, overcoming illegal trade in wildlife and plant products, and promoting biodiversity.¹³⁶ First, it offers original policies that aim to protect the oceans.¹³⁷ The world's most significant fish exporters are in some of the CPTPP parties. Additionally, the subsidies offered by some of the TPP parties created the overfishing issue.¹³⁸ Therefore, owing to the innovation of the environmental chapter in the TPP, the provisions preserving the oceans can assist with mitigating fishery issues. The TPP environmental chapter restricts and attempts to promote sound management of fisheries subsidies.¹³⁹ Additionally, one of the TPP's priorities is to counter illegal, unreported, and unregulated (IUU) fishing. This is accomplished by putting restrictions on unlawful trade of reaped fish and at-sea trans-shipment of such products.¹⁴⁰ Effective measures to combat IUU fishing requires international cooperation. The United Nations's Food and Agriculture Organization Agreement of 2009 (FAO) "on Port State Measures to Prevent, Deter, and Eliminate IUU fishing," mandates such cooperation.¹⁴¹ However, this measure has not yet entered into force. Although TPP members "endeavor to improve cooperation internationally,"¹⁴² the environmental chapter does not require its members to adopt and implement the 2009 FAO.

136. Comprehensive and Progressive Agreement for Trans-Pacific Partnership, art. 20, at 4, 6, 12, 18, Feb. 2, 2018 [hereinafter CPTPP].

137. Jeffrey Schott, *Chapter 3: TPP and the Environment*, in 2 *ASSESSING THE TRANS-PACIFIC PARTNERSHIP, INNOVATIONS IN TRADING RULES* 32, 34 (Jeffrey Schott & Cathleen Cimino-Isaacs eds., 2016).

138. *See id.* (discusses how the TPP addresses the problem of subsidies causing adverse effects for fishing policies).

139. *Id.*

140. *See id.* at 35 (describing the TPP provision that bans subsidies to IUU fishing vessels).

141. *Id.*

142. *See generally* Trans-Pacific Partnership, art. 20.12.1-20.12.3, Feb. 4, 2016, Office of the U.S. Trade Representative ("1. The Parties recognize the importance of cooperation as a mechanism to implement this Chapter, to enhance its benefits and to strengthen the Parties' joint and individual capacities to protect the environment and to promote sustainable development as they strengthen their trade and investment relations. 2. Taking account of their national priorities and circumstances, and available resources, the Parties shall cooperate to address matters of joint or common interest among the participating Parties related to the implementation of this Chapter, when there is mutual benefit from that cooperation. This cooperation may be carried out on a bilateral or plurilateral basis between Parties and, subject to consensus by the participating Parties, may include nongovernmental bodies or organizations and non-Parties to this Agreement. 3. Each Party shall designate the authority or authorities responsible for cooperation related to the implementation of this Chapter to serve as its national contact point on matters that relate to coordination of cooperation activities and shall notify the other Parties in writing within 90 days of the date of entry into force of this Agreement for that Party of its contact point. On notifying the other Parties of its contact point, or at any time thereafter through the contact points, a Party may: (a) share its priorities for cooperation with the other Parties, including the objectives of that cooperation; and (b) propose cooperation activities related to the implementation of this Chapter to another Party or Parties.").

Second, the CPTPP requires combating the illegal take and trade in wildlife and wild plant products.¹⁴³ The commitments under the TPP consist of postponing illegal harvest and trade in logging, wildlife, and plant products. Other commitments include having better cooperation to strengthen environmental management of these resources. MEAs, such as the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), require this.¹⁴⁴ The strongest obligations in the environmental chapter might pertain to the subject of conservation and trade. According to Article 20.17.2 in the TPP,¹⁴⁵ each TPP party shall adopt, maintain, and implement laws, regulations, and any other measures to achieve its obligations under the CITES.

143. Trans-Pacific Partnership, art. 20.17.3, Feb. 4, 2016, Office of the U.S. Trade Representative.

144. *Id.* at art. 20.17:

1. The Parties affirm the importance of combating the illegal take of, and illegal trade in, wild fauna and flora, and acknowledge that this trade undermines efforts to conserve and sustainably manage those natural resources, has social consequences, distorts legal trade in wild fauna and flora, and reduces the economic and environmental value of these natural resources.”
2. Accordingly, each Party shall adopt, maintain and implement laws, regulations and any other measures to fulfil its obligations under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).
3. The Parties commit to promote conservation and to combat the illegal take of, and illegal trade in, wild fauna and flora. To that end, the Parties shall:
 - (a) exchange information and experiences on issues of mutual interest related to combating the illegal take of, and illegal trade in, wild fauna and flora, including combating illegal logging and associated illegal trade, and promoting the legal trade in associated products;
 - (b) undertake, as appropriate, joint activities on conservation issues of mutual interest, including through relevant regional and international fora; and
 - (c) endeavor to implement, as appropriate, CITES resolutions that aim to protect and conserve species whose survival is threatened by international trade.
4. Each Party further commits to:
 - (a) take appropriate measures to protect and conserve wild fauna and flora that it has identified to be at risk within its territory, including measures to conserve the ecological integrity of specially protected natural areas, for example wetlands;
 - (b) maintain or strengthen government capacity and institutional frameworks to promote sustainable forest management and wild fauna and flora conservation, and endeavor to enhance public participation and transparency in these institutional frameworks; and
 - (c) endeavor to develop and strengthen cooperation and consultation with interested non-governmental entities in order to enhance implementation of measures to combat the illegal take of and illegal trade in, wild fauna and flora.

145. See Trans-Pacific Partnership art. 20.17.2, Feb. 4, 2016, Office of the U.S. Trade Representative (“Accordingly, each Party shall adopt, maintain, and implement laws, regulations and any other measures to fulfill its obligations under the *Convention on International Trade in Endangered Species of Wild Fauna and Flora* (CITES).”).

Third, the MEAs and their obligations have been well covered and reflected in the TPP environmental chapter.¹⁴⁶ It is worth addressing that the TPP parties' participation in the MEAs varies widely. Article 20.4 affirms the basic commitment of each country "to implement the multilateral environmental agreements to which it is a party."¹⁴⁷ This exemplary provision is intensified with language linked to specific MEAs. This adopted idea came from the US. The US intention was to ratify TPP provisions that would oblige members to pursue domestic policies and enforce MEA commitments where members were a party.¹⁴⁸ If failing to do so, the country would breach CPTPP obligations and possibly make itself liable for a TPP dispute settlement. As a result, the aim was to better enforce existing MEA obligations where a country was already a member. Nevertheless, TPP's approach to cover disciplines that reinforce CITES and other MEAs is not the best to prevent abusive environmental measures or unlawful trade.¹⁴⁹ "[T]he economic incentives to," avoid "governmental measures are too lucrative," for the summarized result in the CPTPP.¹⁵⁰ However, the CPTPP provisions about compliance with the MEA obligations can have a huge impact.¹⁵¹

The final area covered in the CPTPP environmental chapter regards biodiversity conservation. CPTPP parties have important objectives yet differing priorities concerning the use and protection of biological diversity. This can also be augmented with some provisions in the bilateral FTAs between some TPP parties. Article 20.13.2 in the TPP requires that each member "shall promote and encourage the conservation and sustainable use of biological diversity, in accordance with its law or policy."¹⁵² TPP environmental chapter also requires transparency of government programs and activities "related to the conservation and sustainable use of biological diversity."¹⁵³ It also establishes commitments to cooperate on "the protection

146. See Trans-Pacific Partnership, art. 20.4, Feb. 4, 2016, Office of the U.S. Trade Representative (recognizing that MEAs play an important role in environmental protection).

147. Trans-Pacific Partnership Agreement, art. 20.4.1, Feb. 4, 2016, Office of the U.S. Trade Representative ("The Parties recognize that multilateral environmental agreements to which they are party play an important role, globally and domestically, in protecting the environment and that their respective implementation of these agreements is critical to achieving the environmental objectives of these agreements. Accordingly, each Party affirms its commitment to implement the multilateral environmental agreements to which it is a party.").

148. See Schott, *supra* note 137, at 35 (discussing the value of the TPP in allowing domestic policies that discourage abuse).

149. *Id.* at 38.

150. *Id.*

151. *Id.*

152. The Trans-Pacific Partnership Agreement, art. 20.13.2 Trade and Biodiversity, Feb. 4, 2016, Office of the U.S. Trade Representative.

153. *Id.*

and maintenance of ecosystems” and “access to genetic resources and the sharing of benefits arising from their utilization.”¹⁵⁴ Lastly, this chapter recognizes the importance of “respecting, preserving and maintaining knowledge and practices of indigenous and local communities embodying traditional lifestyles . . .”.¹⁵⁵

Overall, the CPTPP is unprecedented and the single, greenest free trade agreement. This is because of the important obligations addressed in the CPTPP’s environmental chapter, and because it pertains to a wide scope of the law that discourages abusive environmental practices. Despite these merits of the CPTPP’s environmental chapter, the CPTPP also faces criticisms.

First, during its negotiation, environmental groups in the US protested the CPTPP as a fast track without any transparency and environmental consideration.¹⁵⁶ Among all the environmental groups, the Sierra Club has offered several criticisms.¹⁵⁷ Focusing on the weaker conservation language, the Sierra Club provided some of the suggested texts to be adopted in the CPTPP’s environmental chapter.¹⁵⁸ However, the final version of the environmental chapter does not reflect the suggested contents. For example, the Sierra Club suggested adopting the regulations the regional fishing management organization abided by in the CPTPP. However, the CPTPP fails to do so, and also fails to mention the regulations arising from the fishing MEAs, i.e. FAO Agreement on Port State Measures to Prevent, Deter, and Eliminate IUU fishing in 2009.¹⁵⁹ Another critical issue Sierra Club addressed regards the incorporation of effective enforcement of the rampant,

154. See Trans-Pacific Partnership, art. 20.13.6, Feb. 4, 2016, Office of the U.S. Trade Representative, <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text> (last visited Mar. 9, 2019), (“6. Consistent with Article 20.12 (Cooperation Frameworks), the Parties shall cooperate to address matters of mutual interest. Cooperation may include, but is not limited to, exchanging information and experiences in areas related to: (a) the conservation and sustainable use of biological diversity; (b) the protection and maintenance of ecosystems and ecosystem services; and (c) access to genetic resources and the sharing of benefits arising from their utilization.”).

155. See The Trans-Pacific Partnership art. 20.13.3, Feb. 4, 2016, Office of the U.S. Trade Representative, <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text> (last visited Mar. 9, 2019), (“The Parties recognize the importance of respecting, preserving and maintaining knowledge and practices of indigenous and local communities embodying traditional lifestyles that contribute to the conservation and sustainable use of biological diversity.”).

156. See *TPP Text Analysis: Environment Chapter Fails to Protect the Environment*, SIERRA CLUB (2015) 1,1 <https://www.sierraclub.org/sites/www.sierraclub.org/files/uploads-wysiwig/TPPanalysis.pdf> (last visited Mar. 9, 2019) (arguing the TPP negotiations do not meet the minimum required environmental protection).

157. *TPP Text Analysis: Environmental Chapter Fails to Protect the Environment*, SIERRA CLUB (2015), <https://www.sierraclub.org/sites/www.sierraclub.org/files/uploads-wysiwig/TPPanalysis.pdf> (last visited Oct. 15, 2018).

158. *Id.*

159. *Id.* at 1.

widely-documented environmental violations.¹⁶⁰ Presumably, having effective enforcement should prevent the widely-documented environmental violations.

A final concern is the absence of the climate change legal regime in the CPTPP.¹⁶¹ The CPTPP failed to adequately address the challenges to trade and economic growth posed by global warming.¹⁶² While the CPTPP, a mega-regional free trade agreement, entails objectives of liberalizing trade in the Asia-Pacific area and facilitating regional economic integration, it has been subject to criticism in terms of considering the environment.¹⁶³ In other words, since the fundamental value of free trade and environmental protection appear to be contradictory, the CPTPP is promising as a breakthrough development reconciling these two areas.¹⁶⁴ Nonetheless, there might be severe environmental violations and threats that the CPTPP could cause. The governments in the CPTPP must ensure the consideration of environmental protection has been fully implemented. Further, more extensive prior assessments and environmental reviews need to be conducted as well.

In conclusion, the CPTPP, as a regional level FTA, is expected to do more than the existing FTAs. Assessment of the CPTPP's role in establishing regional environmental governance is in the following section.

D. Improving the CPTPP for Better Environmental Governance in Asia-Pacific

According to research, the trends of economic, political, and environmental perspectives resulted in some changes in regional governance practices.¹⁶⁵ These trends also resulted in progress addressing transboundary environmental problems within the institutional structure.¹⁶⁶ While transboundary environmental problems have cross-border effects on the environment and affected countries, it is a significant motivator in establishing regional environmental governance. The Asia-Pacific rim has

160. *Id.*

161. *Id.* at 7.

162. Schott, *supra* note 137, at 39.

163. Richard Higgott and Richard Stubbs, *The Trans-Pacific Partnership: For, Against and Prospects*, E-INT'L REL., (Apr. 13, 2016), <https://www.e-ir.info/2016/04/13/the-trans-pacific-partnership-for-against-and-prospects/> (last visited Mar. 9, 2019).

164. *Overview and Benefits of the CPTPP*, GOV'T OF CAN., (date modified June, 12, 2018), <http://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/cptpp-ptpp/overview-apercu.aspx?lang=eng> (last visited Mar. 9, 2019).

165. Harriet Bulkeley & Michele Betsill, *Rethinking Sustainable Cities: Multilevel Governance and the 'Urban' Politics of Climate Change*, 14 ENVTL. POL. 42, 44, 47 (Feb. 2005).

166. BADENOCH, *supra* note 79, at 9.

abundant natural resources and has been an important in linking trade and the environment. Therefore, an RTA aimed for well-defined and functioning environmental governance is essential.

Generally, RTAs play a key role in coordinating comparative advantages of each signing party through trade activities beyond bilateralism.¹⁶⁷ This connecting and inter-reliable effect enhances opportunities for signing parties to cooperate in dealing with transboundary issues in a global world.¹⁶⁸ Impacts from RTAs appear to exceed bilateral FTAs, as they involve more countries and the results of negotiations are more complex. To some extent, the results reflect the tension and intentions of signing parties to achieve a solution for some issues. Particularly in Asia-Pacific, RTAs can wield influence in sensitive areas, like protecting the environment.¹⁶⁹

Indeed, CPTPP covers many environmental issues. The belief is that linking these environmental issues to a broader range of political and economic cooperation trends can increase benefits received from environmental cooperation.¹⁷⁰ This highlights the importance of intensive institutional cooperation. Furthermore, such cooperation is likely to refine environmental governance.

Additionally, a broadly-defined environmental agenda can encourage the shift from a narrow focus on sectoral management to a more encompassing, process-oriented environmental governance.¹⁷¹ The need for interaction across regional, national, and sub-national levels in transboundary environmental issues is particularly acute.¹⁷² Additionally, in 2006, Shih addressed the challenge facing East Asian countries: the lack of a uniform position regarding the domestic environmental protection policies in the context of international trade.¹⁷³ Following this challenge, this article suggests the CPTPP be improved to restructure environmental institutions and the associated setups.

167. See HAN, *supra* note 38 (discussing how regional agreements can act as a model and help push for trade liberalism and increased investment).

168. See *id.* ("[R]egional integration arrangements makes the partner countries more competitive, it could make them less protectionist and thus more willing to open their markets to outsiders and to seek greater access to non-partner countries").

169. See *id.* at 7 (arguing that the impact of European economic integration on Asia-Pacific countries helps three ways: trade, foreign direct investment, and the world trading system).

170. BADENOCH, *supra* note 79, at 23 (citing Aaron Wolf, *Transboundary Waters: Sharing Benefits, Lessons Learned* (2001) ("In the case of environmental governance gaps between the ASEAN countries and China, although institutions are not yet up to the region's environmental challenges, increased political and economic cooperation has created a number of opportunities for bridging the gap.")).

171. *Id.* at 22.

172. *Id.*

173. Shih, *supra* note 109, at 160110.

The CPTPP should incorporate, apart from the institutional setup, principles of international environmental law, developed from the Rio Declaration; environmental norms; and justice. Major principles, like the precautionary principle and environmental impact assessments, are important foundations and enshrine the significance of implementing effective governance.¹⁷⁴ Badenoch thought regional institutions, in close collaboration with national governments, should develop a vision for and an approach to institutionalizing transboundary issues within environmental assessments, particularly environmental impact assessments.¹⁷⁵

Finally, effective regional environmental governance should adopt enforcement measures that ensure accountability. The CPTPP sets up an environmental dispute settlement mechanism, which covers a large scope of environmental issues. Still, the establishment of an appellate body and an assured rule of transparency can improve the mechanism. Specifically, it is necessary to enhance accountability of the governance. Effective public policy and management can enhance accountability if citizens can hold public officials and political delegates accountable for policy and performance.¹⁷⁶ In this regard, East Asia has progressed more slowly than other regions in the world. However, many countries in the region have established the foundations for institutional accountability, such as important political liberalization.¹⁷⁷ Increasing accountability may take several years and involves many related aspects of governance. Attempts to improve accountability must also be built into public management systems. Finally, performance evaluations and citizen–grievance processes are critical to ensure the accountability of the civil service.¹⁷⁸

CONCLUSION

Unilateral trade measures aimed at environmental protection are not an adequate solution for environmental problems pertaining to transboundary issues.¹⁷⁹ Further, the pending progress of the Doha Round, in the WTO, about linking free trade and environmental protection at a multilateral level

174. U.N. Conference on Environment and Development, *Rio Declaration on Environment and Development*, U.N. Doc. A/CONF.151/26/Rev.1 (Vol. I), principle 15, 17 (Aug. 12, 1992).

175. BADENOCH, *supra* note 79, at 23.

176. *Rio Declaration*, *supra* note 128, at 2.

177. BADENOCH, *supra* note 79, at 20.

178. EAST ASIA: RECOVERY AND BEYOND, *supra* note 59, at 109.

179. Howse, *supra* note 101, at 491.

brought about the urgency of reconciling trade and the environment by means of bilateral or regional trade agreements.¹⁸⁰

Development of Asia-Pacific and its achievement of long-term social and economic goals depend on how well countries are governed. Governance in the region is undergoing profound change in response to new resource constraints and increased demands for accountability.¹⁸¹

This article started with discussing the debate between free trade and environmental protection in terms of the scholarships and WTO Agreements and their disputes. This theoretical discussion demonstrated that free trade and environmental protection can be mutually beneficial. Under Article 20(b)(g) of the GATT, environmental protection measures are recognized exceptions. However, WTO case law implies that if the measures discriminate in favor of principles of free trade, they violate WTO law.

APEC's failure to implement EVSL has left its environmental protection vulnerable. The Asia-Pacific region undoubtedly requires solid and binding regional environmental governance with regulatory effects. While there is a mutually beneficial relationship between trade and the environment, this article argues an RTA is necessary to establish environmental governance in Asia-Pacific. CPTPP and its environmental chapter is an unprecedented example in Asia-Pacific, and such an attempt to establish environmental governance has been recognized. However, its provisions of substance and process can be improved. The substantive issues in the CPTPP's environmental chapter covers suggest the need to incorporate and implement the obligations of the MEAs into the agreement.¹⁸² Moreover, CPTPP does not mention the MEAs that are essential to the fisheries sector management in Asia-Pacific. The climate change legal regime is also not incorporated into the CPTPP.

Apart from the substantive criticisms, the CPTPP is also criticized for its negotiation without transparent and appropriate monitoring.¹⁸³ Regarding the procedural aspect and as shown by the range of outputs produced, an elaborate institutional infrastructure appears to work and function

180. See generally World Trade Organization, Ministerial Declaration 14 Nov. 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002) (recognizing the role of environmental protection in free trade agreements).

181. Elms, *supra* note 53, at 95.

182. See BADENOCH, *supra* note 79, at 19 ("Global norms [along with obligations] might be more relevant if they are modified and adapted to the region's specific needs[. Any approach to regional norms should be accompanied by a process of confidence and consensus building, with the objective of producing not only an acceptable framework but also mechanisms for implementation.").

183. Jane Kelsey, *Submission to the Foreign Affairs, Defence, and Trade Committee on the Revised Trans-Pacific Partnership Agreement, Otherwise Known as the Comprehensive and Progressive Agreement on Trans-Pacific Partnership*, 3–4 (Apr. 17, 2018) (on file with the University of Auckland, Faculty of Law).

adequately.¹⁸⁴ Nevertheless, doubts are continuously expressed about members' strategic commitment, organizational robustness, and policy impact (a broader and more meaningful criterion than output). Additional research is needed to obtain a clearer picture of realities in this particular sphere and their theoretical ramifications.¹⁸⁵ In addition, the provisions of institutional and procedural arrangements in the TPP should pertain to the concept of transparency, since transparency plays an important role in enhancing regional governance.

Regardless of those suggestions for the CPTPP's environmental chapter, the first challenge the CPTPP parties encounter is the agreement's future direction. After the Trump Administration's decision to withdraw, there was a negative view regarding the forthcoming dissolved CPTPP. If dominant economic power proceeds to exit from the CPTPP, international trade will move towards bilateralism and away from multilateralism. Nevertheless, Australia and Japan, two of the remaining parties, still maintain hope and advocate for the CPTPP's importance and benefits for both economic integration and the region's stability.

This article has demonstrated the significance of RTAs in linking trade and the environment. Likewise, transboundary environmental problems require cooperation and governance at a regional level. In Asia-Pacific, this cooperative and governing scheme is particularly crucial, because of the common environmental problems countries face and their inter-reliance on each other for solving the environmental disputes. Presumably, if CPTPP eventually ceases function, what we could reasonably expect as an alternative is the Regional Comprehensive Economic Partnership (RCEP), which is led by China and has some of the ASEAN countries involved. However, RCEP's current negotiations do not show any concern for producing an environmental chapter. RCEP's parties are also from diverse economic backgrounds, which will make negotiations equally complicated and slow in the process. Accounting for these challenges in implementing RTAs in Asia-Pacific, the author claims since the sustainability of the environment is an urgent priority, government officials and policy makers must consider this issue and make cooperative policies between trade and the environment a practical reality. Once policy makers start demanding these cooperative policies, it will attract more attention to the necessity of an RTA with regional environmental governance and will increase the possibility of creating the agreement.

184. See generally, Gene M. Grossman & Elhanan Helpman, *The Politics of Free Trade Agreements* 2 (Nat'l Bureau Econ. Research, Working Paper No. 4597, 1993) (explaining how to achieve FTA equilibrium to assess FTA efficiency).

185. Mushkat, *supra* note 60, 140.

**FROM UN-COORDINATED TO EFFICIENT: A PROPOSAL
FOR REGULATING GE PRODUCTS IN A WAY THAT MEETS
THE NEEDS OF CONSUMERS, PRODUCERS, AND
INNOVATORS**

Sarah Luther*

*Dinosaurs and man, two species separated by sixty-five million years
of evolution have just been suddenly thrown back into the mix
together. How can we possibly have the slightest idea what to
expect? –Alan Grant¹*

Introduction.....	33
I. History of GMOs and a Discussion of the Issues	34
A. History	34
B. Shift in Public Opinion	37
C. Benefits	38
D. Current Climate	41
II. Establishment of the Framework.....	44
A. FDA	47
1. Problems and Abilities	52
B. USDA.....	56
C. EPA.....	59
III. Proposed Changes to the Framework.....	63
Conclusion	68

* Sarah Luther is a clerk at Mills Shirley, LLP in Galveston, Texas, where she will work as an associate after the July 2019 Bar Exam. She holds a Juris Doctor and Master of Business Administration from the University of Houston and served as President of the Intellectual Property Student Organization. She also holds a B.S. in Agricultural and Biological Engineering from the University of Florida. Her background is in production agriculture and prior to law school she worked as an engineer for the Suwannee River Water Management District. There she worked with North Florida farmers on water quality and water quantity improvement projects and collaborated with other agencies on regional planning initiatives.

1. JURASSIC PARK (Universal Pictures 1993).

INTRODUCTION

Humans have been modifying plants and animals since the dawn of agriculture.² This was originally done through “selective breeding” or “artificial selection” and has since evolved into “genetic engineering” (GE).³ Selective breeding has influenced everything from corn and wheat to hunting dogs.⁴ Humans have not regulated the creation of organisms using this older method, other than through intellectual property rights.⁵ However, when humans learned to manipulate mice DNA, scientists, the media, and governmental officials became concerned.⁶ The Organizing Committee for the International Conference on Recombinant DNA Molecules (Recombinant DNA Committee) placed a moratorium on GE projects until the 1975 Asilomar Conference, when scientists created safety and containment regulations.⁷ In 1980, the U.S. Supreme Court upheld the first patent for bacteria and in 1987, scientists tested the first genetically modified (GM) food crops.⁸ In 2003, scientists produced the first commercial GM animal—a glowing fish—causing turmoil among watchdogs because the Food & Drug Administration (FDA) initially decided not to regulate the organism.⁹

2. See e.g., B. M. Chassy, *The History and Future of GMOs in Food and Agriculture*, 54 CEREAL FOODS WORLD 169, 169 (2007) (discussing domestication of plants and animals “to suit the needs of improved production, resistance to diseases and pests, and to serve human preferences”).

3. Gabriel Rangel, *From Corgis to Corn: A Brief Look at the Long History of GMO Technology*, SCI. IN THE NEWS (August 9, 2015), <http://sitn.hms.harvard.edu/flash/2015/from-corgis-to-corn-a-brief-look-at-the-long-history-of-gmo-technology/>.

4. *Id.*

5. See Morten Walløe Tvedt, *Patent Protection in the Field of Animal Breeding*, 57 ACTA AGRICULTURAE SCANDINAVICA 105, 106 (2007) (summarizing the history of patent regulation of selectively bred animals).

6. Rangel, *supra* note 3.

7. *Id.*

8. *Id.*

9. See Zhiyuan Gong et al., *Development of Transgenic Fish for Ornamental and Bioreactor by Strong Expression of Fluorescent Proteins in the Skeletal Muscle*, 308 BIOCHEMICAL & BIOPHYSICAL RES. COMM. 58, 58 (2003) (explaining the development of the glowing fish); see also *Statement Regarding Glofish*, U.S. FOOD & DRUG ADMIN., <https://wayback.archive-it.org/7993/20170404230909/https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm413959.htm> (last updated Sept. 9, 2014) (explaining the FDA did not elect to regulate genetically-engineered zebra danio fish because they posed no heightened threat to the environment); see also *CFS Sues FDA To Regulate Genetically Engineered Glofish*, CENTER FOR FOOD SAFETY (Jan. 14, 2004), <http://www.centerforfoodsafety.org/press-releases/904/cfs-sues-fda-to-regulate-genetically-engineered-glofish> (announcing CFS’s decision to sue the FDA for its failure to regulate GloFish).

This paper discusses the history of genetically modified organisms (GMOs).¹⁰ Part II evaluates the development of GE practices over time and the public outcry they have caused.¹¹ Part III elaborates on the rather intricate and somewhat confusing U.S. framework for evaluating and approving GM products.¹² Lastly, Part IV covers the issues caused by the current framework and possible solutions for addressing those issues. The solutions proposed herein suggest a simpler, more open process led and coordinated by the United States Department of Agriculture (USDA), with input as needed from the Environmental Protection Agency (EPA) and the FDA.¹³

I. HISTORY OF GMOs AND A DISCUSSION OF THE ISSUES

A. History

Humans began altering organisms as early as 32,000 years ago when they started domesticating wolves.¹⁴ Since then, the human race has bred bananas,¹⁵ carrots,¹⁶ corn,¹⁷ and wheat¹⁸ into submission—just to name a few. Humans turned wild, unruly weeds into robust, nutritious crops, making them easier to grow and harvest.¹⁹ Humans chose the most desirable members of each species and encouraged them to breed.²⁰

As technology progressed, scientists found new ways to change plants and animals. In 1973, Herbert Boyer and Stanley Cohen discovered how to

10. Compare *Genetically Modified Organism*, DICTIONARY.COM (3rd ed. 2005) with *Genetic Engineering*, MERRIAM WEBSTER DICTIONARY (2018) (comparing the difference in denotation between “genetic engineering,” “genetic modification,” and “genetically modified organism”—all refer pieces of the same puzzle, but genetic engineering is the field, genetically engineered or modified is the process, and genetically modified organisms are the result).

11. See *infra* Part II. History of GMO’s and a Discussion of the Issues.

12. See *infra* Part III. Establishment of the Framework.

13. See *infra* Part IV. Proposed Changes to the Framework.

14. Carl Zimmer, *From Fearsome Predator to Man’s Best Friend*, N.Y. TIMES (May 16, 2013), <https://www.nytimes.com/2013/05/16/science/dogs-from-fearsome-predator-to-mans-best-friend.html?smid=pl-share>.

15. See Tanya Lewis, *Here’s What Your Food Would Look Like If it Weren’t Genetically Modified Over Millennia*, BUS. INSIDER (Aug. 9, 2015), <http://www.businessinsider.com/foods-before-genetic-modification-2015-8/#wild-carrot-7> (providing examples of foods that appear radically different now as compared to hundreds of years ago).

16. *Id.*

17. GENETIC SCIENCE LEARNING CENTER, EVOLUTION OF CORN, <http://learn.genetics.utah.edu/content/selection/corn> (last visited Oct. 9, 2018).

18. Michael Balter, *Farming was So Nice, It was Invented at Least Twice*, SCIENCE (July 4, 2013, 2:15 PM), <http://www.sciencemag.org/news/2013/07/farming-was-so-nice-it-was-invented-least-twice>.

19. Sean B. Carroll, *Tracking the Ancestry of Corn Back 9,000 Years*, N.Y. TIMES (May 24, 2010), <https://www.nytimes.com/2010/05/25/science/25creature.html>.

20. Chassy, *supra* note 2, at 169.

transfer DNA from one organism to another.²¹ The researchers cut DNA from an antibiotic resistant strain of plasmid pSC101 and inserted it into *Escherichia coli*, transferring pSC101's tetracycline resistance to the bacteria.²² The researchers found that the resistance was still present after reproduction and began experimenting further, eventually adding frog DNA to *E. coli*.²³ Just a year after the groundbreaking discovery, scientists called for a voluntary moratorium on GE projects, outlining potential hazards and the need for guidelines.²⁴ After the 1975 Asilomar Conference, the Recombinant DNA Committee agreed upon standards and containment procedures for use in GE projects.²⁵ Each experiment on an organism falls into a category (1, 2, 3, or 4), which corresponds to a containment measure.²⁶ For example, experiments on animal viruses (category 2) "should be performed only with vector–host systems having demonstrably restricted growth capabilities outside the laboratory and with moderate risk containment facilities."²⁷ In moderate-risk containment facilities "transfer operations should be carried out in biological safety cabinets (e.g., laminar flow hoods), gloves should be worn during the handling of infectious materials, vacuum lines must be protected by filters, and negative pressure should be maintained in the limited access laboratories."²⁸ With these new standards in place, scientists could continue their work, confident that their research would not harm society. The conference, still being written about today, instilled trust in the public and governments around the globe because scientists showed that they could effectively police themselves.²⁹

21. SCI. HISTORY INST., HERBERT W. BOYER & STANLEY N. COHEN, <https://www.sciencedhistory.org/historical-profile/herbert-w-boyer-and-stanley-n-cohen> (last visited Sept. 23, 2018).

22. *Id.*

23. *Id.*

24. Paul Berg et al., Letter to the Editor, *Potential Biohazards of Recombinant DNA Molecules*, 185 SCIENCE, no. 4148, July 26 1974, at 303., <http://science.sciencemag.org/content/185/4148/303> (explaining the Committee on Recombinant DNA Molecules' concerns about genetic engineering research).

25. Paul Berg et al., *Summary Statement of the Asilomar Conference on Recombinant DNA Molecules*, 72 PROC. OF THE NAT'L ACAD. OF LIFE SCI. 1981 (1975), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC432675/pdf/pnas00049-0007.pdf>.

26. NAT'L INST. OF HEALTH, GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES, § II-A-1 (Apr. 2016), https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html (outlining the modern Risk Groups used in GE experiments).

27. Berg et al., *supra* note 25, at 1983.

28. *Id.* at 1982.

29. Rangel, *supra* note 3; Paul Berg, *Asilomar 1975: DNA Modification Secured*, 455 NATURE 290, 290 (2008), <http://www.nature.com/nature/journal/v455/n7211/full/455290a.html>; Ezekiel J. Emanuel, *Tinkers and Tailors: Three Books Look to the Biomedical Frontier*, N.Y. TIMES (Mar. 16, 2017), <https://www.nytimes.com/2017/03/16/books/review/gene-machine-bonnie-rochman.html>.

In 1980, the Supreme Court held that GE organisms are patentable.³⁰ This went completely against the previously held notion that living things were not patentable subject matter under 35 U.S.C. § 101.³¹ Two years later, scientists introduced synthetic insulin to society and twelve years after that, the first GM food product (the Flavr Savr tomato) entered commercial production.³² The public trust gained by the Asilomar Conference did not last, as the Flavr Savr tomato faced a massive amount of public scrutiny even after a seven-year testing and approval process.³³ Researchers engineered the tomato to stay firm longer after ripening, eliminating the need for artificial ripening through ethylene exposure.³⁴ They claimed its ability to ripen naturally also increased, as suggested by the name, its flavor.³⁵ In 1996, Zeneca released a tomato paste in the U.K. made from the Flavr Savr tomatoes.³⁶ While some articles suggest the tomato's demise was due to Monsanto³⁷ purchasing the Flavr Savr brand,³⁸ others suggest Dr. Pusztai's study on rats was responsible.³⁹ Both brands eventually died due to the

30. See generally, *Diamond v. Chakrabarty*, 477 US 303, 309–310 (1980) (holding that the human-made, genetically engineered, oil-eating bacterium qualified as patentable subject matter under 35 U.S.C. § 101 because it had “markedly different characteristics from any found in nature and ... the potential for significant utility.”).

31. 35 U.S.C. § 101 (2012).

32. Lawrence K. Altman, *A New Insulin Given Approval For Use in U.S.*, N.Y. TIMES, Oct. 30, 1982, available at <http://www.nytimes.com/1982/10/30/us/a-new-insulin-given-approval-for-use-in-us.html>; Michael Winerip, *You Call That a Tomato?*, N.Y. TIMES (June 24, 2013), <https://www.nytimes.com/2013/06/24/booming/you-call-that-a-tomato.html?smid=pl-share>.

33. See e.g., G. Bruening & J.M. Lyons, *The Case of the FLAVR SAVR Tomato*, CAL. AGRIC., July-Aug. 2000, at 7, <http://calag.ucanr.edu/Archive/?article=ca.v054n04p6> (explaining Sainsbury and Safeway's declaration against genetically engineered ingredients was in response to consumer concerns).

34. *Id.*

35. See Winerip, *supra* note 32 (describing typical complaints about the tomato's lack of flavor).

36. See Bruening & Lyons, *supra* note 33, at 7.

37. See generally, *About Monsanto Company*, MONSANTO, <https://monsanto.com/company/> (last visited Sep. 28, 2018) (explaining Monsanto, recently acquired by Bayer, was a publicly traded, U.S.-based, agrochemical and agricultural biotechnology corporation).

38. Winerip, *supra* note 32 (suggesting that Monsanto's lack of transparency reduced public confidence in the Flavr Savr tomato).

39. See Bruening & Lyons, *supra* note 33 (explaining that a U.K. House of Commons report credited the decline of tomato paste to Dr. Pusztai's research); SELECT COMMITTEE ON SCIENCE AND TECHNOLOGY, FIRST REPORT, 1998-9, HC 286, at ¶ 25 (UK); see also, Conan Milner, *Top Five GMO Failures*, EPOCH TIMES (Aug. 21, 2013), https://www.theepochtimes.com/top-5-gmo-failures_255547.html (relating the Flavr Savr tomato's demise to Dr. Pusztai's television interview). Dr. Pusztai's published research can be viewed at Stanley W.B. Ewen & Arpad Pusztai, *Effects of Diets Containing Genetically Modified Potatoes Expression Galanthus nivalis Lectin on Rat Small Intestine*, 354 THE LANCET 1353 (1999), [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(98\)05860-7/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(98)05860-7/fulltext).

tomato's GMO designation, and Dr. Pusztai had a very large impact on the public opinion of GE as a whole.⁴⁰

B. Shift in Public Opinion

In 1998, Dr. Pusztai did a television interview on "World in Action" about his research, before his study had been published or peer-reviewed.⁴¹ During the interview, Dr. Pusztai suggested that rats he studied suffered from stunted growth and repressed immune systems resulting from their ingestion of GE potatoes.⁴² Due to the incredible buzz caused by the interview, the Director of Dr. Pusztai's home research facility put a hold on Dr. Pusztai's work and inspected his records, finding them incredibly unorganized.⁴³ An official audit was performed and the committee concluded that Dr. Pusztai's results did not support the conclusion he touted on TV.⁴⁴ But the damage was already done.⁴⁵

Today, those who are anti-GE see Dr. Pusztai as "a hero - the scientist who stood up to the establishment and, as a result, had his career squashed at the behest of shadowy forces in the GM industry and the government."⁴⁶ Professor Chris Leaver, a GM scientist at Oxford University, theorizes that although "the vast majority of people were somewhat neutral at the time," Dr. Pusztai's statements pushed them off the fence into anti-GE territory.⁴⁷ In 1999, the British Royal Society reviewed Dr. Pusztai's data again and reached the same conclusion as the internal audit committee.⁴⁸ Even with that conclusion, debate still exists over what Dr. Pusztai's research shows and just how he went wrong.⁴⁹

40. Bruening & Lyons, *supra* note 33, at 7 (showing that Dr. Pusztai's initial claims were incorrect, but Sainsbury and Safeway still discontinued sale of the Zeneca tomato paste brand); SELECT COMMITTEE ON SCIENCE AND TECHNOLOGY, *supra* note 38, at ¶ 22–27.

41. Dr. Nina V. Fedoroff, *Pusztai's Potatoes - is 'Genetic Modification' the Culprit?*, AGBIOWORLD, <http://www.agbioworld.org/biotech-info/articles/biotech-art/pusztai-potatoes.html> (last visited Sept. 23, 2018).

42. *Id.*

43. *Id.*

44. *Id.*

45. Jeffrey Smith, *Anniversary of a Whistleblowing Hero*, HUFFINGTON POST (Aug. 9, 2010), http://www.huffingtonpost.com/jeffrey-smith/anniversary-of-a-whistleb_b_675817.html (updated Dec. 6, 2017).

46. *Id.*; James Randerson, *Arpad Pusztai: Biological Divide*, THE GUARDIAN (Jan. 15, 2008), <https://www.theguardian.com/education/2008/jan/15/academicexperts.highereducationprofile>.

47. Randerson, *supra* note 45.

48. Fedoroff, *supra* note 40.

49. See, e.g., Randerson, *supra* note 45 (stating that "newspaper stories generated confusion over the nature of the genetic modification. These articles refer to potatoes modified with a lectin gene from jackbean that is poisonous to mammals. But no one can agree on where this came from. The

C. Benefits

Since the beginning of GE technology, there have been no peer-reviewed studies proving GM products are inherently harmful.⁵⁰ Anti-GE advocates still use Dr. Pusztai's research, along with other flawed studies, like the Institute for Responsible Technology's gluten study or Seralini's tumor ridden rats, to call for a permanent moratorium on GE projects.⁵¹ However, countless more studies show GM products are not harmful and can actually be quite beneficial.⁵² Part III discusses potential hazards of GMOs in the

misinformation was formalised in a press release issued by the Rowett. James says Pusztai approved it. Pusztai says he was not aware of it until it was published. Either way, the jackbean experiments that never were have proved extremely damaging to Pusztai. Even now, GM scientists dismiss Pusztai's work on the grounds of a supposed schoolboy error: of course the rats suffered, they say, they were being fed potatoes that were genetically modified to produce a poison.”); Fedoroff, *supra* note 40 (“The transgenic potato lines [used in the study] were different from each other, as well as from the parental potatoes. A later study on transgenic potatoes came to the same conclusion. Here Pusztai jumped to the conclusion that these differences must be attributable to the fact that the plants were transgenic – and he went public with his conclusion. What he probably didn’t know – because he was neither a plant breeder nor a plant biologist – was that the very process through which the plants are put during the introduction of the transgene – culturing through a callus stage and then regeneration of the plant – can cause marked changes in both the structure and expression of genes.”); AGRIC. BIOTECHNOLOGY COUNCIL OF AUSTRALIA *Rats and Potatoes: Toxicity Studies and GM Foods* (2012), <https://docslide.us/documents/issue-paper-1-rats-and-potatoes-toxicity-studies-and-gm-foods.html> (explaining the doubts about Pusztai’s research by independent reviewers); Steve Connor, *Science: Pusztai: The Verdict*, INDEPENDENT, (Feb. 19, 1999, 1:02 AM), <http://www.independent.co.uk/arts-entertainment/science-pusztai-the-verdict-1071729.html>.

50. THE NAT’L ACAD. PRESS, GENETICALLY ENGINEERED CROPS: EXPERIENCES AND PROSPECTS 236 (2016), <https://agbiotech.ces.ncsu.edu/wp-content/uploads/2016/05/NAS-Genetically-Engineered-Crops-Full-Report.pdf?fwf=no>.

51. See e.g., Ronnie Cummins, *Hazards of Genetically Engineered Foods and Crops: Why We Need a Global Moratorium*, IN MOTION (Aug. 24, 1999), <http://www.inmotionmagazine.com/geff4.html> (“A brief look at the already-proven and likely hazards of GE products provides a convincing argument for why we need a global moratorium on all GE foods and crops.”).

52. Elizabeth Weise, *Academies of Science Finds GMOs Not Harmful to Human Health*, USA TODAY (May 17, 2016), <http://www.usatoday.com/story/tech/2016/05/17/gmos-safe-academies-of-science-report-genetically-modified-food/84458872/>; see e.g., Layla Katiraei, *10 Studies Proving GMOs are Harmful? Not if Science Matters*, GENETIC LITERACY PROJECT (Nov. 13, 2015), <https://www.geneticliteracyproject.org/2015/11/13/10-studies-proving-gmos-are-harmful-not-if-science-matters/> (stating that “current scientific consensus regarding GMOs remains unchanged: they are safe and do not pose a health risk to humans.”); see e.g., Megan L. Norris, *Will GMOs Hurt My Body? The Public’s Concerns and How Scientists Have Addressed Them*, HARV. U.: THE GRADUATE SCHOOL OF ARTS AND SCI.: SCI. IN THE NEWS (Aug. 9, 2015), <http://sitn.hms.harvard.edu/flash/2015/will-gmos-hurt-my-body/> (finding that GMOs exhibit no toxicity); see also Jon Entine, *The Debate About GMO Safety Is Over. Thanks To A New Trillion-Meal Study*, FORBES (Sept. 17, 2014), <https://www.forbes.com/sites/jonentine/2014/09/17/the-debate-about-gmo-safety-is-over-thanks-to-a-new-trillion-meal-study/#7719d2d68a63> (explaining that over 2,000 studies document that biotechnology does not pose “an unusual threat to human health . . .”); see also, Mark Lynas, *GMO Safety Debate is Over*, CORNELL ALL. FOR SCI. BLOG (May 23, 2016), <https://allianceforscience.cornell.edu/blog/2016/05/gmo-safety-debate-is-over/> (discussing the report by the National Academies of Science, Engineering, and Medicine which found no evidence that GE crops were less safe than non-GE crops); Steven Novella, *Seralini Fails Replication*, NEUROLOGICA BLOG

context of each agency's responsibilities in the certification process but, as with most new technologies, there are numerous benefits.⁵³ For example, about twenty years ago the Ringspot virus was decimating Hawaiian papaya, until a researcher at Cornell University genetically modified the plant using genes from the virus.⁵⁴ Golden Rice provides an even more potent example of GM's value because of its potential to solve Vitamin A Deficiency (VAD).⁵⁵

The World Health Organization estimates that VAD affects 250 million preschool children, which can cause poor vision and even blindness.⁵⁶ Addressing VAD can reduce child mortality by 23% in the areas that suffer most.⁵⁷ This is why the Rockefeller Foundation created and distributed Golden Rice (GM vitamin A-rich rice), using a food product already common in VAD-affected areas to boost vitamin A consumption.⁵⁸ Scientists pulled genes from daffodils and a soil bacteria to increase the levels of beta-carotene in the rice, which the human body converts to vitamin A.⁵⁹ The Golden Rice project is essentially open source, with the private sector providing free licenses for intellectual property rights and multiple research institutions working together on the project.⁶⁰ Even though the project has proven effective and humanitarians such as Bill and Melinda Gates support the product, anti-GE groups such as Greenpeace still scrutinize Golden Rice.⁶¹ Some opponents go so far as to destroy field trials in an effort to stop the plant's approval and production.⁶² Golden Rice still awaits commercial

(June 8, 2018), <https://theness.com/neurologicablog/index.php/seralini-fails-replication/> (discussing the continued effect of Séralini's study).

53. See *infra* Part III. Establishment of the Framework (discussing the history of the Coordinated Framework for the Regulation of Biotechnology along with its benefits and drawbacks).

54. Dennis Gonsalves et al., *Transgenic Virus Resistant Papaya: From Hope to Reality for Controlling Papaya Ringspot Virus in Hawaii*, APSNET (July 2004), <http://oregonstate.edu/instruct/bi430-fs430/Documents-2004/3B-BIOTECH%20METH/Gonsalves-papaya-story-AmPhytopSoc2004.pdf>.

55. JORGE E. MAYER ET AL., *THE GOLDEN RICE PROJECT 1* (June 17, 2006), http://www.goldenrice.org/PDFs/The_Golden_Rice_Project_Mayer_et_al_2006.pdf.

56. *Micronutrient Deficiencies*, WORLD HEALTH ORGANIZATION, <http://www.who.int/nutrition/topics/vad/en/> (last visited Sept. 21, 2018).

57. *Id.*

58. Dan Charles, *In A Grain Of Golden Rice, A World Of Controversy Over GMO Foods*, NPR (Mar. 7, 2013), <https://www.npr.org/sections/thesalt/2013/03/07/173611461/in-a-grain-of-golden-rice-a-world-of-controversy-over-gmo-foods>.

59. MAYER ET AL., *supra* note 54, at 1–2.

60. *Id.* at 2; see also Laura Lloyd, *Golden Rice Still Struggling for Acceptance in Asia*, WORLD-GRAIN.COM (Aug. 30, 2016), <https://www.world-grain.com/articles/6975-golden-rice-still-struggling-for-acceptance-in-asia> (explaining the company that developed Golden Rice surrendered its intellectual property rights).

61. Amy Harmon, *Golden Rice: Lifesaver?*, N.Y. TIMES (Aug. 24, 2013), <https://www.nytimes.com/2013/08/25/sunday-review/golden-rice-lifesaver.html>.

62. *Id.*

approval in Asia, even though one bowl could provide up to 60% of a child's recommended daily value of vitamin A.⁶³ Despite the pushback from anti-GE groups, Golden Rice's benefits have inspired other GE crops, such as biofortified beans, cassava, sweet potatoes, and more, though some biofortified crops are being created through more traditional methods.⁶⁴

GMOs may also be useful in fighting non-native diseases. For example, many scientists believe genetic modification is the only way to save the Florida Orange.⁶⁵ When the Asian citrus psyllid (an insect) was brought to the U.S., farmers began losing trees by the grove.⁶⁶ The insect causes citrus greening (officially named Huanglongbing), which presents as atrophy in the tree and fruit that never ripens.⁶⁷ Due to the differences in California and Florida oranges,⁶⁸ 90% of America's juice comes from Florida, and 87% of Florida's citrus is processed into juice concentrate.⁶⁹ If Florida oranges die off from greening without a substantial replacement, the U.S. will lose a significant portion of its orange production. The industry's decline has also impacted Florida's culture and economy.⁷⁰ Solving greening may not bring Florida's economy back to its previous state, but it could save hundreds of groves and an entire industry otherwise likely to die out.

GMOs can reduce disease in humans as well. Bill Gates has called for more GMOs by investing in projects like Target Malaria.⁷¹ The project intends to GM mosquitoes to reduce fertility, thereby reducing the population

63. *Id.*; See Lloyd, *supra* note 59 (describing that Golden Rice will not be available to farmers anywhere in the world for "at least a couple years"); see *History of the Golden Rice Project*, GOLDEN RICE PROJECT, http://www.goldenrice.org/Content1-Who/who2_history.php (last visited Oct. 9, 2018) (explaining the difficult approval process for Golden Rice).

64. WORLD HEALTH ORG., BIOFORTIFICATION OF STAPLE CROPS, <http://www.who.int/elena/titles/biofortification/en/> (last updated Oct. 4, 2018); XiaoZhi Lim, *Biofortification: Is it the Next 'Green Revolution' For More Nutritious Food?*, GENETIC LITERACY PROJECT (June 2, 2017), <https://geneticliteracyproject.org/2017/06/02/biofortification-next-green-revolution-nutritious-food/>.

65. Paul Voosen, *Can Genetic Engineering Save the Florida Orange?*, NAT'L GEOGRAPHIC (Sept. 13, 2014), <http://news.nationalgeographic.com/news/2014/09/140914-florida-orange-citrus-greening-gmo-environment-science>.

66. *Id.*

67. *Id.*; *Citrus Greening (Huanglongbing)*, UNIV. OF FLA. CITRUS EXTENSION, <http://www.crec.ifas.ufl.edu/extension/greening/index.shtml> (last visited Oct. 9, 2018).

68. *California vs Florida Oranges, What's the Difference?*, DAVIDSON BROTHERS (Nov. 26, 2013), <http://blog.davidsonbros.com/2013/11/california-vs-florida-oranges-whats.html>.

69. *Facts About Florida Oranges & Citrus*, VISIT FLORIDA, <http://www.visitflorida.com/en-us/eat-drink/facts-about-florida-citrus-oranges.html> (last visited Sept. 25, 2018).

70. Alana Samuels, *Florida Without Oranges*, THE ATLANTIC (Jan. 27, 2015), <https://www.theatlantic.com/business/archive/2015/01/florida-without-oranges/384774> (stating that the Florida citrus industry generated one billion dollars less each year between 2007 and 2013).

71. Antonio Regalado, *Bill Gates Doubles His Bet on Wiping Out Mosquitoes with Gene Editing*, MIT TECH. REV. (Sept. 6, 2016), <https://www.technologyreview.com/602304/bill-gates-doubles-his-bet-on-wiping-out-mosquitoes-with-gene-editing/>.

of mosquitoes that carry and transmit the disease.⁷² GMOs are also known for higher yields and fewer inputs.⁷³ They can reduce erosion and help feed the growing population.⁷⁴ With population estimates reaching nine billion by 2050, something will need to be done to ensure food needs are met worldwide.⁷⁵ A solution may come in the form of increased yields or decreased waste but will likely include both.⁷⁶

D. Current Climate

Those who intend to introduce new GM crops are still facing an uphill battle. Anti-GE proponents are so ardent that even after the devastating earthquake in 2010, which killed more than 300,000 people and left over one million homeless, they burned corn and vegetable seeds donated by Monsanto.⁷⁷ Protestors questioned the seeds and Monsanto's motives, even though Monsanto claimed to have worked closely with the Haitian Ministry of Agriculture.⁷⁸ The Ministry stated that the same seeds and the fungicide coating, meant to protect the seeds during the germination process, were already in use in Haiti.⁷⁹ The most outspoken advocates of burning the seeds

72. See Joe F. Aldrich, *The Rise of The Mutants: Obtaining Regulatory Approval for the Release of Genetically Modified Mosquitoes*, 17 COLUM. SCI. & TECH. L. REV. 292, 296 (2016).

73. U.S. Farmers: GMO Crops Help Reduce Inputs and Enhance Conservation, THE FOOD DIALOGUES (Dec. 15, 2016), <http://www.fooddialogues.com/article/u-s-farmers-gmo-crops-help-reduce-inputs-enhance-conservation/> (discussing farmers' positive experiences with GM crops); U.S. Farmers & Ranchers Alliance, *What are the Benefits of GMOs, Both Today and in the Future?*, THE FOOD DIALOGUES, <http://www.fooddialogues.com/article/benefits-gmos-today-future> (last visited Oct. 9, 2018).

74. U.S. Farmers & Ranchers Alliance, *supra* note 72.; see Anastasia Bondar, *The Promise of GMOs: Conservation Tillage*, BIOLOGY FORTIFIED, (Feb. 19, 2014), <https://www.biofortified.org/2014/02/conservation-tillage/> (discussing the benefits of conservation tillage for GMO soybeans).

75. *Benefits of Food & Ag Biotechnology*, COALITION FOR SAFE & AFFORDABLE FOOD, <http://coalitionforsafeaffordablefood.org/benefits-of-biotechnology> (last visited Sept. 22, 2018); Jonathan Foley, *The Future of Food*, NAT'L GEOGRAPHIC, <http://www.nationalgeographic.com/foodfeatures/feeding-9-billion> (last visited Sept. 30, 2018).

76. H. Charles J. Godfray et. al., *Food Security: The Challenge of Feeding 9 Billion People*, 327 SCIENCE 812, 813, 815-16 (2010).

77. Gary Dunion, *Aftershock in Haiti*, RED PEPPER (Dec. 28, 2010), <https://www.redpepper.org.uk/aftershock-in-haiti/>.

78. *Id.*; Beverly Bell, *Haitian Farmers Commit to Burning Monsanto Hybrid Seeds*, THE WORLD POST, http://www.huffingtonpost.com/beverly-bell/haitian-farmers-commit-to_b_578807.html (last updated May 25, 2011).

79. Mica Veihman, *Five Answers on Monsanto's Haiti Seed Donation*, MONSANTO BLOG (May 20, 2010), <https://web.archive.org/web/20100924082925/http://monsantoblog.com/2010.05.20.five-answers-monsanto-haiti>.

claimed accepting the seeds would irrevocably associate Haitian farmers with multinational corporations.⁸⁰

In fact, the hatred towards GM crops, and Monsanto's association with them, has given rise to groups like March Against Monsanto.⁸¹ These groups use fearmongering and sensationalism to oppose GE projects.⁸² This has even led to personal attacks on GE scientists. Dr. Kevin Folta, a researcher at the University of Florida, was verbally flayed in a front-page article for *The New York Times*.⁸³ Because of the article and additional harassment, Dr. Folta had to take a hiatus from the public eye.⁸⁴ In 2008, the FBI named eco-terrorists and animal rights extremists "one of the most serious domestic terrorism threats in the U.S."⁸⁵ Reaching a consensus on anything is difficult when a large portion of stakeholders are waving torches and pitchforks.⁸⁶

Anti-GE activists, which often includes organic farmers, claim that corporations who own GM crop technology will use it to harass farmers through contamination suits.⁸⁷ Part of this argument is based on misinformation surrounding a Canadian farmer who sprayed his field to isolate the Roundup Ready Canola that had blown into it.⁸⁸ The farmer, Percy

80. Steve Baragona, *Hungry Haitian Farmers Urged to Burn Donated US Seeds*, VOA NEWS (June 07, 2010 8:00 PM), <http://www.voanews.com/a/hungry-haitian-farmers-urged-to-burn-donated-seed-95860699/163933.html>.

81. See MARCH AGAINST MONSANTO, <https://www.march-against-monsanto.com/> (last visited Dec. 9, 2018).

82. Karl Haro von Mogel, Kavin Senapathy, & David Sutherland, *Call For Action: It's Time to March Against the March Against Monsanto*, GENETIC LITERACY PROJECT (Feb. 2, 2015), <https://geneticliteracyproject.org/2015/02/02/call-for-action-its-time-to-march-against-the-march-against-monsanto/>; See also *Why I'm Joining the March Against Monsanto*, THE RISK-MONGER (May 20, 2016), <https://risk-monger.com/2016/05/20/why-im-joining-the-march-against-monsanto> (describing tactics used by March Against Monsanto to rally supporters).

83. Compare Eric Lipton, *Food Industry Enlisted Academics in G.M.O. Lobbying War, Emails Show*, N.Y. TIMES (Sept. 5, 2015), <https://nyti.ms/2kqbjA4>, with David Kroll, *What the New York Times Missed on Kevin Folta and Monsanto's Cultivation of Academic Scientists*, FORBES (Sept. 10, 2015), <https://www.forbes.com/sites/davidkroll/2015/09/10/what-the-new-york-times-missed-on-kevin-folta-and-monsantos-cultivation-of-academic-scientists/#6c25489a619a> (arguing against the NY Times article and that Folta's only "crime is that he works and speaks about GMOs.").

84. Kevin M. Folta, FACEBOOK (Nov. 4, 2015), <https://www.facebook.com/kmfolta/posts/899781960100117>. "Additional harassment" includes threats of violence to his family and his laboratory. Kroll, *supra* note 82.

85. *Putting Intel to Work*, FEDERAL BUREAU OF INVESTIGATION (June 30, 2008), https://archives.fbi.gov/archives/news/stories/2008/june/ecoterror_063008.

86. Figuratively, of course.

87. Dan Charles, *Top Five Myths of Genetically Modified Seeds, Busted*, NPR (Oct. 18, 2012), <http://www.npr.org/sections/thesalt/2012/10/18/163034053/top-five-myths-of-genetically-modified-seeds-busted>; See e.g. Carey Gillam, *Organic Growers Lose Decision in Suit Versus Monsanto Over Seeds*, REUTERS (June 10, 2013: 2:46 PM), <https://www.reuters.com/article/us-monsanto-organic-lawsuit/organic-growers-lose-decision-in-suit-versus-monsanto-over-seeds-idUSBRE9590ZD20130610> (describing farmers' efforts to stop Monsanto from filing contamination suits).

88. Charles, *supra* note 86.

Schmeiser, later harvested those plants for the next year's seed.⁸⁹ Schmeiser planted a patented seed without paying the licensing fees and used contamination as an excuse to evade responsibility.⁹⁰ Though Monsanto has been heavy-handed in going after patent law violators, the stories about the corporation are generally significantly exaggerated.⁹¹

The misinformation spread about GMOs is a large reason for the opposition by farmers and legislators of GMO labeling.⁹² As seen with the Flavr Savr tomato, GMO labeling issues have the potential to destroy a product.⁹³ The hazards of GMO labeling are also supported by companies seeing success from removing GM products from their lineup and publicizing it.⁹⁴ Both sides of the dispute have taken the position that consumers cannot listen to reason and only respond to sensationalism, which has resulted in more sensationalism from anti-GE groups and little communication from pro-GE groups.⁹⁵

Public opinion polls, however, show that the public is mostly ambivalent towards GMOs.⁹⁶ Most members of the public lack knowledge about the science behind GMOs and are concerned about its "unnaturalness," but they accept there is inherent risk in everything and would like more honest appraisals of the risks in GMO products.⁹⁷ Groups like the Coalition for Safe Affordable Food are working toward a middle ground. They propose a label that allows consumers to learn more about the source of their food but avoids the stigma of having a GM label.⁹⁸ The approval process for GM products

89. *Id.*

90. *Id.*

91. See Gillam, *supra* note 86 (describing Monsanto's "reputation for zealously defending [its] patents").

92. See e.g., Jeff Apthorp, *Why We Don't Feed Our Animals GMO Feed – Part 3*, SEVEN SONS FARM, https://sevensons.net/blog/why-we-don-t-feed-our-animals-gmo-feed-part-3?fb_comment_id=1108110275878623_1165280126828304#f5107588f27c3c (last visited Sep. 29, 2018) (citing Séralini's study as one of the reasons the farm does not use GMO feed); Rangel, *supra* note 3.

93. See *supra* Section II.b, *Shift in Public Opinion*; see also Chassy, *supra* note 2, at 171 (explaining McDonald's pulled GM potatoes for fear of consumer rejection).

94. Weise, *supra* note 51; see e.g., *Chipotle (CMG) Eliminates Additives from its U.S. Food Menu*, ZACKS (Mar. 29, 2017), <https://www.zacks.com/stock/news/254543/chipotle-cmg-eliminates-additives-from-its-us-food-menu> (describing how Chipotle no longer uses GMO ingredients or additives and how their stock price is recovering); Maggie Hennessy, *Why Restaurants are Still Saying No to GMO*, QSR (Jan. 2017), <https://www.qsrmagazine.com/health-wellness/why-restaurants-are-still-saying-no-gmo>.

95. Cyrus Martin, *The Psychology of GMO*, 23 CURRENT BIOLOGY (SPECIAL ISSUE), no. 9, 2008, at R356, R356.

96. Claire Marris, *Public views on GMOs: Deconstructing the Myths*, 2 EMBO REP. 545, 545 (2001); HOLLY RHODES & KEEGAN SAWYER, PUBLIC ENGAGEMENT ON GENETICALLY MODIFIED ORGANISMS 6 (2015).

97. *Id.*

98. COAL. FOR SAFE & AFFORDABLE FOOD, National Biotech Disclosure Law, <http://coalitionforsafeaffordablefood.org/common-sense-solution> (last visited Oct. 9, 2018).

should provide the same benefits. It should allow concerned citizens to be involved in, or at least kept abreast of, the process while providing an honest, easy to digest assessment of a product's risks as compared to the current options. Part III of this paper proposes a new framework to meet the needs of consumers, producers, and innovators.

II. ESTABLISHMENT OF THE FRAMEWORK

The Coordinated Framework for Regulation of Biotechnology (Coordinated Framework or the framework), established under President Reagan in 1986, was meant to be a "comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products."⁹⁹ The result, however, has been less than desirable. John Charles Kunich, currently a lecturer in the Department of Political Science and Public Administration at the University of North Carolina at Charlotte, explained:

the environmental risks posed by genetically engineered organisms are not addressed in a coherent manner. There is no single federal statute that governs the subject matter. The regulatory regime that does exist only confronts a few aspects of the issue, and then only in a piecemeal, haphazard fashion. And there is no federal agency with overarching responsibility for the topic; rather, multiple agencies are charged with monitoring disparate portions of it, with no effective means for ensuring comprehensive and consistent coverage. Consequently, there are sizable gaps in coverage, with the concomitant risk of significant harms slipping through the cracks and into the environment. Additionally, proponents of new and potentially important genetically engineered "products" are forced to navigate a confusing maze of agencies and statutes, with resulting inefficiency and needlessly steep economic and opportunity costs and delays for industry and the general public.¹⁰⁰

Professor Kunich later accepted this disorder due to the relative newness of GE,¹⁰¹ but more than 15 years have passed since Professor Kunich's paper,

99. Office of Science and Technology Policy, Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302, 23302(proposed June 26, 1986).

100. John Charles Kunich, *Mother Frankenstein, Doctor Nature, and the Environmental Law of Genetic Engineering*, 74 S. CAL. L. REV. 807, 823 (2001).

101. *Id.*

and the chaos that is the Coordinated Framework should no longer be acceptable.

When the Coordinated Framework was originally introduced, it was expected that the process would evolve as technology did. However, the working group that created the framework concluded that the current laws covered most of the regulatory basis necessary at the time.¹⁰² The 1992 Update to the Coordinated Framework emphasized that new products should not be segregated based on the technology used to produce them, but that they should be evaluated based on their individual characteristics and corresponding potential hazards.¹⁰³ In reality, each product's intended use determines its approval process.¹⁰⁴ Despite stated intentions, we have essentially segregated GE products because non-GE products generally do not require government approval to be marketed and sold.¹⁰⁵

The last update to the framework occurred after the Executive Office of the President released a memorandum in July 2015.¹⁰⁶ The memorandum directed the appropriate agencies to clarify their roles and develop a long-term strategy for future GE products.¹⁰⁷ The improvements were meant to:

- maintain high standards that are based on the best available science and that deliver appropriate health and environmental protection;
- establish transparent, coordinated, predictable, and efficient regulatory practices across agencies with overlapping jurisdiction; and

102. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23302-23303.

103. Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products into the Environment, 57 Fed. Reg. 6,753 (Feb. 24, 1992).

104. *Id.* at 6,757; *but see* MARK A. POLLACK & GREGORY C. SHAFFER, WHEN COOPERATION FAILS: THE INTERNATIONAL LAW AND POLITICS OF GENETICALLY MODIFIED FOODS 277 (1st ed. 2009) (asserting that GE products in the EU are regulated based on the technology used to produce them and not their characteristics).

105. *Cf.* GARY RUSKIN, SEEDY BUSINESS: WHAT BIG FOOD IS HIDING WITH ITS SLICK PR CAMPAIGN ON GMOS 15-16 (Jan. 2015), <https://www.usrtk.org/seedybusiness.pdf> (discussing the approval of GMO food products).

106. Exec. Office of the President, Memorandum for Heads of Food and Drug Administration, Environmental Protection Agency, and Department of Agriculture Regarding Modernizing the Regulatory System for Biotechnology Products 3-4 (July 2, 2015), https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_memo_final.pdf [hereinafter *July 2015 EOP Memorandum*].

107. *Id.* at 4.

- promote public confidence in the oversight of the products of biotechnology through clear and transparent public engagement.¹⁰⁸

The memorandum also stated that the Obama Administration “sought regulatory approaches that protect health and the environment while reducing regulatory burdens and avoiding unjustifiably inhibiting innovation, stigmatizing new technologies, or creating trade barriers.”¹⁰⁹ The Update to the Coordinated Framework,¹¹⁰ published in 2017, contains no real changes or “updates.” It is simply a guidance document.¹¹¹ The Update provides examples, so innovators can see who will review their products and consumers know what products each agency must review.¹¹² Furthermore, the third-party study on the future of biotechnology, conducted as a requirement of the President’s memorandum, only covers GE crops.¹¹³ However, the FDA had already assessed several GE animals by the time of the President’s memorandum.¹¹⁴

Virtually every legal article written on the framework agrees it is confusing, unacceptably slow, and inadequate to address future technologies.¹¹⁵ The Coordinated Framework will need a major overhaul to

108. *Id.* at 3.

109. *Id.* at 2.

110. MODERNIZING THE REGULATORY SYSTEM FOR BIOTECHNOLOGY PRODUCTS: FINAL VERSION OF THE 2017 UPDATE TO THE COORDINATED FRAMEWORK FOR THE REGULATION OF BIOTECHNOLOGY (Jan. 4, 2017), https://www.aphis.usda.gov/biotechnology/downloads/2017_coordinated_framework_update.pdf [hereinafter 2017 UPDATE] (explaining the purpose of and distribution of agency regulation over biotechnology).

111. Roger R. Martella, Jr., *Agency Regulation Through Guidance Documents*, SIDLEY AUSTIN LLP (last visited Sept. 21, 2018), <http://masonlec.org/site/rte/uploads/files/AGENCY%20REGULATION%20THROUGH%20GUIDANCE%20DOCUMENTS.pdf> (explaining that agency guidance documents, though not legally binding, are a powerful compliance tool because of an agency’s enforcement power, as they “set standards for agency implementation and thus can function as de facto regulations.”).

112. 2017 UPDATE, *supra* note 109, at 9, tbl. 1.

113. July 2015 EOP Memorandum, *supra* note 105, at 5; THE NAT’L ACAD. PRESS, *supra* note 49, at xiii.

114. *See infra* notes 118–19 and accompanying text.

115. E.g., Michael P. McEvilly, Lack of Transparency in the Premarket Approval Process for AquAdvantage Salmon, 11 DUKE L. & TECH. REV. 413 (2012); Michael Bennet Homer, Frankenfish . . . It’s What’s for Dinner: The FDA, Genetically Engineered Salmon, and the Flawed Regulation of Biotechnology, 45 COLUM. J.L. & SOC. PROBS. 91, 99–101 (2011); Lars Noah, Whatever Happened to the “Frankenfish”? The FDA’s Foot-Dragging on Transgenic Salmon, 65 ME. L. REV. 606, 607, (2013); Maria R. Lee-Muramoto, Reforming the “Uncoordinated” Framework for Regulation of Biotechnology, 17 DRAKE J. AGRIC. L. 311, 343–44 (2012); Dorothy W. Bisbee, Note, Preparing For a Blue Revolution: Regulating The Environmental Release of Transgenic Fish, 12 VA. ENVTL. L.J. 625, 656 (1993); Holly Beth Frompovicz, Comment, A Growing Controversy: Genetic Engineering in Agriculture, 17 VILL.

align with current technologies and stakeholder expectations. However, we must first understand how the framework currently works and what each piece is meant to accomplish. This section will discuss each agency's part in the framework as well as each agency's statutory territory, what it does well, and what it could do better.

A. FDA

The FDA's Plant Biotechnology Consultation Program evaluates GM crops only on a voluntary basis.¹¹⁶ Though "industry considers consultation with the FDA to be a mandatory process" and the FDA has reviewed over 150 varieties through the program, it remains a voluntary resource for interested developers.¹¹⁷ In creating the program, the FDA concluded that GM crops are not materially different from conventional crops and "companies developing new ingredients, new versions of established ingredients, or new processes for producing a food or food ingredient must make a judgment about whether the resulting food substance is a food additive requiring premarket approval by FDA."¹¹⁸

The FDA also declined to regulate the first GM animal available in the United States, the GloFish, because it was not intended to enter the food supply.¹¹⁹ The first GM animal to go through the formal approval process was a goat in 2009.¹²⁰ The goat was engineered to create an anticoagulant, ATryn, in its milk.¹²¹ Since then, the FDA has approved applications for a

ENVTL. L.J. 265, 277-78 (2006); Gregory Jaffe, Symposium: Remarks on Regulating Genetically Modified Foods in the United States, 10 RICH. J.L. & TECH. 8 (2003).

116. *How FDA Regulates Food from Genetically Engineered Plants*, U.S. FOOD & DRUG ADMIN, <https://www.fda.gov/food/ingredientspackaginglabeling/geplants/ucm461831.htm> (last visited Sep. 28, 2018).

117. *Id.*; PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, ISSUES IN THE REGULATION OF GENETICALLY ENGINEERED PLANTS AND ANIMALS 71 (2004); 2017 UPDATE, *supra* note 109, at 17 ("[T]o the best of FDA's knowledge, all GE food crops intended for marketing have been the subject of a consultation or other relevant premarket processes prior to marketing.").

118. Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,989 (May 29, 1992).

119. *Statement Regarding Glofish*, *supra* note 9 (explaining the F.D.A. has no reason to regulate aquarium fish because the fish are not used as food and pose no risk to the environment).

120. *Genetically Engineered Animals: General Q&A*, U.S. FOOD & DRUG ADMIN (archived 2017), <https://wayback.archive-it.org/7993/20170111175109/http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm113605.htm> [hereinafter *F.D.A. General Q&A*].

121. *Id.*; FOOD AND DRUG ADMINISTRATION, US PACKAGE INSERT, ANTITHROMBIN (RECOMBINANT) ATRYN FOR INJECTION (2009).

faster-growing GM salmon and a chicken that lays eggs containing an enzyme used for treating lysosomal acid lipase deficiency.¹²²

The application for AquAdvantage salmon was filed in 1995, and though it has technically been approved, the process still is not over.¹²³ In November 2015, the FDA determined that AquAdvantage salmon are safe to eat.¹²⁴ However, AquaBounty Technologies, owner of AquAdvantage salmon, cannot import their fish into the United States until the FDA finalizes its labeling requirements as required by Congress.¹²⁵

The FDA gets its statutory authority from the Federal Food, Drug, and Cosmetic Act (FDCA) and the Public Health Service Act (PHSA).¹²⁶ The FDA classifies GM animals as “new animal drugs” under the FDCA, asserting that an “rDNA construct in a GE animal that is intended to affect the structure or function of the animal, regardless of the intended use of products that may be produced by the GE animal, meets the [FDCA] drug definition.”¹²⁷ These provisions were added to the FDCA in 1938, well

122. *F.D.A. General Q&A*, *supra* note 119; *FDA Update: FDA Approves First Drug to Treat Rare Enzyme Disorder in Infants, Children*, AM. ACAD. OF PEDIATRICS (Feb. 10, 2016), <http://www.aappublications.org/news/2016/02/10/FDAUpdate021016>.

123. AQUABOUNTY TECHNOLOGIES, *Chronology of AquAdvantage® Salmon and AquaBounty Technologies* (last visited Sept. 21, 2018), <https://www.aquabounty.com/wp-content/uploads/2014/01/Chronology-of-AquAdvantage-Salmon-F1.pdf>; Brady Dennis, *FDA Bans Imports of Genetically Engineered Salmon — for Now*, WASH. POST (Jan. 29, 2016), https://www.washingtonpost.com/news/to-your-health/wp/2016/01/29/fda-bans-imports-of-genetically-engineered-salmon-for-now/?utm_term=.ca4ec73624d2; *Import Alert 99-40: Genetically Engineered (GE) Salmon*, U.S. FOOD & DRUG ADMIN (Apr. 30, 2016), https://www.accessdata.fda.gov/cms_ia/importalert_1152.html; *AquAdvantage Salmon Approval Letter and Appendix*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/BiotechnologyProductsatCVMA/nimalsandAnimalFood/AnimalswithIntentionalGenomicAlterations/ucm466214.htm> (last updated Dec. 1, 2017) [hereinafter *Approval Letter*].

124. *FDA Has Determined That the AquAdvantage Salmon is as Safe to Eat as Non-GE Salmon*, U.S. FOOD & DRUG ADMIN., <https://wayback.archive-it.org/7993/20180423201237/https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm472487.htm> (last updated Dec. 13, 2017); Dennis, *supra* note 122; *see* Voluntary Labeling Indicating Whether Food Has or Has Not Been Derived From Genetically Engineered Atlantic Salmon; Draft Guidance for Industry, 80 Fed. Reg. 73193, 73194 (Nov. 24, 2015) (providing guidance on whether foods derived from GE plants require labeling by the FDA). Just before this article’s publication, the FDA deactivated its import alert against the AquAdvantage salmon, which means “AquAdvantage salmon eggs can now be imported to the company’s contained grow-out facility in Indiana to be raised into salmon for food.” *Statement from FDA Commissioner Scott Gottlieb, M.D., on continued efforts to advance safe biotechnology innovations, and the deactivation of an import alert on genetically engineered salmon*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm632952.htm> (last updated Mar. 10, 2019).

125. *Id.*

126. 21 U.S.C. § 393 (2012); 42 U.S.C. § 262(k)(5)(B) (2012).

127. The FDCA defines drug as:

“The term “drug” means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or

before the invention of the technology the act currently regulates.¹²⁸ Nevertheless, the FDA is empowered by: (1) its ability to remove dangerous food from market; and (2) its responsibility to evaluate food additives for pre-market approval.¹²⁹ “[A] substance that is intentionally added to food is a food additive, unless the substance is generally recognized as safe (GRAS) for the intended use or is otherwise excluded (e.g., a pesticide, the safety of which is overseen by EPA, or a new animal drug, the safety of which is addressed by the new animal drug approval provisions of the [FDCA]).”¹³⁰ Food additives are subject to the National Environmental Policy Act (NEPA), which requires environmental impact studies (EIS) and toxicological studies.¹³¹

GM animals must go through the New Animal Drug Application (NADA) process before they are marketed.¹³² The FDA’s Center for Veterinary Medicine (CVM) conducts the approval process, evaluating “the safety of any food derived from the GE animal, ... the safety of the article to the target animal,” and “whether the claims made by the sponsor are valid.”¹³³ Under the FDCA, the FDA has 180 days to approve or disapprove a NADA, unless they have agreed to a different time period with the applicant.¹³⁴ As discussed later in this section, the FDA does not follow this rule for most GMO applications. Once approved, the FDA posts a notice to the Federal Register as well as the agency’s website.¹³⁵ Post-approval, sponsors have record-keeping duties and the FDA has monitoring

official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).”

21 U.S.C. § 321(g)(1) (2012). (supporting that GM animals fall under provision C); F.D.A., GUIDANCE FOR INDUSTRY 187, REGULATION OF GENETICALLY ENGINEERED ANIMALS CONTAINING HERITABLE RECOMBINANT DNA CONSTRUCTS 4–5 (Sept. 18, 2008), <https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052463.pdf>.

128. 21 U.S.C. § 360b; FDA New Animal Drugs, 21 C.F.R. §§ 510, 514 (1976).

129. 21 U.S.C. §§ 348(c), 350h(d), 350l(a) (2012).

130. 2017 UPDATE, *supra* note 109, at 16 (citing 21 U.S.C. 321(s)).

131. *Id.*; The National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. §§ 4321-4370 (2012); Margaret Rosso Grossman, *Genetically Engineered Animals in the United States: The AquAdvantage Salmon*, 11 EUR. FOOD & FEED L. REV. 190, 192 (2016).

132. See e.g., *AquAdvantage Salmon - Response to Public Comments on the Environmental Assessment*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/BiotechnologyProductsatCVMA/nimalsandAnimalFood/AnimalswithIntentionalGenomicAlterations/ucm466220.htm>. (last updated Nov. 27, 2018) (responding to comments submitted on the EA of the AquAdvantage Salmon’s NADA).

133. 2017 UPDATE, *supra* note 109, at 19.

134. 21 U.S.C. § 360b(c).

135. 21 U.S.C. § 360b(i); 2017 UPDATE, *supra* note 109, at 19-20.

responsibilities.¹³⁶ Medical products produced by GM animals fall under the PHSA and go through the same process as most other drugs and medical devices.¹³⁷

During the evaluation process, the FDA looks at: (1) the description of the GM animal; (2) the genomic alteration and how it is created; (3) how the genomic alteration is passed from one generation to another; (4) phenotypic characteristics of the GM animal; (5) whether the genomic alteration is stable across generations; (6) any environmental impacts and the safety of foods derived from GM animals; and (7) a demonstration of the claimed GE animal.¹³⁸ Though the FDCA does not explicitly call for FDA review of environmental effects, NADA requires an environmental assessment (EA) that is conducted by the applicant.¹³⁹ In the case of AquAdvantage salmon, environmental concerns included the likelihood of escape, likelihood of survival after escape, possibility of reproduction after escape, and consequences to the environment of a potential escape.¹⁴⁰ However, there was low likelihood of escape or reproduction because the modification rendered only female salmon infertile and AquaBounty grew the salmon in landlocked pens. Therefore, the FDA made a finding of no significant impact (FONSI).¹⁴¹

Applicants are also required to submit reports of all clinical studies, including the individual data sets.¹⁴² Test results for GE animal products include information on toxicity and any changes in the genomic alteration over generations or its phenotypic expression over time.¹⁴³ Post-approval, applicants are required to submit any information that may indicate their approval should be suspended or withdrawn.¹⁴⁴

While the FDA has statutory authority to regulate foods and pull hazardous products from market, it does not have statutory authority over

136. 2017 UPDATE, *supra* note 109, at 20.

137. *Id.*

138. *Id.* at 19.

139. New Animal Drug Applications, 21 C.F.R. § 514.1(b)(14) ((1976); 21 C.F.R. § 25.40(b) (2016); *AquAdvantage Salmon*, *supra* note 130 (“NEPA requires that FDA consider the environmental impacts of any “major federal action” that it takes. 42 U.S.C. § 4332(c). Approval of a new animal drug application is a ‘major federal action.’”).

140. *Questions and Answers on FDA’s Approval of AquAdvantage Salmon*, U.S. FOOD & DRUG ADMIN., <https://web.archive.org/web/20170506025118/https://www.fda.gov/animalveterinary/developmentapprovalprocess/geneticengineering/geneticallyengineeredanimals/ucm473237.htm> (last updated Dec. 21, 2015).

141. *Id.*

142. Federal Food, Drug, and Cosmetic Act § 512(b), *as codified* 21 U.S.C. § 360b(b).

143. F.D.A. GUIDANCE FOR INDUSTRY, *supra* note 125, at 19–23.

144. 21 C.F.R. §§ 510.300(b), 514.80 (1976); FDA GUIDANCE FOR INDUSTRY, *supra* note 125, at 24–25.

meat and poultry.¹⁴⁵ The USDA is the agency responsible for ensuring the safety of meat and poultry, leaving milk and in-shell eggs the only animal food products under FDA purview.¹⁴⁶ The FDA relies on the section of the FDCA which reads, “articles (other than food) intended to affect the structure or any function of the body of man or other animals.”¹⁴⁷ However, the approval process examines the product of the modification (the animal) not the “article” performing the modification (the GE process).¹⁴⁸ So the FDA arguably stretched the definition of an animal drug in order to gain oversight, which is interesting given the FDA’s program for regulating GM crops is voluntary, but not all that surprising given the FDA has a “history of creatively interpreting its statutory authority to regulate novel technologies.”¹⁴⁹ Lars Noah argues the transgenic salmon gene to animal drug analogy is not implausible, but other scholars recognize the hypocritical nature of the FDA’s decisions in regulating GE products.¹⁵⁰ The FDA also elected to evaluate the environmental effects of GM animals, even though the EPA is supposed to be an integral part of the framework and have statutory authority over the AquAdvantage salmon’s approval.¹⁵¹

The FDA effectively made themselves the go-to agency for approving GM animals, even though the EPA and USDA also have jurisdiction.¹⁵² A cursory Google search for “USDA AquAdvantage salmon” or “EPA AquAdvantage salmon” brings up reports from only the FDA. Additionally, the only animal example of the eight used in the Update to the Coordinated

145. 21 U.S.C. § 393 (2012) (listing the duties of the FDA); MOU Between FDA and FSIS Regarding the Listing or Approval of Food Ingredients and Sources of Radiation Used in Production of Meat and Poultry Products, 65 Fed. Reg. 33,330, 33,331 (May 23, 2000) (effective Jan. 31, 2000).

146. 21 U.S.C. § 451 (2012); 21 U.S.C. § 679 (a), (2012); Egg Products Inspection Act, 21 U.S.C. § 1031 (2012); *See What FDA Does and Does Not Regulate*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/animalveterinary/resourcesforyou/animalhealthliteracy/ucm374203.htm#Milk_Eggs_Meat_and_Poultry (last updated Oct. 19, 2017) (explaining the distribution of regulatory authority of milk, eggs, meat, and poultry).

147. 21 U.S.C. § 321 (g) (1) (c) (2012).

148. 21 U.S.C. § 360 (b) (2012).

149. Noah, *supra* note 114, at 611–12.

150. *Id.* at 612; *See generally* Lee-Muramoto, *supra* note 114, at 321 (describing instances where the FDA decided to either waive or execute its statutory authority).

151. *See* U.S. FOOD & DRUG ADMIN., AQUADVANTAGE® ENVIRONMENTAL ASSESSMENT (2015), <https://www.fda.gov/downloads/animalveterinary/developmentapprovalprocess/geneticengineering/geneticallyengineeredanimals/ucm466218.pdf>; *See infra* Part III(c). Establishment of a Framework: EPA.

152. *See* 2017 UPDATE, *supra* note 109, at 3 (designating the EPA, USDA, and FDA as the primary regulatory agencies); *See* 2017 UPDATE, *supra* note 104, at 8 (indicating that the regulating agencies should operate in “an integrated and coordinated fashion” when regulating GM animals); *See* 2017 UPDATE, *supra* note 104, at 18 (“FDA regulates GE animals under the new animal drug provisions of the FD&C Act and the FDA’s implementing regulations.”).

Framework is a hypothetical rabbit that produces insulin.¹⁵³ This chosen example is firmly within the FDA's jurisdiction due to its medical product purpose. Under "II. Which agencies have oversight and why", the only agency mentioned is the FDA.¹⁵⁴ However, the USDA has a statutory duty to ensure animal health, and logically the EPA is the best agency to evaluate the possible environmental effects from the animal's production or its possible escape from containment.¹⁵⁵ The entire purpose of this update seems to be clarification, yet it lacks an example catering to GM food animals. This is extremely disappointing given the agency taking charge of biotechnology regulation just underwent the review process for a GM food animal and knows more are on the way.¹⁵⁶ Most of the other examples used in the update are GM crops, which are only voluntarily regulated under the FDA.¹⁵⁷ Maybe this is a sign that the FDA is not certain how to go about the GM animal approval process, but that means it is the perfect time to reorganize.

1. Problems and Abilities

As noted above, the approval process for AquAdvantage salmon took a very long time.¹⁵⁸ Some have argued the delay was due to politics, pointing out that the FDA issued a positive draft EA in 2010 and virtually the same draft EA two years later, before finally approving the application in 2015.¹⁵⁹ No matter the reason, the extensive amount of time needed to get an application approved has severe consequences, and violates the rule set out in the FDCA requiring that the Secretary of Health and Human Services review applications within 180 days.¹⁶⁰ The AquAdvantage salmon was stuck in the middle of confusing bureaucracy for more than two decades.¹⁶¹ Despite AquaBounty's optimism, its losses continue to grow and a large portion of the losses can be accredited to legal fees related to the FDA's

153. 2017 UPDATE, *supra* note 109, at 49 (explaining that the insulin purified from GE rabbit milk is regulated as a human drug under the FDA Center for Drug Evaluation and Research).

154. *Id.*

155. *See infra* Part III (b). Establishment of a Framework: USDA.

156. *Genetically Engineered Animals: General Q&A*, *supra* note 119 (noting that "[m]any kinds of GE animals are in development.").

157. 2017 Update, *supra* note 105, at 39–51 (providing hypothetical case studies for corn, a plum, a canola, a rose, a two microbial pesticides, and algae).

158. *See AQUABOUNTY TECHNOLOGIES*, *supra* note 122 (discussing the chronology of AquAdvantage Salmon approval).

159. Noah, *supra* note 14, at 606–607; *see* Entine, *supra* note 50 (explaining public perception over GMO foods remains poor even though over 2,000 studies documented that biotechnology does not pose an unusual threat to human health).

160. 21 U.S.C. § 360b(c) (2012).

161. *See AQUABOUNTY TECHNOLOGIES*, *supra* note 122 (explaining the approval process from 1989–2013).

approval.¹⁶² Additionally, AquaBounty's patent on the AquaAdvantage salmon (issued August 13, 1996) expired well before the FDA published its incomplete approval.¹⁶³ Patent law provides for the extension of a patent if the product is kept off the market by a regulatory review during the patent's valid life, but the AquaBounty patent did not receive this privilege.¹⁶⁴ AquaBounty may not have known about the statute or they may have decided not to submit an extension application. Even still, patents can only be extended once and for no more than 14 years or half the time between the submission of a NADA and the beginning of an EA, whichever is less.¹⁶⁵ The statute governing patent extension assumes the product in question completed the approval process and is on the market. In the case of the AquaAdvantage salmon, an extension would have been virtually useless. Our patent system cannot "promote the Progress of Science" if an innovator's entire term of exclusivity is eaten up by a flawed approval process.¹⁶⁶

The approval process also receives complaints for lack of transparency. The Trade Secrets Act prohibits the FDA from disclosing information during the NADA process.¹⁶⁷ The FDA cannot even disclose that an application has been filed, unless the company has already told the public.¹⁶⁸ Though the FDA should always be required to protect a company's intellectual property, the NADA regulations were implemented in 1975 and therefore were not meant to encapsulate GE plants and animals.¹⁶⁹ The FDA did update the NADA provisions,¹⁷⁰ but the AquaAdvantage application process demonstrates that the NADA approval process is not adequate to address all interests.¹⁷¹

162. *Optimism despite mounting losses for GM salmon firm*, THE FISH SITE (Mar. 16, 2017), <http://www.thefishsite.com/fishnews/28938/optimism-despite-mounting-losses-for-gm-salmon-firm>; *AquaBounty's losses widen as uncertainty remains over getting product to market*, UNDERCURRENT NEWS (Mar. 17, 2017), <https://www.undercurrentnews.com/2017/03/17/aquabountys-losses-widen-as-uncertainty-remains-over-getting-product-to-market>.

163. *Compare* 35 U.S.C. § 154 (a) (2) (2012) (indicating patent terms end 20 years from the filing date) *with* U.S. Patent No. 5,545,808 (filed Mar. 10, 1994), *and* APPROVAL LETTER, *supra* note 122 (explaining that because the patent was filed March 10, 1994, it expired on March 10, 2014, which was a year before the FDA approved AquaAdvantage Salmon).

164. 35 U.S.C. § 156 (a) (2012); *see* APPROVAL LETTER, *supra* note 122 (approving AquaAdvantage Salmon a year after the patent expired, and failing to discuss 35 U.S.C. § 156(a) privilege).

165. 35 U.S.C. § 156(c) (2012).

166. U.S. CONST. art. I, § 8, cl. 8.

167. 21 U.S.C. § 331(j) (2012); 18 U.S.C. § 1905 (2012); 21 C.F.R. § 514.11.

168. 21 U.S.C. § 331.

169. 21 C.F.R. § 510; Animal Drug Procedure: Reorganization and Republication, 40 Fed. Reg. 13,802 (Mar. 27, 1975).

170. *See generally* New Animal Drug Applications, 74 Fed. Reg. 54,749, 54,751 (Oct. 23, 2009).

171. *See* Chris D'Angelo, *FDA Sued Over Approval of Genetically Engineered Salmon*, HUFF POST (Mar. 31, 2016), <http://www.huffingtonpost.com/entry/fda-sued-over-genetically-engineered->

Under the Coordinated Framework, the FDA is supposed to work with other agencies to conduct its review.¹⁷² In fact, the FDA is required by law to consult with the National Marine Fisheries Service (NMFS) “to produce a report on any environmental risks associated with genetically engineered seafood products.”¹⁷³ The FDA also must consult with the Fish and Wildlife Service (FWS) if an application’s approval may affect an endangered species.¹⁷⁴ Though many believed the FDA failed its duty to consult the NMFS during the AquAdvantage approval process,¹⁷⁵ the FDA claims it “consulted with FWS and the [NMFS] and shared its ‘no effect’ determination with them.”¹⁷⁶ The FDA eventually “met with NMFS, answered its questions, and, consequently, neither agency objected to FDA’s ‘no effect’ determination.”¹⁷⁷ However, this hardly qualifies as consulting with the NMFS to create a report. The FDA created a report and asked the NMFS to rubber-stamp it. While the FDA may have conducted an adequate environmental review, a true consultation would go a lot further to assuage public fear.

Arguably, the FDA also lacks the expertise to consistently conduct comprehensive evaluations of GE animal applications. Before the introduction of GM animals the FDA regularly reviewed animal drugs, but “conventional animal drugs do not cause animals to have permanent, inheritable genetic alterations.”¹⁷⁸ Also, the FDA generally managed the growth of animals in a laboratory environment, whether for testing, drug production, or medical device purposes.¹⁷⁹ While the USDA has regulated domestic livestock since its inception, the regulation of livestock grown in

salmon_us_56fd75f7e4b083f5c60730bc (reporting over a dozen fishing and environmental groups are suing the FDA to block the approval of genetically modified salmon).

172. 2017 UPDATE, *supra* note 109, at 36 (explaining that the Coordinated Framework tasks the FDA, EPA and USDA with ensuring the safety of biotechnology products).

173. 21 U.S.C. § 2106 (2012).

174. 16 U.S.C. § 1536(a)(2) (2012).

175. Homer, *supra* note 114 at 115; Complaint for Declaratory & Injunctive Relief at 3, Inst. For Fisheries Res. v. Burwell, No. 3:16-cv-01574-VC (N.D. Cal. Mar. 30, 2016).

176. *AquAdvantage Salmon – Response to Public Comments on the Environmental Assessment*, FDA (Jan. 26, 2018, 1:05pm), <https://wayback.archive-it.org/...inary/DevelopmentApprovalProcess/GeneticEngineering/%20GeneticallyEngineeredAnimals/ucm466220.htm>; FDA, *supra* note 142 at 156-57.

177. FDA, *supra* note 164.

178. PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, *supra* note 116 at 120.

179. See *Why are Animals Used for Testing Medical Products?*, About FDA, Transparency, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/aboutfda/transparency/basics/ucm194932.htm> (last updated Aug. 22, 2018); *Product Classification: Medicinal Leeches, Medical Devices, Databases*, U.S. FOOD & DRUG ADMIN., <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpdc/classification.cfm?id=nm> (last updated Dec. 10, 2018).

traditional livestock facilities is new to the FDA.¹⁸⁰ Even a former FDA official felt that, in reference to a mosquito application, “[w]ithout relevant expertise, not surprisingly the FDA has been ill-equipped to review the application expeditiously, and especially to fulfill the requirements of the National Environmental Policy Act, which mandates that such approvals take into consideration possible environmental impacts.”¹⁸¹ His concern is shared by many, including the National Research Council.¹⁸² The FDA has shown that it is unwilling to fully incorporate other agencies in the review process. Not only is this dangerous, as important factors in the evaluation may be missed, but it goes against the intent behind the creation of the framework.¹⁸³

Although the FDA has many faults and the Coordinated Framework is incredibly confusing, the FDA is attempting to help applicants navigate the process. However, this is limited to just the FDA’s requirements, so applicants are virtually on their own in attempting to meet other agencies’ requirements. To assist applicants, the FDA assigns one project manager to each applicant.¹⁸⁴ The project manager is available to answer questions about the process and assist the applicant in setting a schedule for submissions.¹⁸⁵ It is important to note though that there is no mention of assigned project managers in the 2017 Update to the Coordinated Framework. Innovators would likely be more comfortable with the process if they knew the FDA

See *History of APHIS*, U.S. DEP’T. OF AGRIC., https://www.aphis.usda.gov/aphis/banner/aboutaphis/SA_APHIS_History (last updated Aug. 3, 2015); Christopher Doering, *FDA Issues Rules for Genetically Modified Animals*, REUTERS (Sept. 18, 2008 3:12 PM) <https://www.reuters.com/article/us-food-modified-fda/fda-issues-rules-for-genetically-modified-animals-idUSN1839524720080918> (discussing the FDA’s authority to regulate GE animals under the FDCA).

181. John J. Cohnsen & Henry I. Miller, *We Can Beat Zika and Malaria--If the FDA Allows*, FORBES (Jan. 29, 2016) <https://web.archive.org/web/20160215112834/http://www.forbes.com/sites/henrymiller/2016/01/29/eliminating-zika-and-malaria-will-require-real-leadership-and-more-responsive-regulation/amp>.

182. NAT’L RESEARCH COUNCIL, ANIMAL BIOTECHNOLOGY: SCIENCE-BASED CONCERNS 114 (2002); PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, *supra* note 116 at 121, 142; Letter from Congressman Peter DeFazio, et al. to Margaret Hamburg, M.D., Comm’r of the Fed. Drug Admin., (Sept. 28, 2010), available at <http://defazio.house.gov/media-center/press-releases/house-urges-fda-to-protect-american-consumers-and-the-environment-from>.

183. See generally Homer, *supra* note 107 at 100.

184. Alia Albrecht, Leader of Project Management Team, U.S. Food & Drug Admin, ONADE Project Managers, <https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/CVM/WhatWeDo/UCM398005.pdf> (last visited Sept. 21, 2018); *Office of New Animal Drug Evaluation*, U.S. FOOD AND DRUG ADMIN., <https://www.fda.gov/AboutFDA/CentersOffices/%20OfficeofFoods/CVM/WhatWeDo/ucm077923.htm> (last visited Apr. 30, 2017); Angela K. S. Clarke, DVM, U.S. Food & Drug Admin., Commc’ns with ONADE 4, <http://cymcdn.com/sites/www.aavpt.org/resource/resmgr/imported/10Clarke.pdf> (last visited Oct. 9, 2018).

185. Clarke, *supra* note 172, at 5.

assigns a point-of-contact to help each applicant with all of their FDA applications.

B. USDA

The USDA has statutory authority under the Animal Health Protection Act (AHPA) and the Plant Protection Act (PPA) to regulate GM products which may, as the names suggest, have an effect on plant or animal health.¹⁸⁶ Specifically, the USDA may regulate anything that is a pest to, or may cause diseases in, livestock and anything considered a plant pest or noxious weed.¹⁸⁷ The Animal and Plant Health Inspection Service (APHIS) requires developers to submit petitions for nonregulated status to APHIS before transporting or releasing GMOs.¹⁸⁸ In the case of non-animal applications, APHIS may make a finding for nonregulated status, in which there are no post-approval requirements, or it may provide a permit and place marketing and release requirements on the organism.¹⁸⁹

During the application process, APHIS is required to evaluate environmental impacts and provide comment opportunities similar to the FDA; comments are accepted from the public after a draft EA has been published in the Federal Register.¹⁹⁰ In 2012, APHIS updated its commenting opportunities, providing the public a chance to comment on completed petitions before APHIS begins the EA process.¹⁹¹ Along with the publication of a draft EA, APHIS sometimes includes notices of public meetings where concerned citizens can voice their thoughts in person.¹⁹² If public comments raise sufficient concern, APHIS will prepare an EIS, which is more detailed than an EA, and the public may have up to three more chances to comment.¹⁹³ The APHIS website provides a listing of applications and guidance for developers.¹⁹⁴ APHIS also provides an “Am I Regulated?” service, which allows developers to determine whether their products fall under APHIS’s authority.¹⁹⁵ In 2017, APHIS published a proposed rule expanding the list of exempted products, but “plants with traits that [have not] already been

186. 7 U.S.C. §§ 8301-22; 7 U.S.C. §§ 7701-86.

187. 2017 UPDATE, *supra* note 104, at 23.

188. *Id.* at 22-3.

189. *Id.* at 24.

190. *Id.* at 23.

191. *Id.* at 25.

192. *Id.*

193. *Id.*

194. *Id.* at 23-4; *Biotechnology Regulatory Services*, U.S. DEP’T OF AGRIC., <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology> (last visited Apr. 30, 2017).

195. *Id.* at 24.; *Am I Regulated Under 7 CFR Part 340?*, U.S. FOOD & DRUG ADMIN., <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated> (last modified Sep. 12, 2018).

evaluated by APHIS for risk as a plant pest or noxious weed” will still be subject to approval.¹⁹⁶

Additionally, the USDA has jurisdiction under the Virus-Serum-Toxin Act (VSTA) to regulate GMOs in veterinary biologics and the USDA’s Food Safety and Inspection Service (FSIS) regulates meat, poultry, eggs, and fish under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act respectively.¹⁹⁷ Veterinary biologics always have post-approval requirements and are required to immediately report any data concerning the “purity, safety, potency, or efficacy of a product.”¹⁹⁸ The FSIS is supposed to inform the public and stakeholders of any decisions involving GE animals.¹⁹⁹ In the 2017 Update, FSIS stated that it “will utilize ask FSIS, a Web-based computer application, designed to help more effectively respond to technical and policy-related questions, including determinations regarding GE product[s], from inspection program personnel, industry, consumers, other stakeholders, and the public.”²⁰⁰

The USDA’s programs provide plenty of opportunities for feedback and the agencies under it have made efforts to provide guidance to developers.²⁰¹ The USDA made real efforts to modernize its rules and the application process through the 2017 Update. Though the USDA has a level of statutory authority over GM animals, the FDA does not appear to have involved them in a significant way when evaluating the AquAdvantage salmon. Involving the USDA more in the process may, at the very least, emphasize the importance of process transparency and stakeholder investment. Recognizing the vast capital investment required to bring a new GM product through the approval process may bring internal attention to the fact that the FDA’s foot-dragging, if continued, will chase away developers.

In the past, however, there have been concerns that the USDA is too motivated by stakeholder investment. Scholars have argued the USDA was at one time, and maybe even still, controlled by the lumber and agribusiness industries.²⁰² They argue this control resulted in producer friendly policies

196. Importation, Interstate Movement, and Environmental Release of Certain Genetically Engineered Organisms, 82 Fed. Reg. 7,008, 7,016 (Jan. 19, 2017) (to be codified at 7 C.F.R. pt. 340); Kelly Servick, *Proposed U.S. Biotech Rules Raise Industry Hopes and Anxieties*, SCIENCE (Jan. 27, 2017, 1:30 PM), <http://www.sciencemag.org/news/2017/01/proposed-us-biotech-rules-raise-industry-hopes-and-anxieties>.

197. See generally 21 U.S.C. §§ 151-9 (2018) (regulating veterinary products for domestic animals); See 21 U.S.C. §§ 601-95 (2012); 21 U.S.C. § 451 (2012); Egg Product Inspection, 21 U.S.C. §§ 1032.

198. 2017 UPDATE, *supra* note 107, at 25.

199. *Id.* at 26-7.

200. *Id.* at 27.

201. 2017 UPDATE, *supra* note 107, at 5.

202. Jason Waanders, *Growing A Greener Future: USDA and Natural Resource Conservation*, 29 ENVTL. L. 235, 275 (1999).

while conservationists were left by the wayside.²⁰³ The potential conflict of interest between assisting producers and setting dietary guidelines has long been a point of concern for many members of the public.²⁰⁴ Most notable are the concerns over the USDA's promotion of dairy products, which some argue are linked to many health risks and should not be promoted so heavily by a department of the United States.²⁰⁵ The USDA has also been the subject of several discrimination lawsuits. One such batch was over the servicing of farm loans for Hispanic and woman growers.²⁰⁶ These lawsuits and concerns over special interests may serve to cancel out any goodwill that would come from the USDA's feedback policies in review processes. If the public does not trust the agency to be unbiased, even a transparent review process may not engender confidence on the safety of new technologies that get approved. The public already has a skeptical view of GMOs, a poor public opinion of the reviewing agency would not help anything, but the USDA has been working to be more inclusive and unbiased.

The 2008 Farm Bill created the Office of Advocacy and Outreach (OAO) within the USDA.²⁰⁷ In 2015, the USDA announced \$8.4 million in grants to "provide training, outreach and technical assistance for socially disadvantaged, tribal and veteran farmers and ranchers."²⁰⁸ The Farm Service Agency, which manages loans for new farmers, has an additional pot of money set aside specifically for minority and women farmers and ranchers.²⁰⁹ The agency also has a Student Diversity Program which teaches

203. *Id.*

204. Green, *Not Milk: The USDA, Monsanto, and the U.S. Dairy Industry*, ALTERNET (July 8, 2002, 7:00 pm), http://www.alternet.org/story/13557/not_milk%3A_the_usda%2C_monsanto%2C_and_the_u.s._dairy_industry; Evelyn Theiss, *Should the USDA make Dietary Guidelines while it promotes meat and dairy industry?*, CLEVELAND.COM, (March 8, 2011 9:24 AM), http://www.cleveland.com/healthfit/index.ssf/2011/03/should_the_usda_make_dietary_g.html.

205. Michael Moss, *While Warning About Fat, U.S. Pushes Cheese Sales*, N.Y. TIMES (Nov. 6, 2010), <https://www.nytimes.com/2010/11/07/us/07fat.html>.

206. Stephen Carpenter, *The USDA Discrimination Cases: Pigford, InRe Black Farmers, Keepseagle, Garcia, and Love*, 17 DRAKE J. AGRIC. L. 1, 33 (2012); Associated Press, *Lawmakers Urge U.S.D.A. to Discuss Bias Complaints*, N.Y. TIMES (Dec. 26, 2015), https://www.nytimes.com/2015/12/27/us/lawmakers-urge-usda-to-discuss-bias-complaints.html?_r=0; Kari Lyderson, *Native American Farmers and Ranchers Press USDA on Bias Complaints*, WASHINGTON POST (July 30, 2010), <http://www.washingtonpost.com/wp-dyn/content/article/2010/07/29/AR2010072905738.html>.

207. U.S. DEPT. OF AGRIC., *About the Office of Advocacy and Outreach*, <https://www.outreach.usda.gov/aboutus.htm> (last visited Sept. 22, 2018).

208. Press Release, U.S. Dept. of Agric., *USDA Announces \$8.8 Million to Support a Diverse Next Generation of Farmers and Ranchers* (Sept. 28, 2015), available at <https://www.usda.gov/media/press-releases/2015/09/28/usda-announces-88-million-support-diverse-next-generation-farmers>.

209. FARM SERV. AGENCY, *MINORITY AND WOMEN FARMERS AND RANCHERS*, <https://www.fsa.usda.gov/programs-and-services/farm-loan-programs/minority-andwomen-farmers-and-ranchers/index> (last visited Sep. 27, 2018).

students about current issues in agriculture.²¹⁰ In 2016, the USDA won the Federal Agency of the Year award from the League of United Latin American Citizens.²¹¹ Under the direction of Tom Vilsack, the USDA made major strides in their diversity efforts, improving the discrimination complaint process and establishing official policies to prevent discrimination based on age and English proficiency.²¹² With the number of farmers in the United States continuing to plummet, the USDA saw a 21 percent increase in Hispanic farmers and a 12 percent increase in black farmers between 2007 and 2012.²¹³ Despite its poor history, the USDA is working to increase its diversity and get rid of any cultural biases that may exist in the agency.²¹⁴ The USDA's efforts to repair its relationship with minority groups should give some confidence to anyone who doubts the agency's neutrality. As the head of any GMO review framework, they are liable to receive negative feedback based on previous mistakes. However, the USDA's transparent review process policies are much better than those of the FDA and would help the public begin to understand and embrace GMOs.

C. EPA

The EPA has authority under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) to regulate “the sale, distribution, and use of all pesticides, including those produced through genetic engineering.”²¹⁵ The EPA will approve a product for use if the adverse effect on the environment is not unreasonable.²¹⁶ The EPA is supposed to balance the economic, social, and environmental costs of using the product.²¹⁷ The EPA is also in charge of evaluating any human dietary risks that may arise from residues of pesticides.²¹⁸ “FIFRA provides EPA broad authority to establish or modify data needs and timing for registrations to achieve program and statutory objectives”²¹⁹ and “the Agency can issue data waivers, accept additional data

210. OFFICE OF THE CHIEF ECONOMIST, STUDENT DIVERSITY PROGRAM, https://www.usda.gov/oce/forum/diversity/diversity_program.htm (last visited Sep. 27, 2018).

211. Tom Vilsak, *The People's Department: A New Era for Civil Rights at USDA*, MEDIUM (Aug. 2, 2016), <https://medium.com/usda-results/https-medium-com-usda-results-chapter-8-b57f91b64d49>.

212. *Id.*

213. *Id.*

214. *See generally Id.* (describing steps the USDA took to eliminate discrimination and increase diversity).

215. 2017 UPDATE, *supra* note 104, at 10 (citing 7 U.S.C. § 136a(a)).

216. *Id.*

217. *Id.*

218. *Id.*

219. *Id.*

or accept alternative approaches as appropriate.”²²⁰ For any experimental testing covering more than 10 acres, developers must receive an Environmental Use Permit. This permit allows the EPA to set acre limits and other protective conditions on a product’s use while developers collect data to support their applications.²²¹ Following approval, developers are required to pay maintenance fees on their product registration and, much like the other agencies, submit any negative findings immediately.²²²

The EPA also has jurisdiction over dietary risks through the FDCA.²²³ Developers must gain a “tolerance” or “tolerance exemption” from the EPA before marketing foods for humans or animals.²²⁴ Tolerances or exemptions may be temporary and may be modified or revoked at any time.²²⁵ Tolerances set by the EPA are enforced by the FDA.²²⁶

Through the Toxic Substances Control Act (TSCA), the EPA also has jurisdiction over new and existing chemical substances, including those produced using biotechnology.²²⁷ Other statutes cover food, food additives, drugs, cosmetics, medical devices, pesticides, tobacco, nuclear material, and firearms.²²⁸ Similar to the FIFRA process, the EPA evaluates the potential environmental and health risks associated with a particular new chemical before allowing it to be manufactured and distributed.²²⁹ The EPA publishes a notice when it approves a new chemical substance.²³⁰

While the EPA may not provide the mid-application commenting opportunities of the USDA, in the 2017 Update, the EPA claims to have an online tool for developers to determine their regulatory status.²³¹ In actuality, the EPA is steering developers towards the same online comment form any concerned citizen would use.²³² This is likely a very busy communication channel for the EPA and does not seem like the best method for such a specific need. A cursory search does not provide any more information on

220. *Id.* at 11.

221. *Id.*

222. *Id.*

223. 21 U.S.C. § 346a(b)(2)(i) (2012).

224. 2017 UPDATE, *supra* note 104, at 12.

225. *Id.* at 13.

226. *Id.*

227. 15 U.S.C. § 2601-97 (2012).

228. 2017 UPDATE, *supra* note 104, at 13 (citing 15 U.S.C. § 2601-97 (2012)).

229. *Id.* at 14.

230. *Id.*

231. *Id.*

232. ENVTL. PROT. AGENCY, CONTACT US ABOUT THE REGULATION OF BIOTECHNOLOGY UNDER TSCA AND FIFRA, <https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/forms/contact-us-about-regulation-biotechnology-under> (last visited Oct. 9, 2018).

the possibility of a “pre-notice consultation,” though the EPA’s section of the 2017 Update makes it sound like this is a normal, common tool.²³³

Compared to the FDA and USDA, the EPA’s regulatory jurisdiction is limited. Therefore, even though they are the “Environmental” Protection Agency, their expertise in evaluating environmental concerns from biotechnology may also be somewhat limited. In 1998, the EPA approved StarLink corn.²³⁴ The EPA determined that the Bt toxin engineered into the corn may be allergenic if consumed by humans but approved it for use in animal feed.²³⁵

Because of the biology of corn and the nature of the U.S. crop-handling system, however, segregating StarLink corn from the food supply proved to be extremely difficult. In September 2000, genes from StarLink corn were detected in taco shells and other corn products intended for human consumption, a clear violation of its registration. This discovery resulted in huge recalls of food products containing the genetically engineered corn.²³⁶

When reports of StarLink contamination in products intended for humans started coming in, the EPA asked the FDA to intercede and remove StarLink from the market.²³⁷ The EPA issued a formal recall and everyone thought the product was gone until it reappeared in Saudi Arabia in 2013.²³⁸ Though most GMOs are relatively safe, StarLink is an example of how difficult it can be to contain a product and how far contamination can spread.²³⁹ It will be very important, as the number of GMOs grow, to ensure that products are both safe and able to be separated in the pipeline if necessary.

233. 2017 UPDATE, *supra* note 104, at 14.

234. FEDERATION OF AMERICAN SCIENTISTS, INTRODUCTION TO THE AGRICULTURAL BIOSECURITY CASE STUDIES, *Agricultural Biotechnology: Safety, Security and Ethical Considerations, StarLink Corn: A Cautionary Tale*, <https://fas.org/biosecurity/education/dualuse-agriculture/2.-agricultural-biotechnology/starlink-corn.html> (last visited Jan. 16, 2018).

235. *Id.*

236. *Id.*

237. Letter from Joseph A. Levitt, Center for Food Safety Director, to Steve Johnson, U.S. Envtl. Prot. Agency Acting Assistant Administrator (Jun. 12, 2001), <https://archive.epa.gov/scipoly/sap/meetings/web/pdf/letter.pdf>.

238. *StarLink Resurfaces: GM Corn Banned Decade Ago Found in Saudi Arabia*, RT NEWS (Aug. 27, 2013), <https://www.rt.com/news/banned-gm-resurfaces-saudi-arabia-074/>.

239. *StarLink Corn: A Cautionary Tale*, FED’N OF AM. SCI., <https://fas.org/biosecurity/education/dualuse-agriculture/2.-agricultural-biotechnology/starlink-corn.html> (last visited Sept. 26, 2018); *Frequently Asked Questions on Genetically Modified Foods*, WORLD HEALTH ORG. (May 2014), www.who.int/foodsafety/areas_work/food-technology/faq-genetically-modified-food/en/.

The EPA is an official part of the Coordinated Framework and should be actively involved in the approval of GM products. The FDA's failure with the review and monitoring of StarLink are proof that the entirety of the Framework should be responsible for reviewing GMOs. This is especially true since the EPA has so many monitoring programs tracking the status of environmental conditions like air quality, water quality, and erosion.²⁴⁰ The EPA also works closely with local agencies to ensure that states meet drinking water and air quality standards.²⁴¹ Therefore, the EPA is an important resource for evaluating the potential environmental effects of new GMOs, which will be vital to avoid the issues that come with a lack of biodiversity.

Genetic engineering can create disease- and pest-resistant crops, but can also result in species becoming extremely similar—even to the point of danger. A particular example of this issue is the banana.²⁴² Because they were planted or exported by United Fruit in the late 1800s, most banana trees across the world are genetically similar.²⁴³ Most of the plants were created through a form of cloning.²⁴⁴ This created a banana—the Gros Michel—that was ideal for consumers and shippers, but every Gros Michel tree was resistant or susceptible to the same diseases.²⁴⁵ In the early 1900s, a Panamanian disease appeared in Guatemala, where most bananas were grown.²⁴⁶ The Gros Michel banana variety was quite susceptible to the disease, and because the trees were clones, the disease spread easily.²⁴⁷ As Gros Michel banana trees started dying off, United Fruit began replacing them with Cavendish bananas.²⁴⁸ Now, the Cavendish variety is even more dominant than the Gros Michel was at the time of the blight.²⁴⁹ Consequently, the next foreign disease to come through will likely wipe out almost all

240. EPA, MONITORING PROGRAMS, <https://www.epa.gov/measurements/monitoring-programs> (last visited Sept. 24, 2018).

241. EPA, REGULATORY INFORMATION BY TOPIC: WATER, <https://www.epa.gov/regulatory-information-topic/regulatory-information-topic-water#drinking> (last visited Sep. 27, 2018); EPA, PUB. NO. EPA-456/K-07-0013, THE PLAIN ENGLISH GUIDE TO THE CLEAN AIR ACT 3 (2007), <https://www.epa.gov/regulatory-information-topic/regulatory-information-topic-air> (last visited Oct. 9, 2018).

242. Rob Dunn, *Humans Made the Banana Perfect – But Soon, It'll Be Gone*, WIRED (Mar. 14, 2017), https://www.wired.com/2017/03/humans-made-banana-perfect-soon-itll-gone/?mbid=nl_31417_p2&CNDID=.

243. *Id.*

244. *Id.*

245. Nathaniel Scharping, *The Banana As We Know It Is Dying...Again*, DISCOVER (Dec. 27, 2017), <http://blogs.discovermagazine.com/crux/2017/12/27/banana-fungus-panama-disease/#.WlwlMqhKuhc>.

246. *Id.*

247. *Id.*

248. *Id.*

249. *Id.*

commercially produced bananas grown today. This situation is similar to that of the Florida Orange, and while GE can help us fight diseases, over commitment to GE may do more harm than good.²⁵⁰ It will be important to have all hands on deck as we continue to review GMOs especially if the Coordinated Framework's goal is to complete comprehensive evaluations.

III. PROPOSED CHANGES TO THE FRAMEWORK

The Pew Initiative on Food and Biotechnology, after a study on the Coordinated Framework, noted that one of the main arguments against changing the system was that “[t]here is no scientific justification for changing the regulatory system.”²⁵¹ Another argument claims the following:

The concerns about inadequate or uncertain authority in the current system and coverage of future genetically engineered plants and animals are not significant. Agencies have sufficient flexibility in their laws to reach all biotechnology products that might raise concerns. Uncertainty and possible duplication can be clarified through agency policy guidance. While agencies may have to creatively and expansively interpret their legal authority to reach some biotechnology products, the risk that these interpretations will be successfully challenged—and that some products might go unregulated—is actually very low. As a practical matter, technology developers are unlikely to challenge an agency's questionable assertion of jurisdiction over its GE products, out of concern that the marketplace will reject a product if an agency claims that the developer has evaded a review or approval process.²⁵²

While there may be no scientific justification, agencies should not be “creatively interpreting” their legal authority. One argument, gathered by the Pew Initiative, in favor of changing the system focuses on the fact that the Coordinated Framework is behind current technology:

The regulatory system needs to be improved in order to catch up with the technology, and a failure to do so could not only pose human health and environmental risks, but undermine public trust in the regulatory system and jeopardize market

250. *Id.*

251. PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, *supra* note 109 at 19.

252. *Id.*

acceptance of agricultural biotechnology. The gaps and inadequacies in the current system are becoming increasingly apparent with the development of new biotechnology products that do not fit into the system.²⁵³

Several others note that “[t]rust in government regulators is a critical component to build market acceptance of a new technology” and “stretching an agency’s authority through creative legal interpretations can strain credibility and trust in the system.”²⁵⁴ For the public to believe in the safety of GMO crops, the Coordinated Framework needs to change.

While change is necessary, it is unlikely that Congress will create an entirely new agency to handle the regulation of biotechnology. The Coordinated Framework could be simpler if developers of the products covered by multiple agencies could merely submit a single application to one agency which then coordinates with all the others. Given the effort the USDA has put into answering developers’ questions, providing comment opportunities to the public, and updating its regulations to more closely match the state of biotechnology, this single application process should flow through the USDA. As shown in Part III(b) above, the USDA has regulatory authority over GM plants, animals, and other organisms. Consequently, all of the overlapping products should only have to go through one application and approval process; products like drugs and miscellaneous chemicals would only go through the singular agency responsible for their approval. A singular agency could reduce the massive amount of paperwork and coordination required to get a new GM product approved. The current process not only chases large companies away but severely limits the abilities of small developers to get their product to market. Although one overarching agency would vastly simplify the process, GM animal developers will have to get used to navigating the agencies already in place.

To truly promote innovation, the program needs to be reasonably navigable for the average developer. Comments to the 2017 Update identified this as an issue:

Referring to the 1986 Coordinated Framework, which identified a “lead agency” for products requiring regulatory oversight and/or review from multiple agencies, one commenter pointed out that the Proposed Update to the Coordinated Framework does not mention “lead agencies” and noted that identification of a lead agency would make it

253. *Id.* at 20.

254. *Id.* at 18.

clear to a potential applicant which agency to approach for an initial consultation. Another commenter asked for APHIS to be clearly identified as having the lead role and primary responsibility for regulatory assessments.²⁵⁵

Additionally, the USDA regularly coordinates with other agencies. For example, the Huanglongbing Multi-Agency Coordination framework, established in December, 2013 by the USDA, included “representatives from the California, Florida, and Texas citrus industry; Arizona, California, Florida, and Texas State departments of agriculture; USDA's Agricultural Research Service, Animal and Plant Health Inspection Service, and National Institute of Food and Agriculture; and the [EPA].”²⁵⁶ The group solicited applications for and funded 31 projects across the southeastern United States and California.²⁵⁷ The EPA also regularly coordinates with other agencies, which is why it is so disappointing that the FDA seemingly failed to meaningfully involve the other agencies in the Coordinated Framework. Comments given in the process of updating the Coordinated Framework addressed this issue:

Several responses expressed the need for better coordination among regulatory agencies, including on risk assessments and data collection on unintended consequences. One response suggested the creation of a “review” board consisting of representatives from all three regulatory agencies to review all new genetically engineered and non-genetically engineered crops. Another response suggested establishing a group of experts under the National Academy of Sciences (with representation from each regulatory agency) to determine whether a product is exempt from review and creating and publishing decision trees for developers to determine whether and which products are exempt. . . . Another response requested coordination among relevant agencies such that burden on industry with respect to obtaining multiple permits for conducting trials could be

255. 2017 UPDATE, *supra* note 104, at 59.

256. USDA, *Huanglongbing (HLB) Multi-Agency Coordination Updates* (Jul. 12, 2017), <https://web.archive.org/web/20170712105533/https://www.usda.gov/topics/disaster/multi-agency-response-devastating-citrus-disease/huanglongbing-hlb-multi-agency>.

257. *Id.*; *HLB-MAC Funded Research*, U.S. DEP'T OF AGRIC. (Jul 12, 2017), <https://www.usda.gov/sites/default/files/documents/2016-hlb-mac-funded-projects.pdf>, [<https://web.archive.org/web/20170520203600/https://www.usda.gov/sites/default/files/documents/2016-hlb-mac-funded-projects.pdf>].

reduced. Some responses also identified specific case studies to highlight these concerns.²⁵⁸

Several other comments recommended adding even more agencies to the Coordinated Framework, such as the U.S. Fish and Wildlife Service for environmental assessments.²⁵⁹ The Fish and Wildlife Service is particularly abreast of issues involving migratory and invasive species. Contamination possibilities for GM animals will likely be much worse than those with plants, since animals have the ability to move on their own. The United States is already fighting many invasive species all over the country. For example, pythons, once kept as pets, often get released by owners who are overwhelmed with the size of the snakes as they grow.²⁶⁰ As a powerful predator unusual to the region, pythons are thriving in the Everglades, and now researchers are worried that pythons are passing a dangerous lung disease onto native snakes in the area.²⁶¹ As GM animals grow in number, the characteristics of GM species could become much different from native species. This could result in the GM species being uniquely suited to survive in their given environment, possibly resulting in invasive-species-like issues. The U.S. Fish and Wildlife Service would be quite valuable in evaluating the possible environmental or ecological effects of new modified species.

Other commenters identified the Department of Defense, Department of Health & Safety, Department of Commerce, and Department of State as agencies which should be involved in the review process.²⁶² Many of these agencies may be involved in enforcement and regulation after products are approved, so involving them on the front-end would likely be useful. At least, agencies in the Coordinated Framework need to work with other agencies as needed to ensure the products going through the review process are evaluated fully and impartially. The FDA is not currently doing a very good job of coordination, but if the USDA were the lead agency for the Coordinated Framework, consumers would likely see much more collaboration and communication.

Furthermore, the statutes and rules surrounding the application process should be updated to adapt to new technologies, with some forethought to the technologies yet to be developed. Some companies, like Recombinetics,

258. 2017 UPDATE, *supra* note 104, at 54.

259. *Id.* at 59.

260. FLA. FISH & WILDLIFE CONSERVATION COMM'N, *Nonnatives-Burmese Python*, <http://myfwc.com/wildlifehabitats/nonnatives/reptiles/burmese-python/> (last visited Sep. 27, 2018).

261. Jenny Staletovich, *Florida's latest python problem: They may spread disease to other snakes, study shows*, MIAMI HERALD (Dec. 21, 2017), <http://www.miamiherald.com/news/local/environment/article190898924.html>.

262. 2017 UPDATE, *supra* note 104, at 59.

believe their method of GE does not fall under the current statutes.²⁶³ Recombinetics uses Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR), which allows developers to find and edit specific genes.²⁶⁴ The USDA has determined that plants created with the CRISPR technology will not be regulated, as they do not “contain foreign DNA from plant pests such as viruses or bacteria.”²⁶⁵ Allowing new technologies, such as CRISPR, to go unregulated will not sit well with the average consumer. As a result, the public’s attitude toward GMOs is unlikely to change significantly any time soon.

Regulating products by their individual characteristics rather than by the technology used to create them is a nice story to deflect developers’ concerns about technological bias; but, it is just a story. The Coordinated Framework already regulates every GM product in some way, and developers are already voluntarily sending applications to the FDA for each new GM crop. Navigating the system would be much easier if developers could presume that all new GM products are regulated through the single system. Agencies could then exclude products as the federal government gains a better understanding of the particular technologies used to create GMOs and their resulting characteristics. The USDA did exactly this with its 2017 updated rulemaking.²⁶⁶

Updated rules should also create more transparency to benefit consumers. The USDA provides at least two opportunities for public comment, one of which may be a live discussion. This process begins as soon as a complete application is filed.²⁶⁷ The FDA’s ability to match this process is limited by the laws surrounding drug applications.²⁶⁸ Updating the laws to take GM animals out of the NADA process would allow agencies the opportunity, at the very least, to announce that a new application had been filed. Hiding the application for the evaluation of new GM products does not improve the public’s opinion of GMOs. To overcome the stigma, the public must feel involved in the evaluation process and see the incredible benefits and low risks of properly-regulated GMOs.

263. Heidi Ledford, *Salmon Approval Heralds Rethink of Transgenic Animals*, NATURE (Nov. 23, 2015), <https://www.nature.com/news/salmon-approval-heralds-rethink-of-transgenic-animals-1.18867>.

264. *What are genome editing and CRISPR-Cas9?*, U.S. NATIONAL LIBRARY OF MEDICINE (AUG. 2017), <https://ghr.nlm.nih.gov/primer/genomicresearch/genomeediting>.

265. Emily Waltz, *Gene-edited CRISPR mushroom escapes US regulation*, 532 NATURE 293, 293 (2016) (internal quotations omitted); Press Release, USDA, Secretary Perdue Issues USDA Statement on Plant Breeding Innovation (2018) <https://www.usda.gov/media/press-releases/2018/03/28/secretary-perdue-issues-usda-statement-plant-breeding-innovation>.

266. 2017 UPDATE, *supra* note 104, at 2.

267. See *supra* text accompanying notes 159-62.

268. 21 U.S.C. § 360b(c) (2012).

At the same time, it will be important to ensure that applicants' vulnerable intellectual property is protected throughout the process. Agencies in the Coordinated Framework will need to develop policies to protect the trade secrets associated with products under review. Thomas Corriher has argued that "[a]pproving genetically engineered salmon as a veterinary drug allows for research data to be conveniently hidden from the public, under the guise of trade secrets."²⁶⁹ It may be that no amount of change to the current process will appease those who believe the FDA is hiding behind intellectual property concerns. However, the USDA's experience communicating with skeptical consumers should be sufficient to increase the transparency while protecting developers.

CONCLUSION

Centering the GM product application process under the USDA will facilitate better communication with developers and consumers. It will also result in more coordination among the relevant agencies and likely make the evaluation process timelier. Increasing transparency in the application process is vital to securing the support of the public. If the United States wants to attract the business of GMO developers, it must make the approval process more expedient. GE technology has incredible potential and as new organisms are developed, the Coordinated Framework must be able to comprehensively evaluate each one.

Researchers are already working on several new GM animals. Researchers at Recombinetics have been working on developing hornless dairy cows.²⁷⁰ Dairy cows generally have their horns removed at a young age to protect workers at the dairy.²⁷¹ Some cattle breeds are naturally hornless, but most cattle breeds are not.²⁷² Recombinetics's development would eliminate the need to dehorn cows.²⁷³ Hornless cows already exist naturally, so the change should not cause any harmful environmental effects. The GM dairy cows would be very useful to producers, but it is likely that they would get caught up in the review process for a very long time if no change happens, just like AquAdvantage salmon. The current review process of the

269. Thomas Corriher, *The F.D.A. is Using a Unique G.M.O. Salmon Approval Process to Bypass U.S. Regulations*, THE HEALTH WYZE REPORT (Sept. 30, 2009), <https://healthwyze.org/reports/499-the-fda-is-using-a-unique-gmo-salmon-approval-process-to-bypass-us-regulations>.

270. Servick, *supra* note 185.

271. *Id.*

272. Laine J. Misch, et. al., *An Investigation into the Practices of Dairy Producers and Veterinarians in Dehorning Dairy Calves in Ontario*, 48 CAN. VETERINARY J. 1249 (2007).

273. Servick, *supra* note 185.

Coordinated Framework is detrimental to the development of new GM products. It may also turn out to be detrimental to species that are currently in trouble. The North American honeybee has been dying off in massive quantities for some time now.²⁷⁴ Every year, 30-40% of America's bee colonies die off and are not replaced.²⁷⁵ Honeybees have been fighting disease, climate change, lack of food, and parasites.²⁷⁶ Honeybees are a necessary part of our environment and food supply. They keep other pests at bay and fertilize our crops.²⁷⁷ Genetic engineering may be able to help them, but if new developments are stuck in review for several decades, we may be unable to save the honeybee. The Coordinated Framework needs to change, and soon.

274. Sean Rossman, *A Third of the Nation's Honeybee Colonies Died Last Year. Why You Should Care*, USA TODAY (May 26, 2017), <https://www.usatoday.com/story/news/nation-now/2017/05/26/third-nations-honeybee-colonies-died-last-year-why-you-should-care/348418001>.

275. *Id.*

276. *Id.*

277. *Id.*

**A CURRENT AFFAIR:
ENSURING SUSTAINABLE AQUACULTURE IN THE
U.S. EXCLUSIVE ECONOMIC ZONE**

*Colby Stewart**

Introduction.....	71
I. Background.....	73
II. The Value and Risks of Aquaculture	74
A. The Value.....	75
B. The Risks	76
III. Current Legal Status of Aquaculture in the U.S.	79
A. The Clean Water Act	79
1. Aquaculture Facilities as “Point Sources”	80
2. Living Organisms as “Pollutants”.....	81
3. NPDES Permit Guidelines.....	82
B. The Magnuson-Stevens Fishery Conservation and Management Act.....	84
1. Authority to Regulate “Fishing”	84
2. NOAA’s 2016 Aquaculture Regulations for the Gulf of Mexico ..	85
IV. A Proposal For a New National Framework.....	86
A. The National Sustainable Offshore Aquaculture Act of 2011	87
1. Establishment of a Separate Advisory Board	87

* Colby K. Stewart works as an Attorney-Advisor for the U.S. Environmental Protection Agency within its Suspension and Debarment Division. He received his J.D. in 2015 and his LL.M. in Environmental and Natural Resources Law in 2016, both from Lewis and Clark Law School. During his time at Lewis and Clark Law School, he served as Co-Editor in Chief of Animal Law Review and served as a legal intern for the Municipality of Anchorage, U.S. Army Corps of Engineers, and U.S. Department of Interior. Following his graduation, he lived in the Northern Mariana Islands—on the island of Saipan—for two years, working first for the CNMI Judiciary’s Law Revision Commission and then for the CNMI Office of the Attorney General as counsel assigned to the Bureau of Environmental and Coastal Quality.

This work is not a product of the United States Government or the United States Environmental Protection Agency. The author/editor is not doing this work in any governmental capacity. The views expressed are his/her own and do not necessarily represent those of the United States or the US EPA.

2019]	<i>A Current Affair</i>	71
2. Regional Environmental Impact Statements.....		88
3. Permit Application Process.....		89
4. Permit Terms and Requirements.....		90
B. Lessons from the CWA and MSA		92
Conclusion		93

INTRODUCTION

Modern society is increasingly reliant upon “fish farms” to supplement dwindling wild fish populations.¹ However, fish farms (also referred to as aquaculture) have historically been a source of numerous and significant problems for wild fish populations and for the eventual consumers of the farmed fish—humans.² For example, aquaculture takes place on such a scale in China that the waste generated by the process poses serious health risks to humans.³ The health risks associated with aquaculture are found in the ecosystems surrounding fish farms and inside the farmed fish that eventually go to market.⁴ Although the problems created for water quality and human consumption represent just a small sample of the issues that often accompany aquaculture, they alone amply justify the need to revise the limited aquaculture regulations in the United States (US). Such revisions are particularly necessary if the US wants to reduce its annual trade deficit for seafood, which surpassed 14 billion dollars in 2016.⁵ As national and global demand for fish grows, the growth of aquaculture seems equally inevitable.⁶

-
1. Rebecca Goldburg & Rosamond Naylor, *Future Seascapes, Fishing, and Fish Farming*, 3 FRONTIERS IN ECOLOGY AND THE ENV'T 21, 21 (2005).
 2. U.S. Pub. Interest Research Grp. v. Atl. Salmon Me., LLC., 215 F. Supp. 2d 239, 247 (D. Me. 2002).
 3. See David Barboza, *In China, Farming Fish in Toxic Waters*, NY TIMES (Dec.15, 2007), http://www.nytimes.com/2007/12/15/world/asia/15fish.html?pagewanted=all&_r=0 (explained best by Ye Chao) (“Our waters here are filthy... [t]here are simply too many aquaculture farms in this area. They’re all discharging water here, fouling up other farms.”).
 4. *Id.*
 5. U.S. DEP’T. OF COMM., NAT’L. OCEANIC AND ATMOSPHERIC ADMIN., CURRENT FISHERY STATISTICS NO. 2016-2, IMPORTS AND EXPORTS OF FISHERY PRODUCTS ANNUAL SUMMARY, 1 (July 19, 2016), <https://www.st.nmfs.noaa.gov/Assets/commercial/trade/Trade2016.pdf>.
 6. See U.S. DEP’T OF COMM., NOAA AQUACULTURE PROG. (2010), http://www.nmfs.noaa.gov/aquaculture/docs/aquaculture_docs/aq_fact_sheet_march_2010.pdf (discussing why aquaculture plays a critical role as the primary source in supplying fish as a food source against increasing global consumer demand. The supply of consumable fish is even more vulnerable since the Department of Agriculture and Health and Human Services recommended Americans to double seafood consumption published in the 2010 Dietary Guidelines for Americans; National Science and

If the US wants to reduce its seafood trade deficit while ensuring its aquaculture market develops safely and sustainably, now is the time for action.

One proposed solution to reduce the US trade deficit and meet the nation's growing demand for fish is to expand aquaculture operations into the US's Exclusive Economic Zone (EEZ). This type of aquaculture—as opposed to the type found in freshwater systems such as rivers and lakes—is referred to as “open ocean aquaculture.”⁷ Until recently, this practice only existed in the US EEZ in a minor, research-based capacity or close to the shore and therefore under an individual state or territory's authority.⁸ Although there are a variety of statutes that indirectly address offshore aquaculture, the lack of clear federal guidance and regulation in the US EEZ has prevented the practice from expanding further into off-shore territory.⁹ Recently, however, the National Oceanic and Atmospheric Administration (NOAA) has taken concrete steps to open up certain parts of the US EEZ to aquaculture.¹⁰

However, NOAA's recent steps rely on a patchwork of regulatory authority—none of which was enacted with aquaculture in mind.¹¹ In other words, multiple agencies have a variety of roles and overlapping jurisdiction. State laws applicable to offshore aquaculture vary widely, while there is currently no national framework in place.¹² Structurally, these fish farms have changed dramatically since the relevant laws were put into place, and those changes continue to increase in both scope and complexity.¹³ The US needs to proceed quickly to ensure a proper framework is in place to meet the growing demand for, and changing landscape of, aquaculture, as well as the environmental concerns that accompany both. In the polarized political climate of 2018, decreasing our national trade deficit while ensuring

Technology Council Committee on Science Interagency Working Group on Aquaculture, National Strategic Plan for Federal Aquaculture Research (20142019)) [hereinafter “*National Research Plan*”].

7. INSTITUTE FOR AGRICULTURE AND TRADE POLICY, OPEN OCEAN AQUACULTURE (2004).

8. *Id.*

9. *See, e.g.* Marine Aquaculture Act of 1995, S. 1192, 104th Cong. § 2(a)(6) (1995) (stating that the Congressional findings state that the reason private industry has not invested in and developed marine aquaculture facilities within the U.S. is in part because “[O]ur marine waters are not susceptible to private ownership and because our marine waters also support other public trust uses, including navigation, fishing, recreation, and national defense.”).

10. Fisheries of the Caribbean, Gulf, and South Atlantic; Aquaculture, 81 Fed. Reg. 1,761, 1,762 (Jan. 13, 2016) (to be codified in 50 C.F.R. pt. 600 and 50 C.F.R. pt. 622).

11. *Id.* at 1,768–1,769.

12. Food and Agriculture Organization of the United Nations, National Aquaculture Legislation Overview United States of America (2018), http://www.fao.org/fishery/legalframework/nalo_usa/en.

13. Fisheries of the Caribbean, Gulf, and South Atlantic; Aquaculture, 81 Fed. Reg. 1,761, 1,798.

sustainable growth in an emerging industry should be a fairly non-partisan issue.

To understand the context in which these developments are occurring, as well as the need for a national framework, Section II provides a brief explanation of the background behind aquaculture and EEZs generally. Section III examines the economic reasons for allowing aquaculture to expand into the US EEZ, as well as the environmental problems created by open ocean aquaculture. Section IV provides an overview of the current legal regime applicable to aquaculture in the US EEZ, including NOAA's recent rule. Finally, Section V draws from Section IV, the National Sustainable Offshore Aquaculture Act of 2011, as well as state law, to suggest a bipartisan, comprehensive national framework to govern aquaculture in the US EEZ.

I. BACKGROUND

Aquaculture is believed to have begun sometime between 2000 and 1000 B.C.E., specifically with the cultivation of the common carp in China.¹⁴ Although aquaculture has existed for thousands of years, the scale has recently increased quite dramatically—just as it has with industrial factory farms for livestock. Historically, many civilizations have viewed fisheries as a limitless resource that mankind could utilize without ever affecting.¹⁵ Post World War II, the so-called “Blue Revolution” saw a tremendous increase in the harvest of our planet's marine fisheries.¹⁶ In 1977, the year the United Nations Convention on the Law of the Sea (UNCLOS) was adopted, economically important fisheries began to collapse as a direct result of harvests regularly exceeding the fisheries' maximum sustainable yield.¹⁷ As the reality of this limited resource set in, governments and aid agencies began to look to aquaculture as a feasible alternative from depleting wild fisheries to allow economic development to continue unhampered.¹⁸ In 1970, NOAA supplied a grant to engineers, oceanographers, and marine biologists to explore the potential of aquaculture in that context.¹⁹ Since then, aquaculture is considered a potential means to supplement dwindling fishery populations

14. Herminio R. Rabanal, *History of Aquaculture*, ASEAN/SF/88/Tech. 7 (Apr. 1988), <ftp://ftp.fao.org/docrep/fao/field/009/ag158e/ag158e00.pdf>.

15. HUGO GROTIUS, *THE LAW OF WAR AND PEACE* 94 (1625) (effusing in 1625 that “The extent of the ocean is in fact so great that it suffices for any possible use on the part of all peoples for drawing water, for fishing, for sailing.”).

16. Michael Skladany, et al., *Offshore Aquaculture: The Frontier of Redefining Oceanic Property*, 20 SOC'Y & NAT. RESOURCES: AN INT'L J. 169 (2007).

17. *Id.*

18. *Id.* at 169–72.

19. *Id.* at 172.

to continue feeding the planet's ever-increasing population.²⁰ Only recently has the open ocean been considered for this purpose.

The UNCLOS established the EEZs for each nation.²¹ The EEZs encompass the immediate waters adjacent to the coast of each nation and, generally, extend outward 200 miles.²² The EEZs were established to hopefully avoid many of the armed conflicts which occurred when nations attempted to access resources off the shores of other countries.²³ EEZs provide each nation an exclusive right to utilize the fisheries within that zone or the option to lease that right to another nation when it is unable or unwilling to use the entirety of its fisheries' maximum sustainable yield ("MSY").²⁴

Originally, a nation's ocean territorial boundary was governed by the "cannon shot" rule, which extended roughly three nautical miles off a nation's shoreline.²⁵ Because of the unique federal/state system of the US, authority within the three-mile "cannon shot" range was left to the states.²⁶ The territory past which the individual states have authority, out to a distance of 200 miles from the shore, falls under federal jurisdiction.²⁷ The US's EEZ is vast; in fact, it is the largest EEZ in the world.²⁸ As the US opens its EEZ to aquaculture, it is important to understand the potential benefits, as well as all the possible pitfalls.

II. THE VALUE AND RISKS OF AQUACULTURE

Open ocean aquaculture, if done right, could help reduce the annual US trade deficit, potentially alleviate stress from wild fishery stocks, and

20. UNITED STATES CENSUS BUREAU, <https://www.census.gov/popclock/world> (last visited October 7, 2018) (showing that the current world population is roughly 7.5 billion).

21. United Nations Convention on the Law of the Sea art. 55 Dec. 10, 1982, 1833 U.N.T.S. 396, 418.

22. *Id.* at 419.

23. *Id.* at 397 (stating the treaty was "[p]rompted by the desire to settle, in the spirit of mutual understand and cooperation, all issues relating to the law of the sea and aware of the historic significance of this Convention as an important contribution to the maintenance of peace, justice and progress for all peoples of the world").

24. *Id.* at 418.

25. NAT'L OCEANIC AND ATMOSPHERIC ADMIN., LAW OF THE SEA: HISTORY OF THE MARITIME ZONES UNDER INTERNATIONAL LAW, http://www.nauticalcharts.noaa.gov/staff/law_of_sea.html (last visited Sept. 28, 2018).

26. U.S. DEP'T OF COMMERCE, OFFSHORE AQUACULTURE IN THE UNITED STATES: ECONOMIC CONSIDERATIONS, IMPLICATIONS & OPPORTUNITIES [hereinafter "*Commerce Report*"], at 2 (July 2008).

27. *Id.*

28. Rosamund L. Naylor, *Environmental Safeguards for Open-Ocean Aquaculture*, 22 ISSUES IN SCIENCE AND TECH., 3 (2006) (stating that the US EEZ covers 4.5 million square miles or 11.65 million km²); Commerce Report, *supra* note 26, at 3 (This figure is roughly 20% more than all U.S. terrestrial lands, and includes portions of the Arctic all the way to tropical marine habitats).

improve the nutritional value of American's diets. On the other hand, if implemented poorly, open ocean aquaculture has a significant potential to harm wild populations, deteriorate water quality, and harm the eventual consumer.

A. The Value

"In 2012, consumers in the United States spent an estimated \$82.6 billion on seafood, making the U.S. one of the top three seafood markets worldwide."²⁹ However, the Department of Commerce estimates aquaculture production in the U.S. to amount to only \$1.3 billion annually.³⁰ Therefore, despite an increase in both global and national trends, the U.S. supplies only an estimated five-percent of the seafood that is consumed domestically.³¹ This tremendous gap means that roughly "80 to 90 percent (by value) of the seafood that Americans eat is imported, creating a seafood trade deficit nearing \$11 billion in 2012."³²

Half of all seafood the U.S. imports are produced through some form of aquaculture.³³ Aquaculture also supplies half of the world's seafood (60 million tons of seafood annually, valued at \$70 billion). The United Nations projects that to meet the growing demand for seafood most of the future supply will have to come from aquaculture.³⁴ In fact, according to a report by the World Resources Institute, aquaculture production will have to more than double by 2050 just to meet demand.³⁵ In the U.S., growth in aquaculture "has been below the world average, rising annually by 4% in volume and 1% in value."³⁶

It is apparent that U.S. investors are not waiting for the federal government to sort out the problems with the regulatory scheme for

29. NAT'L SCI. AND TECH. COUNCIL COMMITTEE ON SCI. INTERAGENCY WORKING GROUP ON AQUACULTURE, NAT'L STRATEGIC PLAN FOR FED. AQUACULTURE RES. (2014-1019) at 1 [hereinafter *National Research Plan*].

30. *Id.*

31. *Id.* at 7.

32. *Id.*

33. NAT'L OCEANIC AND ATMOSPHERIC ADMIN., MARINE AQUACULTURE POLICY 4 (2011).

34. *Supra* note 33.

35. Maanvi Singh, *Can Farmed Fish Feed The World Without Destroying The Environment?* NATIONAL PUBLIC RADIO: THE SALT (June 6, 2014, 12:27 PM), <http://www.npr.org/blogs/thesalt/2014/06/06/319247280/can-farmed-fish-feed-the-world-without-destroying-the-environment> (citing the World Resource Institute).

36. NAYLOR, *supra* note 28, at 1 (Worldwide, aquaculture production has grown annually by 10%, and its value by 7%. As demand grows and technology improves, it is believed these rates will only increase).

aquaculture, but are instead investing in other areas.³⁷ Japan, Korea, Ireland, Norway, China, and Spain are all improving offshore aquaculture technology and their accompanying legal regulatory schemes.³⁸ Only recently in the U.S., though, has this problem begun to be addressed. Under its authority to regulate “fishing,” NOAA set targets for producing \$5 billion worth of aquaculture, 600,000 jobs, and \$2.5 billion worth of goods and services.³⁹ However, without a proper regulatory framework to govern aquaculture, the environmental impacts from such a move could be tremendous.

B. The Risks

Conservative estimates put the amount of EEZ territory needed to balance out the annual seafood deficit at roughly 500 km², or less than 0.01% of the U.S. EEZ.⁴⁰ Proponents argue that this means the potential environmental effects could be spread out widely, minimizing the concentrated harm that can otherwise occur.⁴¹ However, the environmental concerns accompanying aquaculture are not limited to pollution but also disease transfer to wild populations, invasive or genetically inferior species escapes, and additional stress on wild “feeder” fish populations.⁴²

In Vietnam, Thailand, and China, the wastewater discharged by fish farming has destroyed entire mangrove forests, heavily polluted many waterways, and radically altered the ecological balance of coastal areas.⁴³ China, though, is by far the world’s leading producer, consumer, and processor of fish.⁴⁴ Fish farming in China has dramatically changed the waters of the country,⁴⁵ and although the same scale isn’t likely to occur in the U.S., it should serve as a precautionary example as the U.S. looks to expand its aquaculture production.

37. U.S. DEPT. OF COM., *supra* note 26, at 5.

38. *Id.* (Additionally, in 2007, the European Union established an Offshore Aquaculture Technology Platform with partners from 16-member countries and Norway).

39. STEPHEN PHILLIPS, MARINE AQUACULTURE ISSUE PAPER (2005).

40. DEP’T OF COM., *supra* note 26, at 4-5.

41. OCEAN CONSERVANCY, RIGHT FROM THE START: OPEN-OCEAN AQUACULTURE IN THE UNITED STATES 15-16 (2011).

42. See Garrett Wheeler, *A Feasible Alternative: The Legal Implications of Aquaculture in the United States and the Promise of Sustainable Urban Aquaculture Systems*, 6 GOLDEN GATE U. ENVTL. L.J., 297, 300-01 (2013) (proposing one solution to these problems, though outside of the scope of this article, such as using more expensive closed-loop, land-based fish farms).

43. Barboza, *supra* note 3.

44. Ling Cao et al., *China’s Aquaculture and the World’s Wild Fisheries*, 347 SCIENCE, 133 (2015).

45. Barboza, *supra* note 3 (stating “more than half of the rivers in China are too polluted to serve as a source of drinking water” and many of “the biggest lakes in the country regularly succumb to harmful algal blooms” due to the practice).

Because the process—like Concentrated Animal Feeding Operations (“CAFOs”) in the U.S.—concentrates a significant amount of animals into a small space, the waste generated by those animals can pose problems for the surrounding environment. In China, farmers have coped with the toxic water arising from fish farms by mixing illegal veterinary drugs and pesticides into their fish feed.⁴⁶ This practice may help keep their fish stocks alive, but it also leaves harmful residues in the seafood, which can create health risks for consumers.⁴⁷ Recently, the U.S. has blocked imports of certain types of fish from China after inspectors detected traces of illegal drugs linked to cancer.⁴⁸ Both the European Union and Japan have also imposed temporary bans as well after illegal drug residues were discovered in Chinese seafood.⁴⁹

When a disease called infectious salmon anemia spread through farmed salmon in Maine, 1.5 million fish were destroyed (valued at \$25 million).⁵⁰ Although supporters of the industry called the event a natural disaster, workers hired to dispose of the fish blamed inadequate management practices, including overstocking the pens.⁵¹ These diseases can also affect human health because often the producer will still send the fish to market so long as it doesn’t exhibit excessive symptoms.⁵² Additionally, naturally occurring parasites known as sea lice can have similarly devastating consequences on wild populations.⁵³ Sea lice do not normally pose a threat to wild populations, but high concentrations of fish create high concentrations of sea lice.⁵⁴ When wild fish migration routes move through high concentrations of the parasite the result can be disastrous for wild juvenile fish.⁵⁵

One of the biggest environmental concerns surrounding aquaculture is escaped species. From 1996 to 2012, 25,768,729 farmed fish were reported to have escaped their enclosures.⁵⁶ That number is certainly a conservative estimate, as escapes occur due to bad weather, technology failure, and a variety of other occurrences that make it difficult to actually know how many fish escape.⁵⁷ Some estimates put the total number of escapes between 3–5%

46. *Id.*

47. *Id.*

48. *Id.*

49. *Id.*

50. Courtney Carroll, *Fish Farming and the Boundary of Sustainability: How Aquaculture Tests Nature’s Resources*, 2 WR: J. OF THE ARTS & SCI. WRITING PROGRAM 56, 60 (2009/2010).

51. *Id.*

52. *Id.* at 61.

53. *Id.*

54. *Id.*

55. *Id.*

56. CENTER FOR FOOD SAFETY, REPORTED ESCAPES FROM FISH FARMS: 1996–2012 (2012).

57. EVA B. THORSTAD ET AL., INCIDENCE AND IMPACTS OF ESCAPED FARMED ATLANTIC SALMON *SALMO SALAR* IN NATURE 44 (NINA Special Report 36, 2008).

of all farmed fish.⁵⁸ One additional problem with escaped farm fish is that, in 2005, 36% of the total world production of farmed fish was in regions where the species is exotic.⁵⁹ These escaped farmed fish compete for resources and, in some cases, can quickly dominate ecosystems.⁶⁰

Another problem with certain species of escaped farm fish is that they are sometimes capable of interbreeding with wild populations. For example, successful spawning by escaped female salmon has been documented frequently.⁶¹ The physical and genetic differences affect behavior, competitive ability, and spawning success rates.⁶² These are then passed on to new generations of wild salmon, affecting the population's overall survival and breeding chances.⁶³

Finally, many farmed fish are fed a diet of smaller bait fish, species like anchovies and menhaden, which are ground up and converted into "fishmeal."⁶⁴ It can take a full five pounds of fishmeal to produce just one pound of farmed salmon.⁶⁵ Bait fish are also used for nonfood products like pet food, makeup, farm animal feed, and fish oil supplements.⁶⁶ Thus, although the aquaculture business often touts the notion that farms are necessary to meet society's growing populations, there are many estimates that argue fish farming is actually consuming more fish than produced.⁶⁷ Because China's fish production has tripled in the past 20 years, with roughly three-quarters of its supply now coming from fish farms, its industry is still putting tremendous pressure on wild fisheries because of the demand for fishmeal and fish oil produced from wild species.⁶⁸ However, some forward-thinking fish farmers have begun to experiment with more sustainable fish feed.⁶⁹ The current legal patchwork in the US involving aquaculture is not

58. CENTER FOR FOOD SAFETY, *supra* note 56.

59. THORSTAD, ET AL., *supra* note 57, at 7.

60. *The National Wildlife Federation, Invasive Species Asian Carp (2018)*, <https://www.nwf.org/Educational-Resources/Wildlife-Guide/Threats-to-Wildlife/Invasive-Species>.

61. THORSTAD, ET AL., *supra* note 57, at 49.

62. *Id.* at 49.

63. *Id.*

64. Maddie Oatman, *We're Fishing the Oceans Dry. It's Time to Reconsider Fish Farms*, MOTHER JONES (July 2, 2014), <http://www.motherjones.com/environment/2014/07/aquaculture-feed-algae-nuts-mcfarland-springs-kenny-belov>.

65. *Id.*

66. *Id.*

67. Carroll, *supra* note 50, at 58.

68. Cao et al., *supra* note 44, at 1.

69. *See, e.g.* Oatman, *supra* note 64 (discussing the use of nuts from California that can't be sold because they're broken or disfigured. Additionally, the farmer discussed in the article has begun looking to excess barley produced as surplus in the beer industry as another alternative protein source for his fish which include: cobia, Florida pompano, coho salmon, Atlantic salmon, walleye, yellowtail, and White seabass).

sufficient to deal with the potentially disastrous effects of expanding US aquaculture into the EEZ.

III. CURRENT LEGAL STATUS OF AQUACULTURE IN THE U.S. EEZ

Although Congress passed the National Aquaculture Act in 1980, the Act contains very little substance relevant to aquaculture in the US EEZ.⁷⁰ Partly due to the weakness of the 1980 Act, commercial aquaculture never expanded past the 3-mile “cannon shot” range that falls under state jurisdiction.⁷¹ Other federal laws, however, do have some teeth when it comes to aquaculture regulation in the US EEZ—primarily the Clean Water Act (“CWA”) and the Magnuson-Stevens Fishery Conservation and Management Act, commonly referred to as the Magnuson–Stevens Act (“MSA”).⁷² It is important to note that Congress did not have EEZ aquaculture in mind when passing these acts.⁷³ Therefore, neither act sufficiently provides for the environmental safeguards necessary to protect wild fisheries and the ocean environment.

A. The Clean Water Act

The CWA applies to all “waters of the United States,”⁷⁴ which includes the EEZ and any discharges into those waters. The CWA’s objective is “to restore and maintain the chemical, physical, and biological integrity of the Nation’s waters.”⁷⁵ Under the CWA, “any discharge of any pollutant” into the Nation’s waters is deemed unlawful unless under the terms of a permit.⁷⁶ The permitting program, administered by the Environmental Protection Agency (“EPA”) under the broad authority provided to it by the

70. See The National Aquaculture Act 16 U.S.C. § 2801 (2016) (occupying less than ten pages this Act is hardly a comprehensive regulatory scheme); 16 U.S.C. § 2801(a)(1) (1985) (acknowledging that “certain species of fish and shellfish exceed levels of optimum sustainable yield,” and that the sole focus of the Act is economic); 16 U.S.C. § 2801(c) (1985) (“declar[ing] that aquaculture has potential for reducing the United States trade deficit in fisheries products, for augmenting existing commercial and recreational fisheries and for producing other renewable resources, thereby assisting the United States in meeting its future food needs and contributing to the solution of world resource problems,” and failing to provide attention to environmental issues and establish safeguards).

71. Naylor, *supra* note 28, at 2.

72. See Jillian P. Fry et al., *Offshore Finfish Aquaculture in the United States: An Examination of Federal Laws that Could be Used to Address Environmental and Occupational Public Health Risks*, 11 INT’L J. OF ENVTL RES. AND PUB. HEALTH 11964, 11969–70 (2014).

73. *Id.*

74. 33 C.F.R. § 323.2 (2012).

75. 33 U.S.C. § 1251(a) (2012).

76. 33 U.S.C. § 1311(a) (1995).

CWA, is called the National Pollutant Discharge Eliminating System (“NPDES”).⁷⁷ Applying the CWA to the EEZ, a “discharge” is considered “any addition of any pollutant to the waters of the contiguous zone or the ocean from any point source other than a vessel or other floating craft.”⁷⁸ The “vessels or other floating craft” is an exclusion that applies only if the point source is used for transportation.⁷⁹

1. Aquaculture Facilities as “Point Sources”

A “point source” is defined as “any discernible, confined and discrete conveyance, including but not limited to any... concentrated animal feeding operation, or vessel or other floating craft... from which pollutants are or may be discharged.”⁸⁰ An aquaculture facility is regulated as a “point source” by EPA if it qualifies as a Concentrated Aquatic Animal Production Facility (CAAP facility).⁸¹ A CAAP facility can be either a cold-water facility or a warm water facility. A cold-water facility discharges for a minimum of 30 days per year, produces over 20,000 pounds of fish per year, and uses 5,000 pounds or more of feed per month. A warm-water facility discharges for a minimum of 30 days per year and produces 100,00 pounds of fish or more per year.⁸² Additionally, EPA may designate a facility as a CAAP facility if EPA determines that the facility is a “significant contributor of pollution to waters of the United States.”⁸³

Because offshore aquaculture facilities and their accompanying technologies are highly capital-intensive, for them to be economically sustainable for extended periods of time, it is likely that their production volumes will trigger the CAAP facility criteria.⁸⁴ Pilot projects, research facilities, and even small facilities which produce lower volumes of higher valued species would likely elude the CAAP facility designation. An

77. 40 C.F.R. § 122.1 (2015).

78. 33 U.S.C. § 1362(12)(B) (2012).

79. *Nw. Env'tl. Advocates v. U.S. EPA*, 537 F.3d 1006, 1024 (9th Circ. 2008) (noting that Congress had subsequently “approved of the EPA’s decision not to exempt from the permitting process marine discharges from nontransportation vessels”); *See* 40 C.F.R. § 122.2 (2012) (defining “discharge of any pollutant” to mean “any addition of any pollutant to the waters of the contiguous zone or the ocean from any point source other than a vessel or other floating craft that is being used as a means of transportation.”) (*emphasis added*).

80. 33 U.S.C. § 1362(14) (2012).

81. 40 C.F.R. § 122.24(a) (2018).

82. *Id.* § 122.24 app. C(b) (1–2) (stating that one exception applies to warm-water facilities if they operate in closed ponds and discharge only during periods of excess runoff).

83. *Id.* § 122.24(c).

84. *See generally* Michael Rubino, ed., *Offshore Aquaculture in the United States: Economic Considerations, Implications & Opportunities* (2008) (explaining the capital-intensive nature of offshore aquaculture facilities).

example is the Kona Blue facility, which has received a permit to use federal waters near Hawaii but falls below the CAAP facility requirements, and is therefore not subject to regulation as a point source nor the accompanying NPDES permit.⁸⁵

2. Living Organisms as “Pollutants”

The CWA does not adequately address whether an escaped aquaculture fish is considered a pollutant.⁸⁶ Under the CWA, “pollutant” is defined as “dredged spoil, solid waste, incinerator residue, sewage, garbage, sewage sludge, munitions, chemical wastes, biological materials, radioactive materials, heat, wrecked or discarded equipment, rock, sand, cellar dirt and industrial, municipal, and agricultural waste discharged into water.”⁸⁷ Most of the byproduct that comes from aquaculture facilities—including fecal matter, excess feed, antibiotics, and pesticides—falls within the definition of “pollutant.”⁸⁸ It is less clear, however, whether the fish that escape from aquaculture facilities are considered pollutants.

Although some courts have held that living organisms constitute “biological materials” within the definition of a “pollutant,” other courts have held that living organisms do not constitute “biological materials.”⁸⁹ In *U.S. PIRG v. Atlantic Salmon of Maine, LLC*, the District Court determined that the release of non-native salmon from the aquaculture facility in which the salmon were raised constituted an addition of a pollutant.⁹⁰ The determining factor for the court was that the salmon were not native to the area.⁹¹ Similarly, the Ninth Circuit has held that invasive species released into the waters during the discharge of ballast water from large ships falls within the definition of “biological material.”⁹² In contrast, the Ninth Circuit, in an earlier case, held the definition of “biological materials” does not include excrement from mussels suspended from rafts.⁹³ Again, like *Atlantic Salmon*

85. NAT’L OCEANIC AND ATMOSPHERIC ADMIN., FINDING OF NO SIGNIFICANCE IMPACT, ISSUANCE OF A PERMIT TO AUTHORIZE THE CULTURE AND HARVEST OF A MANAGED CORAL REEF FISH SPECIES (*SERIOLA RIVOLLANA*) IN FEDERAL WATERS OF THE WEST COAST OF THE ISLAND OF HAWAII, STATE OF HAWAII (2011).

86. 33 U.S.C. § 1362(6) (2012).

87. *Id.*

88. United States Pub. Interest Research Grp. v. Atl. Salmon of Me., LLC, 215 F. Supp. 2d 239 (D. Me. 2002).

89. *Id.*

90. *Id.* at 247.

91. *Id.*

92. *Nw. Env’tl. Advocates v. U.S. EPA*, 537 F.3d at 1021 (holding that the EPA did not actually challenge this characterization, so the court did not directly address the question).

93. *Ass’n to Protect Hammersley, Eld, & Totten Inlets v. Taylor Res., Inc.*, 299 F.3d 1007, 1009 (9th Cir. 2002).

of *Maine*, whether the biological material occurred naturally in the area, or whether it was the result of human activity played a determinative role for the court.⁹⁴ Therefore, whether a living organism falls under the definition of “biological materials” is currently analyzed on a case-by-case basis, failing to provide aquaculture facilities with notice as to their liability when species escape.⁹⁵ Although unlikely, the individual NPDES permit of a CAAP facility could feasibly include such stipulations..

3. NPDES Permit Guidelines

The EPA has the authority to set different standards to ensure that point source pollutant discharges remain within particular environmental criteria.⁹⁶ EPA can set general effluent limitations guidelines (“ELG”) that apply to an entire industry and designate a specific numerical limit on the allowable discharge of a pollutant.⁹⁷ EPA also sets water quality standards (WQS) for point sources, requiring the facility to ensure their discharges do not exceed a particular limit.⁹⁸ Additionally, the EPA can set ocean discharge criteria (ODC), which establishes particular numerical limits for discharges that operate in the open ocean.⁹⁹

The EPA established ELGs for aquaculture facilities in 2004, which apply to a majority of recirculating, flow-through, and net-pen facilities so long as they produce a minimum of 100,000 pounds of fish annually (though certain types of hatcheries are exempt).¹⁰⁰ This means all facilities that meet the minimum production may discharge pollutants under the terms of the ELG.¹⁰¹ Whereas, any facility below this minimum production must obtain a NPDES permit with effluent limitations established by the individual permit, based solely on the judgment of the permit writer.¹⁰²

In contrast, the ELGs for aquaculture facilities do not include numeric limitations, but only textual criteria.¹⁰³ Therefore the discharges of any

94. *Id.*

95. *Compare* *Kahea v. Nat’l Marine Fisheries Serv.*, No. 12-16445, with U.S. Pub. Interest Research Group, 215 F. Supp. 2d 239 at 247.

96. U.S. ENVTL PROT. AGENCY, FINAL 2016 EFFLUENT GUIDELINES PROGRAM PLAN 11-12 (2018), https://www.epa.gov/sites/production/files/2018-05/documents/final-2016-eg-plan_april-2018.pdf.

97. *Id.*

98. 33 U.S.C. § 1313(c)(4) (2012).

99. 33 U.S.C. § 1343(a) (2012).

100. 40 C.F.R. § 451.20 (2017).

101. 40 C.F.R. § 451.22 (2007).

102. Effluent Limitations Guidelines and New Source Performance Standards for the Concentrated Aquatic Animal Production Source Category, 69 Fed. Reg. 51,892, 51,906 (Aug. 23, 2004) (hereinafter “2004 ELGs”).

103. *Id.* at 51,899.

aquaculture facility which requires an ELG for specific types of pollutants do not have to fall below specific numeric thresholds. Instead, these facilities must comply with requirements such as “efficient feed management and feeding strategies that limit feed input to the minimum amount reasonably necessary to achieve production goals and sustain targeted rates of aquatic animal growth[.]”¹⁰⁴ However, permit writers have discretion to impose site-specific numeric effluent limitations “in appropriate circumstances.”¹⁰⁵ Pursuant to complying with the textual provisions, the facility is required to develop and maintain best management practices (BMP), which describe the facility’s plan to achieve the provided narrative standard. Part of EPA’s reasoning for providing only textual criteria, is that some states had already established “numeric limits tailored to the specific production systems, species raised, and environmental conditions in the state.”¹⁰⁶

EPA only requires water quality-based effluent limitations when technology-based limitations are inadequate to ensure the adequacy of the water quality.¹⁰⁷ Therefore, the national framework should include a requirement that the EPA set WQS for any EEZ area open to aquaculture. WQS identify designated uses for the area at issue, establish criteria to protect those uses, and include antidegradation provisions.¹⁰⁸ Under the CWA, states and tribes are required to create WQS for their waterbodies including coastal waters. But, the EPA must set the standards if a state or tribe fails to do so.¹⁰⁹ The CWA does not require the EPA to establish WQS for the EEZ, therefore it has not.¹¹⁰

The current ODC were issued by EPA in 1980,¹¹¹ and require the EPA administrator to make a determination whether a pollutant discharge into ocean water under federal authority “will cause unreasonable degradation of the marine environment.”¹¹² Unreasonable degradation includes “significant adverse changes in ecosystem diversity, productivity and stability of the biological community within the area of discharge and surrounding biological communities.”¹¹³ The ODC provide specific factors to use in the evaluation¹¹⁴ and a NPDES permit may only be issued when the

104. 40 C.F.R. § 451.11(a)(1) (2018).

105. 2004 ELGs, *supra* note 102, at 51,899.

106. *Id.*

107. 33 U.S.C. § 1312(a) (2012).

108. U.S. ENVTL. PROT. AGENCY, WATER QUALITY STANDARDS HANDBOOK (2018), <https://www.epa.gov/sites/production/files/2014-10/documents/handbook-chapter1.pdf>

109. 33 U.S.C. § 1313 (b) (2012).

110. *Id.*

111. Ocean Discharge Criteria, Final Rule, 45 Fed. Reg. 65,942 (Oct. 3, 1980).

112. 40 C.F.R. § 125.122(a) (2017).

113. 40 C.F.R. § 125.121(e)(1).

114. 40 C.F.R. § 125.122(a)(1)-(10).

administrator determines that the discharge will not result in unreasonable degradation.¹¹⁵ Additionally, every permit issued must specify a monitoring program, and allow for the permit to be modified or revoked if new data suggests the continued discharge may result in unreasonable degradation.¹¹⁶ After the CWA, the Magnus-Stevens Act (MSA) has the next most statutory basis for regulating aquaculture in the US, and it is under this authority that NOAA has begun to take steps towards more regulation.

B. The Magnuson-Stevens Fishery Conservation and Management Act

The Magnuson-Stevens Act authorizes NOAA to regulate fishing in federal waters by producing Fishery Management Plans (FMP), which are developed by Regional Fishery Management Councils (Regional Councils). Once a Regional Council officially adopts an FMP, NOAA may approve and then formalize the FMP by issuing regulations pursuant to it.¹¹⁷ Congress drafted and passed the MSA specifically with harvesting fish from wild fisheries in mind.¹¹⁸ Yet NOAA has regularly issued policies outlining its position that aquaculture is within NOAA's authority under the Act.¹¹⁹ Very few FMPs currently in operation address aquaculture. For example, a limitation on the use of unapproved gear. A vast majority of FMPs have limitations, which essentially prevent development of aquaculture projects without specific authorization. In 2016, NOAA finalized regulations to govern aquaculture in the U.S. EEZ.¹²⁰

1. Authority to Regulate "Fishing"

Under the MSA, the Regional Councils have authority to create FMPs "for each fishery... that requires conservation and management."¹²¹ NOAA believes it has authority under the MSA to regulate aquaculture because the MSA defines "fishery" to include "one or more stocks of fish which can be treated as a unit for purposes of conservation and management" and subsequently "any fishing of such stocks."¹²² "Fishing," is defined to include

115. 40 C.F.R. § 125.123(b).

116. *Id.* at § 125.123(d).

117. 16 U.S.C. §§ 1852–1853a.

118. 16 U.S.C. § 1801(b).

119. Fishery Management Plan for Regulating Offshore Aquaculture in the Gulf of Mexico-, 81 Fed. Reg. 1762, 1768 (Jan. 13, 2016) (to be codified in 50 C.F.R. pts. 600, 622) [hereinafter *2016 Final Rule*].

120. *Id.* at 1762.

121. 16 U.S.C. § 1852(h)(1).

122. 16 U.S.C. § 1802(13).

the actual or attempted “catching, taking or harvesting of fish.”¹²³ Under these definitions, NOAA’s Office of General Counsel issued a legal opinion in 1993 that concluded “fishing” includes aquaculture because “[u]se of the term harvesting is particularly significant since it adds an additional concept beyond ‘catching’ or ‘taking’—harvesting connotes the gathering of the crop.”¹²⁴ NOAA has since reiterated this stance.¹²⁵ But, NOAA’s authority under the MSA is in question because courts have interpreted the MSA differently.¹²⁶

2. NOAA’s 2016 Aquaculture Regulations for the Gulf of Mexico

NOAA recently finalized regulations for its Gulf of Mexico FMP, which opened the region to commercial aquaculture for the first time.¹²⁷ These regulations require any aquaculture facility in the Gulf of Mexico to first obtain a permit from NOAA.¹²⁸ Under these new regulations, the Regional Administrator responsible for wild fishery stocks is also responsible for issuing aquaculture permits.¹²⁹ Although NOAA allows the public a brief opportunity to comment on each application,¹³⁰ NOAA provides no guidance as to how each determination is made.¹³¹ Additionally, there is no mandatory consultation with the EPA prior to the issuance of an aquaculture permit.¹³² In essence, although the regulations establish some standards (e.g. no genetically modified animals),¹³³ the Regional Administrator evaluates

123. *Id.* at § 1802(16).

124. Memorandum from Jay S. Johnson, NOAA Deputy General Counsel, and Margaret F. Hayes, NOAA Assistant General Counsel for Fisheries, to James W. Brennan, NOAA Acting General Counsel (Feb. 7, 1993).

125. Memorandum from Constance Sathre, to Lois Schiffr (June 9, 2011).

126. *Compare* *Kahea v. Nat’l Marine Fisheries Serv.*, No. 12-16445 (9th Cir. Oct. 29, 2013) (holding that NOAA has jurisdiction to regulate offshore aquaculture under the MSA, based on Skidmore deference to agency interpretation of a statute that the agency itself administers) *with* *Gulf Fishermen Ass’n v. Nat’l Marine Fisheries Serv.*, No. 2:16-cv-01271 (E.D. La. Sept. 25, 2018) (holding that NOAA does not have jurisdiction to regulate offshore aquaculture, based on the MSA’s plain language, purpose, statutory scheme, and legislative history).

127. 2016 Final Rule *supra* note 119, at 1762.

128. *Id.*

129. *Id.* at 1763.

130. *Id.* (allowing the public to comment for “up to 45 days”).

131. *Id.* at 1765–66, 1782, 1798 (failing to realize that such a case-by-case determination leaves the public in the dark as to how NOAA will evaluate such things as facility technology, the monitoring system used, the allowable concentration of fish in individual pens, type and quantity of feed as well as whether more sustainable alternatives have been explored, and the distance of the proposed site from potentially affected wild fisheries—just to name a few).

132. 2016 Final Rule *supra* note 119, at 1797–98 (requiring only consultation with “the Bureau of Ocean Energy Management and the Bureau of Safety and Environmental Enforcement, and other Federal agencies as appropriate.”).

133. *Id.* at 1,765.

adequacy of each applicant on a case-by-case basis, and without any baseline of environmental safeguards.

NOAA's lack of expertise in this area seems readily apparent, yet this has not deterred the agency from moving forward with its regulations. In explaining the apparently arbitrarily-created minimum site distance requirement (1.6 nautical miles), "NMFS notes there is no widely accepted standard for how far apart facilities should be sited and specifically seeks comment on this distance..."¹³⁴ Arguably, consultation with the EPA, which has expertise in water quality and water pollution distribution, might be a start. Even though CAAP facilities need to secure a permit from both NOAA and the EPA for the same activity, there is no indication that the two agencies communicate during the process.¹³⁵ If NOAA develops expertise on aquaculture technologies and species, EPA could use NOAA's expertise to develop a NPDES permit to ensure environmental compliance. Because the recent NOAA regulations do not include any requirement for consultation with EPA, there may still be confusion with the permits.

The final Environmental Impact Statement (EIS) for the Gulf Coast region was issued on June 26, 2009. On April 20, 2010, the Deepwater Horizon oil spill occurred in the Gulf of Mexico, which was the largest oil spill of its kind.¹³⁶ Although NOAA announced a Notice of Intent to prepare a supplemental EIS in January, 2013, no such supplemental EIS was issued. Not only is NOAA moving ahead with a potentially environmentally unsound proposal, it is doing so in the wake, and region, of one of the greatest environmental disasters known to mankind. Instead, Congress should act to ensure the US moves aquaculture into its EEZ with the proper environmental safeguards in place.

IV. A PROPOSAL FOR A NEW NATIONAL FRAMEWORK

NOAA's recent proposal for governing aquaculture in the Gulf of Mexico is wholly inadequate, specifically with respect to environmental safeguards and agency consultation. The U.S. government should create a new national framework to address environmental problems from EEZ

134. Fishery Management Plan for Regulating Offshore Aquaculture in the Gulf of Mexico, 79 Fed. Reg. 51424, 51428 (proposed Aug. 28, 2014) (to be codified at 50 C.F.R. pts. 600, 622 [hereinafter *Fishery Management Plan*]).

135. See NAT'L OCEANIC AND ATMOSPHERIC ADMIN ET AL., A GUIDE TO THE APPLICATION PROCESS FOR OFFSHORE AQUACULTURE IN THE U.S. FEDERAL WATERS OF THE GULF OF MEXICO (2017), https://sero.nmfs.noaa.gov/sustainable_fisheries/gulf_fisheries/aquaculture/documents/pdfs/permit_applicant_guide_updated_aug2017.pdf.

136. Campbell Robertson & Clifford Krauss, *Gulf Spill Is the Largest of Its Kind, Scientists Say*, N.Y. TIMES (Aug. 2, 2010), http://www.nytimes.com/2010/08/03/us/03spill.html?_r=1&fta=y.

aquaculture before they actually occur. As a starting point, the National Sustainable Offshore Aquaculture Act of 2011 (“2011 Act”) demonstrates a good initial foundation for this framework. However, the national framework should include additional requirements.

A. The National Sustainable Offshore Aquaculture Act of 2011

The 2011 Act departs substantially from its predecessors.¹³⁷ It includes many significant environmental safeguards that should be incorporated into any new national framework for aquaculture in the US EEZ. Therefore, the 2011 Act should serve as a starting point for the proposed national framework to govern aquaculture in the US EEZ.

1. Establishment of a Separate Advisory Board

The 2011 Act proposes to establish an Advisory Board within NOAA. The Advisory Board is responsible for environmental impact studies, permits and regulatory programs, research programs, coordination with other NOAA departments, outreach and training, consultation with Regional Fishery Management Councils (“Regional Councils”) and nonprofit conservation organizations, maintenance of informational database, among other things.¹³⁸ The Advisory Board must at minimum be comprised of: “representatives from the National Marine Fisheries Service, the commercial and recreational fishing industries, State or local governments, the Coast Guard, non-profit conservation organizations, members of academia with scientific or technical expertise in ocean and coastal matters, and representatives of the aquaculture industry.”¹³⁹ Advisory Board members must meet “at least once every six months[,]” serve two-year terms, and elect a chairperson.¹⁴⁰ The establishment of a separate advisory board for offshore aquaculture, which does not exist in the 2016 Final Regulations, is important for three reasons. First, wild fisheries and aquaculture harvesting are considerably different.¹⁴¹ Interests of Advisory Board and Regional Council members may be similar, but their interests do not necessarily align because Regional Councils were

137. Cf. The National Sustainable Offshore Aquaculture Act of 2009, H.R. 4363, 111th Cong., (2009).

138. National Sustainable Offshore Aquaculture Act of 2011, H.R. 2373, 112th Cong. § 3(a)-(b) (2011) [hereinafter *2011 Act*].

139. *Id.* § 3(b)(2).

140. *Id.* § 3(b)(3) – (5)(A).

141. Porter Hoagland, Di Jin & Hauke Kite-Powell, *The Optimal Allocation of Ocean Space: Aquaculture and Wild-Harvest Fisheries*, 18 MARINE RESOURCE ECONOMICS 129, 130–31 (2003).

established to create FMPs for regulating wild fisheries, which do not always agree with the relatively new offshore aquaculture practices and technologies.¹⁴² Second, the Regional Councils do not require representatives from non-profit conservation organizations,¹⁴³ which is crucial to ensure that environmental and conservation voices have an adequate say in the industry's development. Although representatives from the commercial and recreational fishing industries may often be at odds with conservation groups, requiring both parties on the Advisory Board will place them on the same side of this issue because both will be primarily concerned with the protection of wild fish populations. Third, election of the board's chairperson allows any representative, including those from non-profit organizations, to chair the board. This positive feature of the Act hopefully provides additional protection against agency capture.

2. Regional Environmental Impact Statements

The 2011 Act requires the Secretary of Commerce ("Secretary") to issue an offshore aquaculture Environmental Impact Statement (EIS) under the National Environmental Policy Act (NEPA) for each established region (which is the same as the geographic regions established under the MSA).¹⁴⁴ Each regional EIS must designate specific regions "that are not appropriate locations for the conduct of offshore aquaculture[.]"¹⁴⁵ Every regional EIS must consider siting offshore aquaculture facilities to avoid and minimize adverse impacts to the marine ecosystem, sensitive habitats, plants, and animals (specifically including impacts of escaped fish and use of "feeder" fish on wild fish populations).¹⁴⁶ All regional EISs must also consider cumulative effects of multiple aquaculture facilities and the designs, technologies, and operations intended to be employed by any aquaculture facility.¹⁴⁷ These regional EISs must be reviewed, revised, and published in the Federal Register every ten years.¹⁴⁸

The regional EIS requirement is absolutely necessary to ensure that the agency considers the proper scope of potential impact. Because offshore aquaculture necessarily entails the discharge of various pollutants into the ocean, pollutants will disperse and can affect a wide area. These regional EISs will inform the Board of the particular regions that may be more heavily affected by aquaculture, prompting the Board to prohibit aquaculture in those

142. 2016 Final Rule, *supra* note 119, at 1784.

143. 16 U.S.C. § 1852(b)–(c), (f)–(g) (2007).

144. 2011 Act § 4(a)–(b).

145. *Id.* § 4(c)(1).

146. *Id.* §§ 4(d)(1)–(2).

147. *Id.* §§ 4(d)(3)–(4).

148. *Id.* § 4(e).

regions. Maintaining and updating these regional EISs will require the agency to constantly monitor not just individual facilities and their immediate vicinity, but the impact on the entire region and necessarily all ecosystems within that region. Additionally, requiring each EIS to specifically address the impacts of escaped fish, forage fish used as feed, and fishmeal on wild populations can directly address some of aquaculture's biggest proven environmental problems. Finally, NOAA should require a regional EIA before opening the region for aquaculture. However, NOAA's 2016 Final Regulations are moving forward without an adequate EIS for the Gulf of Mexico that considers the potential environmental effects of aquaculture.

3. Permit Application Process

The 2011 Act requires a permit for any person to engage in offshore aquaculture.¹⁴⁹ Before a permit can be issued, the 2011 Act requires: an additional site-specific NEPA analysis;¹⁵⁰ notice to the public and a minimum of 90 days for comment;¹⁵¹ the posting of a bond sufficient to cover the cost of removing the facility;¹⁵² and consultation with federal agencies and coastal states, which are allowed to submit "a list of locations, species, or categories of species ... for which the coastal State opposes the conduct of offshore aquaculture."¹⁵³ If the coastal state submits any location or species for exception during consultation, NOAA may not issue a permit.¹⁵⁴ The 2011 Act prioritizes issuing permits to those proposed facilities "using technologies and practices that will substantially exceed compliance with the permit terms and conditions"¹⁵⁵

However, the permit guidelines proposed by the 2011 Act are much stronger than what NOAA has proposed with its 2016 Final Regulations, though both may require a permit for the operation of an aquaculture facility. For any permit to be issued, the 2011 Act requires a site-specific NEPA analysis in addition to the regional EIS requirement, which would provide additional information and stronger environmental safeguards. Before the Board issues the permit, it must consider any information from the regional EIS. Additionally, every application must provide for public notice and comment for a minimum of 90 days. Any interested party has the opportunity to address any information they believe necessary to the permitting authority, which is then required to take that information into account when

149. *Id.* § 5(a)(1).

150. *Id.* § 4(g).

151. *Id.* §§ 5(e)(1)(3).

152. *Id.* § 6(c).

153. *Id.* § 8(c)(2)(A).

154. *Id.* § 8(c)(2)(C).

155. *Id.* § 5(h)(2).

determining whether or not to issue a permit. Finally, consultation with agencies and states provides yet another safeguard to ensuring that all relevant information will be in front of the permitting authority when it makes its decision. Allowing coastal states to designate locations, species, or categories of species for which permits cannot be issued provides an option for potentially affected states to take a precautionary approach until better information becomes available.

Another substantial difference exists between the 2011 Act and NOAA's 2016 Final Regulations. The 2011 Act requires the agency to give priority to applicants that will "substantially exceed compliance with the permit terms and conditions,"¹⁵⁶ which ensures that competition between potential applicants will minimize harmful environmental effects on the area at issue. This priority may also encourage prospective applicants to plan on more stringent technologies in order for the permitting agency to assess their application more positively. Additionally, the 2011 Act requires a bond from the applicant, which ensures that the private entity seeking a permit will suffer significant financial loss if they do not adhere to the specific terms of the permit. Ideally, this requirement will result in better management practices to ensure that the bond provided will not be forfeited because of simple negligent conduct. This requirement will also hopefully deter potential facilities that may plan on operations which would barely comply with the terms of their permit.

4. Permit Terms and Requirements

Under the 2011 Act, every permit will be valid for a ten-year period and is eligible for renewal for another ten-year period.¹⁵⁷ Each permit issued:

"shall—(A) to the extent feasible, establish numerical standards for environmental performance under such permits; (B) to the extent such numerical standards are not feasible, establish narrative standards for such performance; and (C) to the extent such numerical standards and narrative standards are not feasible, require management practices, including implementation of best management practices for such performance."¹⁵⁸

Every permittee must submit a comprehensive annual report that includes: data on escape events; estimates of stocks, harvests, and mortalities; nutrient

156. *Id.* § 5

157. *Id.* §§ 5(g)(1)(A) – (B).

158. *Id.* § 5(b)(2).

data; impact on the water column and benthos; prevalence and extent of disease and parasites; use of antibiotics, pesticides, prescription and nonprescription drugs, and other chemical treatments; and sources of fish feed.¹⁵⁹ Every permittee must also make these annual reporting requirements public.¹⁶⁰

Because of the relatively new nature of exposing the U.S. EEZ to aquaculture, the terms of each permit should be reduced to five-year intervals, at least for the initial period of the Act's implementation. The reduced term will force the permitting authority to reevaluate each permit to accommodate changes in each permit based on new information. However, this concern is already relatively addressed because the Act allows for the suspension, modification, or revocation of a permit "based on information obtained after the issuance of the permit (including information obtained under the research program [established by the Act])."¹⁶¹ Ideally, instead of allowing for the agency to determine whether numerical criteria are "feasible," Congress should modify the Act to require the EPA to establish Water Quality Standards ("WQS") for areas designated for aquaculture facilities. These WQS would, in turn, be used as a basis for the permitting authority to establish numeric effluent limitations for discharges under each individual permit. Although the language of the act requiring numerical standards "to the extent feasible" is laudable, it provides too much discretion to the permitting authority to default to narrative standards that can be difficult to enforce. However, the stringent standards for annual reporting are significant requirements that allow for annual evaluation of the facility's ability to comply with the permit terms of its permit. Because the Act also allows for suspension, modification, or revocation of a permit for repeated violations,¹⁶² this reporting requirement could quickly lead to the revocation of a permit for facilities having difficulty meeting the permit terms.

Permits must limit facilities to species only of a genotype that is native to the geographic region. Yet facilities must "ensure[] fish escapes will not harm the genetics of local wild fish," restrict cultivation of any species of special concern, and prohibit genetically modified species.¹⁶³ The use of wild fish as feed ingredients is prohibited, unless "they are sourced from populations with ecosystem-based management measures in place; and ... shows biomass is at or above maximum sustainable yield."¹⁶⁴ Additionally,

159. *Id.* §§ 5(i)(2)(A) – (E).

160. *Id.* § 5(i)(3).

161. *Id.* § 11(d)(3).

162. *Id.* § 11(d)(1).

163. *Id.* § 5(j)(1)(A) – (D).

164. *Id.* §§ 5(j)(5)(A)(i)(ii).

permittees must minimize the use of fishmeal and fish oil derived from forage fisheries and use alternatives “to the maximum extent practicable.”¹⁶⁵ Finally, the Act specifically provides for enforcement of any permit terms by private citizen suits.¹⁶⁶

The 2011 Act goes well beyond NOAA’s 2016 Final Regulations, particularly with the requirement for public reporting by aquaculture facilities and the citizen suit provision. The citizen suit provision is a tremendously important component for any action that opens up the US EEZ to aquaculture. Because of the federal government’s limited resources, citizen suits can help keep facilities in check prospectively because concerned citizens will monitor effluent discharges. Additionally, the 2011 Act provides more guidelines to the permit issuer so that the public will better understand the decision-making process—such as minimizing or prohibiting certain sources of fishmeal, requiring numeric effluent limitations on permits, prohibiting antibiotics, etc. However, the US government can ensure sustainable aquaculture from the start by improving the 2011 Act and enhancing its benefits.

B. Lessons from the CWA and the MSA

Although a majority of facilities in the U.S. will likely trigger the CAAP facility classification,¹⁶⁷ the potential environmental harms from smaller facilities that do not trigger the classification are significant enough to merit requiring a NPDES permit.¹⁶⁸ A national framework could require a separate, perhaps less costly permitting process for these smaller facilities, but should still require the permitting agency to perform some type of environmental analysis. Such an analysis needs to include an evaluation of the proposed facility’s location, type of aquaculture performed, proposed technology and methods used, pathways of migratory fish and other potential environmental factors, and cumulative effects from other facilities in the area. Requiring a NPDES permit of smaller facilities would also allow the permitting authority to consider input from states that could be potentially affected by the facility.

Any implemented national framework should include a provision that defines living organisms that escape from aquaculture facilities—or are intentionally released—as “biological material” under the CWA. Including these organisms under the definition of “pollutant” would require facility operators to take measures to prevent escape events and hold them accountable for any negative environmental harms that result from

165. *Id.* § 5(j)(5)(B)(C).

166. *Id.* § 11(f).

167. 40 C.F.R. § 122.24(b) (2018).

168. *See, e.g. supra* Section II (discussing the problem of escaped, invasive species).

negligence, improper management practices or use of technology, or simply a lack of proper planning.

Additionally, the national framework should require EPA to develop NPDES permitting guidance for aquaculture facilities. This guidance should include numeric effluent limitations for specific types of pollutants (fecal matter, excess feed, escaped fish, etc.). This guidance should prohibit discharges of certain types of dangerous substances (e.g. oil, grease, invasive species) and require water quality testing to ensure facility compliance. This permitting guidance should apply to all facilities, including those below the aquaculture ELG's current size threshold. These requirements are necessary to ensure that water quality of the surrounding area remains adequate for local species. Additionally, this guidance should require EPA to establish areas viable for open-ocean aquaculture and establish WQS for those areas. Because open-ocean aquaculture technology is relatively new, technology-based limitations would be ineffective at ensuring adequate water quality for any organisms within the area. These WQS will, in turn, help guide the numeric effluent limitations in the permitting process for that area.

EPA's current ODCs do not provide specific information as to when the agency will exercise its discretion because they do not include numeric standards defining "unreasonable degradation" or the extent and type of monitoring requirements. The national regulatory framework for offshore aquaculture should include a requirement for the EPA to update its ODCs at certain intervals, such as every ten or 15 years, and include specific monitoring requirements. Finally, the framework should include a requirement that the EPA define "unreasonable degradation" with numeric criteria, based on the WQS set for the area, so that a facility will automatically lose its permit if testing of the effluent limitations or water quality exceeds such a level.

CONCLUSION

With NOAA's recent move authorizing and regulating aquaculture within the US EEZ, it has never been so important to implement a national framework. The CWA and the MSA are clearly inadequate for ensuring that proper environmental safeguards apply to any proposed facility. Because NOAA implemented its 2016 regulations with no national framework in place, the US will be forced to—like China—deal with environmental issues as they arise instead of before they happen. Because of these recent developments, now is the time for a renewed push by Congress to implement a strong national framework, with a focus on research and environmental precautions. If Congress does not act now, the environmental consequences of NOAA allowing private enterprise to move into the Gulf of Mexico could

be devastating. Aquaculture has already wrought tremendous havoc in China because of the focus on economic expansion at the cost of environmental safeguards. The US needs to heed this lesson if it wants to develop and ensure sustainable aquaculture in the US EEZ, both economically and environmentally.

FERC COMPLIANCE WITH NEPA: UPSTREAM AND DOWNSTREAM IMPACTS

*Ata Akiner**

Introduction.....	96
I. NEPA Overview	99
II. FERC’s Consideration of Upstream and Downstream Impact:	
Appropriate and in the Public Interest?	101
A.Upstream Impacts — Overview	102
B. Downstream Impacts — Overview	104
C. Policy Arguments	106
D. Legal Precedent and Arguments	108
1. Reasonably Foreseeable Effects	110
2. Cumulative Analysis	111
3. Causally Related.....	112
III. Filling the gap: Proposal for a new system	113
A. The Problem with States and Need for a National Solution	113
B. Proposal for a Revision of the NGA to Designate FERC and EPA Joint Review for Upstream and Downstream Impact.....	115
C. A Win-Win-Win for the FERC, the Public, and the EPA	116
Conclusion	118

* Georgetown University Law Center, J.D. 2019. I would like to thank Professors Donald Santa and William Massey for their guidance and feedback in writing this article. I also thank Gillian Giannetti for her advice and helpful comments on the earlier draft of this article. Finally, I wish to thank my wife, Aygen, for her love and patience.

INTRODUCTION

In recent years, shale gas and hydraulic fracturing (fracking) have led to what has widely been described as the “shale gas revolution” in the United States.¹ The consequences of this *revolution* indeed are profound, with its impact felt in energy supply, energy prices,² carbon dioxide (CO₂) levels,³ energy security,⁴ energy independence,⁵ and renewable energy.⁶ Natural gas now fuels nearly one-third of electricity generation,⁷ and most recent estimates report that the United States has enough natural gas to last about 86 years.⁸ Low-cost shale gas is also credited as a catalyst for a “manufacturing renaissance” in America—“revitalizing the chemical industry and enhancing the global competitiveness of energy-intensive manufacturing sectors such as aluminum, steel, paper, glass, and food.”⁹

Liquefied natural gas (LNG) terminals, which previously were built to receive imports across the country, lie idle.¹⁰ Although, there is a boom in the construction of new LNG export terminals, the United States is expected to become a net exporter of natural gas on an average annual basis by 2018,¹¹

1. See Richard Middleton et. al., *The Shale Gas Revolution: Barriers, Sustainability, and Emerging Opportunities*, 199 APPL. ENERGY 88-95 (2017).

2. Vipin Arora and Yiyong Cai, *US natural gas exports and their global impacts*, AUSTL.NAT'L UNIV. CRAWFORD SCH. OF PUB. POLICY, Working Paper No. 22, (2014).

3. See David Biello, *Fact or Fiction?: Natural Gas Will Reduce Global Warming Pollution*, SCIENTIFIC AMERICAN (Aug. 3, 2015), <https://www.scientificamerican.com/article/fact-or-fiction-natural-gas-will-reduce-global-warming-pollution/>.

4. See Jasmin Cooper et al., *Shale Gas: A Review of the Economic, Environmental, and Social Sustainability*, 4 ENERGY TECH. REV. 772 (2016) (“Recent estimates of large shale gas reserves across the globe have raised expectations for cheap energy and improved security of supply....”).

5. See Daniel Yergin, *Congratulations, America. You're (Almost) Energy Independent. Now what?*, POLITICO, Nov. 2013, <https://www.politico.com/magazine/story/2013/11/congratulations-america-youre-almost-energy-independent-now-what-098985>.

6. See Garvin Heath et al., *Harmonization of initial estimates of shale gas life cycle greenhouse gas emissions for electric power generation*, 111 PROC. NATL ACAD. SCI. E3167–76 (2014) (“Natural gas, consisting mostly of methane, has the lowest amount of carbon per unit of energy among fossil fuels and has been promoted as a transition to lower carbon economy....”).

7. See *FAQ: What is U.S. electricity generation by energy source?* U.S. ENERGY INFO. ADMIN., <https://www.eia.gov/tools/faqs/faq.php?id=427&t=3>.

8. See *FAQ: How Much Natural Gas Does the United States Have, and How Long Will It Last?* U.S. ENERGY INFO. ADMIN. Apr. 9, 2018, <https://www.eia.gov/tools/faqs/faq.php?id=58&t=8>.

9. See Mark Barteau & Sridhar Kota, U. Mich., *Shale Gas: A Game-Changer for U.S. Manufacturing* 5 (2014), <http://fliphtml5.com/izxr/tmlq>.

10. See Naureen Malik, *Loneliest Natural Gas Terminal in U.S. Bucks Pipeline Trend*, BLOOMBERG, July 12, 2016, <https://www.bloomberg.com/news/articles/2016-07-12/pipeline-phobia-keeps-new-england-s-unlikely-trade-route-open>.

11. See Katie Dyl, *Liquefied Natural Gas Exports Expected to Drive Growth in U.S. Natural Gas Trade*, U.S. ENERGY INFO. ADMIN.: TODAY IN ENERGY at 1 (Feb. 22, 2017), <https://www.eia.gov/todayinenergy/detail.php?id=30052>

and by 2040 U.S. LNG exports will grow to 8.4 trillion cubic feet (Tcf) or 23 billion cubic feet per day (23 Bcf/d).¹² The Sabine Pass facility in Louisiana became the first operating LNG export facility in the lower 48 states in 2016, shipping its first cargo of domestically sourced natural gas to Brazil.¹³ As of January 24, 2018, the Federal Energy Regulatory Commission (FERC) approved ten other U.S. LNG export terminals, six of which are currently under construction.¹⁴ FERC has an additional 12 pending applications for LNG export terminals, in addition to three others that are in pre-filing status.¹⁵

This bounty has not come without its problems and controversies. Environmental concerns such as: drinking and groundwater contamination,¹⁶ induced seismic activity due to wastewater disposal,¹⁷ and fugitive emissions are gaining the most public attention.¹⁸ To be sure, natural gas is not environmentally neutral, but it is much cleaner compared to other fossil fuel alternatives.¹⁹ However, health concerns raised quickly, especially as shale gas development moved closer to highly developed areas not used to mineral extraction—such as the enormous Marcellus Shale near large population centers on the East Coast.²⁰ Vermont was the first state to ban fracking in

12. *Id.* at 2.

13. See *Natural Gas Weekly Update*, U.S. ENERGY INFO. ADMIN., Feb. 25, 2016, https://www.eia.gov/naturalgas/weekly/archivenew_ngwu/2016/02_25/index.php.

14. FERC, *North American LNG Import/Export Terminals Approved*, Jan. 24, 2018, <https://www.ferc.gov/industries/gas/indus-act/lng/lng-approved.pdf>.

15. FERC, *North American LNG Export Terminals Proposed*, as of July 13, 2018, <https://www.ferc.gov/industries/gas/indus-act/lng/lng-proposed-export.pdf>.

16. Executive Summary, *Hydraulic Fracturing for Oil and Gas: Impacts from the Hydraulic Fracturing Water Cycle on Drinking Water Resources in the United States*, EPA (Dec. 2016), at 9,13, https://www.epa.gov/sites/production/files/2016-12/documents/hfdwa_executive_summary.pdf.

17. *How is Hydraulic Fracturing Related to Earthquakes and Tremors?* U.S. GEOLOGICAL SURVEY (Sept. 25, 2018), https://www.usgs.gov/faqs/how-hydraulic-fracturing-related-earthquakes-and-tremors?qt-news_science_products=0#qt-news_science_products.

18. Science, *Fugitive emissions from shale gas: our Q&A*, CARBON BRIEF, (May 29, 2012), <https://www.carbonbrief.org/fugitive-emissions-from-shale-gas-our-qa>.

19. See *Natural Gas and the Environment*, U.S. Energy Information Administration, August 22, 2018, https://www.eia.gov/energyexplained/index.cfm?page=natural_gas_environment. (“Burning natural gas for energy results in fewer emissions of nearly all types of air pollutants and carbon dioxide (CO₂) than burning coal or petroleum products to produce an equal amount of energy. About 117 pounds of carbon dioxide are produced per million British thermal units (MMBtu) equivalent of natural gas compared with more than 200 pounds of CO₂ per MMBtu of coal and more than 160 pounds per MMBtu of distillate fuel oil”).

20. See ALANDRA KAHL, *MANAGEMENT OF ENVIRONMENTAL IMPACTS* (Francis J. Hopcroft ed., 201

2012.²¹ New York banned the practice in 2014, Maryland followed suit in March 2017, and 22 states passed local ordinances to limit fracking.²²

The nexus of this controversy is the matter of natural gas pipelines, which are necessary to transport the gas. Many pipelines exist already. In years to come many more will connect from processing plants in producing regions to LNG export facilities, power plants, factories, and—ultimately—consumers. As part of this process, under section 7 of the Natural Gas Act (NGA), FERC reviews applications to construct and operate natural gas pipelines.²³ Furthermore, besides natural gas pipelines, FERC has exclusive authority to review LNG terminal applications under Section 3 of the NGA.²⁴ FERC, as a federal agency, must take into account “environmental effects of their proposed actions prior to making decisions” as mandated by the National Environmental Policy Act of 1969 (NEPA). Also, the NGA designates FERC as the lead agency to do so.²⁵ Therefore, FERC is a significant actor in the shale gas revolution. FERC is in a dominant position not just to shape the course of American energy independence and security, but also the environmental impact these developments will cause.²⁶

FERC’s siting decisions are increasingly unpopular with environmental activists, affected landowners, and their elected representatives. These decisions are increasingly challenged in court. One of the substantive issues raised in connection with this, is the scope of FERC’s review under NEPA.²⁷ This paper explores the following question: to what degree must FERC

21. Editorial, *Vermont First State to Ban Fracking*, CNN, (May 17, 2012), <https://www.cnn.com/2012/05/17/us/vermont-fracking/index.html>.

22. James Cromwell & Pramilla Malick, Opinion, *New York State's Final Chance to Stop Fracking is Slipping Away*, THE HILL, (Aug. 25, 2017), <http://thehill.com/blogs/pundits-blog/energy-environment/347983-new-york-states-final-chance-to-stop-fracking-is>; see also John Hurdle, *With governor's signature, Maryland becomes third state to ban fracking*, ST. IMPACT PENN., (Apr. 4, 2017), <https://stateimpact.npr.org/pennsylvania/2017/04/04/with-governors-signature-maryland-becomes-third-state-to-ban-fracking/> (Asserting Maryland banned fracking in 2017).

23. FERC *Gas Pipelines*, <https://www.ferc.gov/industries/gas/indus-act/pipelines.asp>.

24. *LNG*, FERC (Jul. 26, 2018), <https://www.ferc.gov/industries/gas/indus-act/lng.asp>.

25. National Environmental Policy Act of 1969, 42 U.S.C. § 4321, 4332(1)(C) (1970); see also Natural Gas Act, 15 U.S.C. § 717a(b)(1) (2011) (“Commission shall act as the lead agency...”).

26. National Environmental Policy Act of 1969, 42 U.S.C. § 4821 (1969).

27. Ellen M. Gilmer, *Pipelines Appeals court tosses major challenge to FERC eminent domain use*, E&E NEWS (July 26, 2018), <https://www.eenews.net/stories/1060091229> (litigants challenged FERC’s practice of letting pipeline builders use eminent domain to take land); Office of Gov. Phil Murphy, *AG Grewal Challenges Federal Government’s Inadequate*, ST. OF NJ. (July 26, 2018), <https://nj.gov/governor/news/news/562018/approved/20180726b.shtml> (New Jersey Attorney General “joins comments urging [FERC] to focus on climate change impacts when approving new pipelines”); Jamison Cocklin, *Delaware Riverkeeper Challenging FERC in Court Over PennEast*, NGI’S DAILY GAS PRICE INDEX (May 16, 2018), <https://www.naturalgasintel.com/articles/114397-delaware-riverkeeper-challenging-ferc-in-court-over-penneast> (Delaware riverkeeper is seeking a federal court order that would force FERC to respond to the organization’s request that the Commission rehear the January certificate authorizing PennEast Pipeline).

consider upstream and downstream impacts, including the consequences of hydraulic fracturing. This paper contends: (1) that FERC's current review excluding upstream impacts is appropriate and in the public interest, as defined under the regulatory framework; and (2) these upstream and downstream impacts can be most effectively addressed by Congress amending the NGA to designate FERC and the Environmental Protection Agency (EPA) as co-leads for NEPA's mandated pipeline and LNG terminal review.

I. NEPA OVERVIEW

Signed into law on January 1, 1970, NEPA establishes a "national policy [to] encourage productive and enjoyable harmony between man and his environment." NEPA was intended to reduce or eliminate environmental damage and to promote "the understanding of the ecological systems and natural resources important to" the United States.²⁸ NEPA was the first major environmental law in the United States and is often referred to as the *Magna Carta* of Federal environmental laws.²⁹

The purpose of NEPA is two-fold: (1) to ensure that the agency proposing a major federal action "will have available, and will carefully consider, detailed information concerning significant environmental impacts";³⁰ and (2) to guarantee that the relevant information will be made available to the larger public audience.³¹ However, "NEPA itself does not mandate particular results" to accomplish these ends.³² Rather, it imposes only procedural requirements on federal agencies to analyze the environmental impact of their proposals and actions.³³ In the words of the Ninth Circuit, NEPA is considered "more procedural than prophylactic."³⁴ Specifically, where legislation and major federal actions significantly affect the quality of the human environment, NEPA requires federal agencies to include a detailed statement in every recommendation or report on proposals. This detailed statement is called an Environmental Impact Statement (EIS).³⁵

EIS are made by the responsible officials on:

-
- 28. National Environmental Policy Act of 1969, 42 U.S.C. § 4321 (1970).
 - 29. *Council on Env. Quality*, EXEC. OFF. OF THE PRESIDENT (Sept. 26, 2018), <https://www.whitehouse.gov/ceq/>.
 - 30. *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 349 (1989).
 - 31. See 42 U.S.C. § 4332(2)(c).
 - 32. See *Robertson*, 490 U.S. at 350.
 - 33. *Id.*
 - 34. See *South Coast Air Quality Mgmt. Dist. v. FERC*, 621 F.3d 1085, 1092 (9th Cir.2010), (quoting James J. Hoecker, *The NEPA Mandate and Federal Regulation of the Natural Gas Industry*, 13 Energy L.J. 265, 265 (1992)).
 - 35. National Environmental Policy Act, 42 U.S.C. § 4332(2)(C) (1970).

- (i) the environmental impact of the proposed action;
- (ii) any adverse environmental effects which cannot be avoided should the proposal be implemented;
- (iii) alternatives to the proposed action;
- (iv) the relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity; and
- (v) any irreversible and irretrievable commitments of resources which would be involved in the proposed action should it be implemented.³⁶

The President's Council of Environmental Quality (CEQ), established by Title II of NEPA, has the following duties: (1) ensuring that federal agencies meet their obligations under NEPA; (2) overseeing federal agency implementation of the environmental impact assessment process; and (3) issuing regulations and other guidance to federal agencies regarding NEPA compliance.³⁷

NEPA sets out procedures that federal agencies must follow to ensure that the environmental effects of proposed actions are "adequately identified and evaluated."³⁸ If an agency's proposed action is neither categorically excluded from the requirement to produce an EIS nor would clearly require the production of an EIS, the CEQ regulations allow an agency to prepare a more limited document. This document is called an Environmental Assessment (EA). The EA is to be a "concise public document" that "[b]riefly provide[s] sufficient evidence and analysis for determining whether to prepare an [EIS]."³⁹ According to CEQ regulations, agencies must evaluate the direct, indirect, and cumulative impacts that are reasonably foreseeable.⁴⁰

Specifically, regarding FERC, the Energy Policy Act of 2005 amended the NGA to provide that FERC shall act as the lead agency for purposes of complying with NEPA. Also, for purposes of conducting environmental, safety, and security reviews of LNG plants and related pipeline facilities. This includes siting natural gas pipelines and LNG terminals.⁴¹ As the lead

36. *What is the National Environmental Policy Act?*, EPA, <https://www.epa.gov/nepa/what-national-environmental-policy-act> (emphasis added).

37. *What does NEPA Require?*, EPA <https://www.epa.gov/nepa/what-national-environmental-policy-act>. (last visited Nov. 3, 2018).

38. *See* 40 C.F.R. § 1501.4(a)–(b).

39. 40 CFR § 1508.9(a) (2017).

40. Council on Env'tl. Quality, 40 C.F.R. § 1508.25(a)(3)–(c) (2017).

41. Natural Gas Act, 15 U.S.C. § 717n(b)(1).

agency, FERC is to supervise the preparation of the EIS if more than one federal agency is involved in the same action, including the EPA.⁴² LNG exports have a slightly different process and are a joint procedure shared by the Department of Energy (DOE) and FERC.⁴³ Under the NGA, an entity seeking to export natural gas to other countries must obtain DOE's authorization.⁴⁴ Section 3 of the NGA requires that DOE *shall issue* such authorization unless it finds that the proposed export “will not be consistent with the public interest.”⁴⁵ In 2016, the D.C. Circuit held that DOE has sole authority to authorize LNG exports. Therefore, FERC could not be considered the legally relevant or proximate cause of the alleged effects of those exports.⁴⁶ For purposes of NEPA, the court in *Freeport* held that FERC had no legal authority to consider the environmental effects of those exports, and thus no NEPA obligation stemmed from those effects.⁴⁷ That said, licensing for LNG export terminal siting is solely under the jurisdiction of FERC. FERC is accountable for purposes of NEPA.

II. FERC'S CONSIDERATION OF UPSTREAM AND DOWNSTREAM IMPACT: APPROPRIATE AND IN THE PUBLIC INTEREST?

To be sure, there are legitimate concerns about fracking and the upstream and downstream impacts of natural gas pipelines and LNG terminals. These are activities that FERC has exclusive jurisdiction over. However, FERC meets and exceeds congressionally mandated goals in NGA and NEPA, and CEQ regulations in the current review process.⁴⁸ Reconciling these environmental concerns about fracking in particular and FERC's interests are discussed further in Section III.

FERC assesses direct greenhouse gas (GHG) impacts from construction and operation of projects in the NEPA reviews—this is not as controversial.⁴⁹ But we must consider if upstream and downstream impacts are even contemplated under CEQ's regulations. These regulations require agencies

42. See 40 C.F.R. § 1501.5(a).

43. Department of Energy, Federal Registrar, *Small-Scale Natural Gas Exports*, Vol 83, No. 143 (2018).

44. 15 U.S.C. § 717(3)(a) (2012).

45. *Id.*

46. See *Sierra Club v. FERC*, 827 F.3d 36, 40 (2016) (mentioning *Freeport* and the fact that the commission authorized that pipeline and the broad authorization supporting the commission's decision).

47. See *Sierra Club*, 827 F.3d at 40.

48. *Id.*

49. See *Sierra Club v. FERC (Sabal Trail)*, 867 F.3d 1357, 1365 (D.C. Cir. 2017). (noting that a grievance under NGA by a FERC order can be challenged under NEPA).

to examine the direct, indirect, and cumulative impacts of proposed actions.⁵⁰ Since they are not direct impacts, upstream and downstream impacts would fall under the *indirect impact* category. According to the regulations, indirect impacts are defined as those “which are caused by the action and are later in time or farther removed in distance, but are still reasonably foreseeable.”⁵¹ Furthermore, indirect effects “may include growth inducing effects and other effects related to induced changes in the pattern of land use, population density or growth rate, and related effects on air and water and, other natural systems, including ecosystems.”⁵² Therefore, to determine whether an impact should be studied as an indirect impact, FERC must determine whether it: (1) is caused by the proposed action, and (2) is reasonably foreseeable.⁵³

This section is divided as follows: Part A explores the question of to what degree the Commission must consider upstream impacts, and Part B similarly, for downstream impacts. Part C addresses policy arguments relevant to upstream and downstream impacts, and Part D addresses legal precedent and arguments relevant to both.

A. Upstream Impacts — Overview

FERC’s view on upstream impacts, including fracking, is that they do not meet the definition of indirect impacts. Therefore, “NEPA does not require [its] review to include induced upstream natural gas production.”⁵⁴ As FERC states, “the environmental effects resulting from natural gas production are generally neither caused by a proposed pipeline (or other natural gas infrastructure) project nor are they reasonably foreseeable consequences of our approval of an infrastructure project, as contemplated by CEQ regulations.”⁵⁵ To be sure, CEQ did release a 34-page document in August 2016, recommending federal agencies to quantify a proposed action’s projected direct and indirect GHG emissions.⁵⁶ However, the change in

50. 40 C.F.R. § 1508.25(c) (1978).

51. 40 C.F.R. § 1508.8(b) (1978).

52. *Id.*

53. Gillian Giannetti, *FERC Takes a Step Backward on Environmental Impacts*, BLOG (May, 21 2018), <https://www.nrdc.org/experts/gillian-giannetti/ferc-takes-step-backward-environmental-impacts>.

54. Aaron Flyer, Note, FERC Compliance Under NEPA: *FERC’s Obligation to Fully Evaluate Upstream and Downstream Environmental Impacts Associated with Siting Natural Gas Pipelines and Liquefied Natural Gas Terminals*, 27 Georgetown L. Rev. 301, 305 (2012).

55. *Id.* at 305.

56. *Fact Sheet: White House Council on Environmental Quality Releases Final Guidance on Considering Climate Change in Environmental Reviews*, THE WHITE HOUSE: PRESIDENT BARACK OBAMA, (Aug. 2, 2016), <https://obamawhitehouse.archives.gov/the-press-office/2016/08/02/fact-sheet-white-house-council-environmental-quality-releases-final>.

administration and dissolution of this initiative renders the guidance moot for present purposes. FERC has successfully defended its view repeatedly before courts that:

[a] causal relationship sufficient to warrant Commission [NEPA] analysis of the non-pipeline activity . . . as an indirect impact would only exist if the proposed pipeline would transport new production from a specified production area and that production would not occur in the absence of the proposed pipeline (i.e., there will be no other way to move the gas).⁵⁷

To date, FERC “has not been presented with a proposed pipeline project that the record shows will cause the predictable development of gas reserves.”⁵⁸ Although this FERC interpretation was challenged, the court’s acceptance of them has remained intact post-*Sabal Trail*. This case changed things drastically in relation to downstream impact analysis, as discussed below.⁵⁹

In relation to upstream impact, for a limited period of time, despite not being required to do so by a court or as part of NEPA or any other regulatory requirement, FERC decided to provide upstream impact information.⁶⁰ FERC did so “to provide the public additional information.”⁶¹ On November 28, 2017, an “order issuing certificate” for the Valley Lateral Project (Millennium Pipeline) was issued. The certificate gives GHG emissions estimate for upstream impact.⁶² However, FERC won concerning upstream impact at *Sabal Trail*. The case caused the agency to modify its strategy in relation to providing a quantitative estimate of the impact of upstream emissions. It remains to be seen if this becomes the norm for upstream analysis. Currently, FERC still toes the line that it is not required to assess

57. See e.g., *Northwest Pipeline LLC*, Fed. Energy Reg. Comm’n, Docket No. CP17-441-000, Order Issuing Certificate and Approving Abandonment 164 FERC ¶ 61,038, at ¶ 32 (July 19, 2018).

58. *Id.* at 155; Fed. Energy Reg. Comm’n, Docket No. PL18-1-000, 1, 2 Order Issuing Certification 163 (2018).

59. See *Sabal Trail*, 867 F.3d at 1357.

60. *Dominion Transmission, Inc.*, Fed. Energy Reg. Comm’n, Docket No. CP14-497-001, Order Denying Rehearing, 163 FERC ¶ 61,128, at ¶ 41 (May 18, 2018) (“For a short time, the Commission went beyond that which is required by NEPA, providing the public with information regarding the potential impacts associated with unconventional natural gas production and downstream combustion of natural gas, even where such production and downstream use was not reasonably foreseeable nor causally related to the proposals at issue. That information was generic in nature and inherently speculative, providing upper-bound estimates of upstream and downstream effects using general shale gas well information and worst-case scenarios of peak use.”) (hereinafter *New Market*).

61. FED. ENERGY REG. COMM’N, DOCKET NO. CP16-486-000, ORDER ISSUING CERTIFICATE 159 (2017).

62. *Id.* at 1, 160–62.

upstream impacts as a part of NEPA analysis—and the courts agree. Sections C and D below, further discuss upstream impacts from the legal and policy perspective.

B. Downstream Impacts — Overview

A 2017 D.C. Circuit Court had a significant impact on FERC, relating its policy on assessing downstream impacts. FERC adjusted its policies to take this decision into account.⁶³ In *Sabal Trail*, the Southeast Market Pipelines Project was at issue. This project comprised of three natural gas pipelines under construction in Alabama, Georgia, and Florida—the lynchpin of which was the Sabal Trail pipeline connecting the upstream and downstream pipelines.⁶⁴ FERC's EIS was challenged as inadequate by environmental groups.⁶⁵ The court ultimately held that “where it is known that the natural gas transported by a project will be used for end-use combustion, the Commission should ‘estimate[] the amount of power-plant carbon emissions that the pipelines will make possible.’”⁶⁶

Overall, the court agreed with the Sierra Club and its partners that FERC's refusal to analyze “downstream” emissions violated NEPA.⁶⁷ In the words of the court: “We conclude that the EIS for the [project] should have either given a quantitative estimate of the downstream GHG that will result from burning the natural gas that the pipelines will transport or explained more specifically why it could not have done so.”⁶⁸ The court reasoned that because “FERC could deny a pipeline certificate on the ground that the pipeline would be too harmful to the environment, the agency is a ‘legally relevant cause’ of the direct and indirect environmental effects of pipelines it approves.”⁶⁹ This directly addressed a Supreme Court-approved argument that the agency had successfully used repeatedly concerning downstream impact. The argument was espoused in *Public Citizen*: that when the agency has no legal power to prevent a particular environmental effect, there is no decision to inform, and the agency need not analyze the effect in its NEPA

63. See *Sabal Trail*, 867 F.3d at 1357.

64. *Id.* at 1363.

65. *Id.* at 1357.

66. See *Id.* at 1357.

67. See *South Coast Air Quality Mgmt. Dist. v. FERC*, *supra*, (quoting James J. Hoecker, *The NEPA Mandate and Federal Regulation of the Natural Gas Industry*, 13 *Energy L.J.* 265, 297 (1992)); Elly Benson, In Major Climate Decision, D.C. Circuit Rejects Federal Approval of Sabal Trail Pipeline, *Sierra Club*, (August 28, 2017), <https://www.sierraclub.org/planet/2017/08/sabal-trail-pipeline-ferc-fracked-gas-pipeline>.

68. *Sabal Trail*, 867 F.3d at 1374.

69. *Id.*

review.⁷⁰ However, the court here found that FERC was, in fact, more potent than it claimed to be. Congress had given it the power to deny a pipeline certificate—it has the power to prevent such environmental effects caused downstream, and therefore had to consider them.⁷¹

Subsequently, FERC took action to incorporate this requirement for downstream impact: a quantitative estimate of the downstream GHG that will result from the project, in an effort to apparently satisfy what the court required the Commission to consider for downstream impact purposes. In September 2017, FERC issued a supplemental EIS for Sabal Trail.⁷² It also took similar action in other projects it was approving. For example, on November 28, 2017, FERC issued an “order issuing certificate” for the Millennium Pipeline, giving downstream GHG emissions estimate.⁷³ The GHG estimate was calculated using “EPA’s GHG Equivalencies Calculator and references.”⁷⁴

It appeared that going forward such practice would become the *modus operandi*, but this changed on May 18, 2018 when FERC shifted course and stated that it will no longer discuss upstream and downstream environmental impacts it deems to be outside of NEPA.⁷⁵ Two of the five commissioners dissented, disagreeing with the policy change.⁷⁶ A nonprofit group, with which six states⁷⁷ and the District of Columbia have sided, is contesting at the agency’s decision the D.C. Circuit.⁷⁸

Sections C and D further discuss downstream impacts from the legal and policy perspective.

70. See *Dep’t of Transp. v. Pub. Citizen*, 541 U.S. 752 (2004) (arguing that when the agency can’t prevent a certain environmental effect, there is no decision to inform, and the agency need not analyze the effect in its NEPA review).

71. See *Sabal Trail*, 867 F.3d at 1373.

72. *Sabal Trail Draft Supplemental EIS*, FERC, Sept. 27, 2017, <https://www.ferc.gov/industries/gas/enviro/eis/2017/09-27-17-DEIS/supplemental-DEIS.pdf>.

73. FED. ENERGY REG. COMM’N, DOCKET NO. CP16-486-000, ORDER ISSUING CERTIFICATE 1, 163–65 (2017).

74. See *Greenhouse Gas Equivalencies Calculator*, EPA, <https://www.epa.gov/energy/greenhouse-gas-equivalencies-calculator> (last visited Nov. 3, 2018).

75. *New Market*, *supra* note 60, at ¶44 (“Accordingly, to avoid confusion as to the scope of our obligations under NEPA and the factors that we find should be considered under NGA section 7(c), we will no longer prepare upper-bound estimates . . . where, as here, the upstream production and downstream use of natural gas are not cumulative or indirect impacts of the proposed pipeline project, and consequently are outside the scope of our NEPA analysis.”).

76. *Id.*, Dissents of Commissioner LaFleur and Glick.

77. New York, Maryland, New Jersey, Oregon, Washington, and Massachusetts.

78. See Ellen M. Gilmer, *N.Y. group takes FERC climate issue to federal court*, E&E NEWS, July 16, 2018, <https://www.eenews.net/stories/1060089313>

C. Policy Arguments

FERC's actions concerning upstream and downstream impact consideration are appropriate and meet the standard of public interest. FERC's mandate requires it to act in the public interest, and the agency undoubtedly serves this goal. FERC's mission is to "[a]ssist consumers in obtaining reliable, efficient and sustainable energy services at a reasonable cost through appropriate regulatory and market means."⁷⁹ The actions that FERC takes by assessing pipelines and LNG terminals thoroughly and on a timely basis are well documented.⁸⁰ Thus, FERC also succeeds in achieving the principal purpose of the NGA, which is "to encourage the orderly development of plentiful supplies of ... natural gas at reasonable prices."⁸¹

Going beyond calculating the GHG levels of upstream and downstream impact, which was implemented post-*Sabal Trail* until *New Market*, for FERC would be exceeding its congressionally mandated role and ability to act appropriately and serve the public interest. For example, regarding upstream impact FERC's argument made time and again is persuasive; whether or not FERC builds a pipeline, new drilling will occur. To be sure, there is no other practical way to transmit natural gas except by pipelines, but it is not FERC's role to stop the drilling. As put by FERC:

The fact that natural gas production and transportation facilities are all components of the general supply chain required to bring domestic natural gas to market is not in dispute.⁸² This does not mean, however, that approving this particular project will induce further shale gas production. Rather, as we have explained in other proceedings, a number of factors, such as domestic natural gas prices and production costs drive new drilling.⁸³

79. *About FERC*, FED. ENERGY REG. COMM'N (Sept. 26, 2018), <https://www.ferc.gov/about/about.asp>.

80. *Federal Energy Regulatory Commission, Performance and Accountability Report*, 2014 FERC. On Performance and Accountability.

81. *Public Utilities Commission of California v. FERC*, 900 F.2d 269, 281 (D.C. Cir. 1990) (quoting *NAACP v. FPC*, 425 U.S.662, 670 (1976)).

82. *See generally* Department of Energy, *Understanding Natural Gas and LNG Options 2* (Oct. 2017) https://www.energy.gov/sites/prod/files/2017/11/f46/Understanding%20Natural%20Gas%20and%20LNG%20Options%20October%2011%202017_1.pdf.

83. FED. ENERGY REG. COMM'N, DOCKET NO. CP16-486-000, ORDER ISSUING CERTIFICATE 157 (2017).

Any further restrictive action by FERC at the upstream level would be treading on dangerous ground, as it essentially would be moving beyond pipeline regulation and venturing into regulating drilling activity: FERC's ability to act on the findings is limited.⁸⁴ Necessarily, this policy argument is what *Public Citizen* held in legal form, and why the court repeatedly sides with FERC: when the agency has no legal power to prevent a certain environmental effect, there is no decision to inform, and the agency need not analyze the effect in its NEPA review.⁸⁵ Because FERC has no legal power to stop fracking and drilling, FERC has no duty to analyze. Calculating potential GHG level increases due to downstream—which is what FERC started to implement post-*Sabal Trail*—is very different from shutting down a project based on potential environmental concerns upstream (i.e., fracking).⁸⁶ The regulation of fracking itself is well beyond FERC's purview. This is unlike the direct, indirect, and cumulative environmental analysis FERC does at present regarding the pipelines themselves for NEPA purposes; ordering a pipeline to take a slightly different route (which is something that does happen as a result of such analysis) is very different from asking a company to drill elsewhere. To be sure, upstream data may be useful information for other agencies, but that is about it: FERC's mandate is set forth and limited by Congress.⁸⁷ This is, therefore, a powerful policy and legal argument.

As for downstream impacts, FERC has no blank check to go beyond its legal boundaries. In *Sabal Trail*, the court held that because FERC could deny a pipeline certificate on the ground that the pipeline would be too harmful to the environment, the agency is a “legally relevant cause” of the direct and indirect environmental effects of pipelines it approves.⁸⁸ The consequences remain to be seen. As discussed above, FERC initially decided to provide data about the downstream impact for other projects, and then changed its course in *New Market*, and now the matter is pending before the D.C. Circuit. That said, there are policy implications to consider in this regard. Although, as the court points out, Congress indeed has given FERC the authority to deny applications based on downstream environmental impact, the denial of a pipeline on such grounds would be contrary to FERC's mission to provide reliable, efficient, and cost-effective energy.⁸⁹ Especially

84. See *Sabal Trail*, 867 F.3d at 1372-73 (establishing when FERC's ability to act is limited and when it is not).

85. See *Dep't of Transp. v. Public Citizen*, 541 U.S. 752, 752-54 (2004).

86. *Sabal Trail*, *supra*, 867 F.3d at 1383.

87. *What FERC Does?*, FERC, <https://www.ferc.gov/about/ferc-does.asp?csrt=1109683367713> (last visited Nov. 3, 2018).

88. *Sabal Trail*, 867 F.3d at 1374.

89. *Id.* at 1373.

if the pipeline is a prestigious project, FERC's denial could possibly result in a backlash from Congress (the Keystone Pipeline is beyond the scope of this paper, but the controversy it has resulted in is worth recalling).⁹⁰ The famous *TVA v. Hill* case is a relevant reminder of how Congress can amend legislation if Congress considers agency action under the statutory directive beyond the legislative intent.⁹¹

That said, environmental concerns about upstream and downstream activity—fracking-related—is legitimate, and this article addresses the solutions to these fears.

D. Legal Precedent and Arguments

As discussed, FERC temporarily quantified downstream GHG emissions before reversing course. Whether this will be considered in compliance with NEPA by the courts, especially in light of *Sabal Trail*, remains a pending question before the D.C. Circuit.⁹² FERC also had gone above and beyond what the court in *Sabal Trail* mandated by additionally providing upstream numbers for GHG, before changing tack on that as well.⁹³ Either way, assuming that FERC is in compliance with NEPA, the court will only overturn FERC if they are acting “arbitrary and capricious.”⁹⁴ In the words of the D.C. Circuit in *Sabal Trail*:

[a]n EIS is deficient, and the agency action it undergirds is arbitrary and capricious, if the EIS does not contain sufficient discussion of the relevant issues and opposing viewpoints,” or if it does not demonstrate ‘reasoned decision-making.’ ... The overarching question is whether an EIS's deficiencies are significant enough to undermine informed public comment and informed decision-making.⁹⁵

Previously, courts have accepted the following types of explanations argued by FERC: (1) FERC need not engage in a “speculative analysis”

90. Sam Brodey, *Obama Blocks Keystone Pipeline, Ending Debate for Rest of Term*, MINN. POST (Nov. 6, 2015), <https://www.minnpost.com/dc-dispatches/2015/11/obama-blocks-keystone-pipeline-ending-debate-rest-term/>.

91. *Tenn. Valley Auth. v. Hill*, 437 U.S. 153 (1978), *superseded by statute*, Endangered Species Act Amendments of 1978, Pub. L. No. 95-632, 92 Stat. 3751 (1978) (now codified as 16 U.S.C. § 1531-43 (1988)).

92. *Otsego 2000 et al. v. FERC*, Case No. 18-1188 (D.C. Cir.).

93. *Sabal Trail*, 867 F.3d at 1360.

94. *Id.* at 1374.

95. *Id.*

because there is no standard methodology for quantifying the downstream environmental effects of GHG emissions that result from a pipeline project;⁹⁶ (2) Projects would not significantly contribute to the cumulative impact of GHG emissions, given that the power plants that contracted for the Projects' capacity would use much of the delivered natural gas to replace the burning of higher-emissions coal;⁹⁷ and (3) the *Public Citizen* argument discussed in the previous section. The D.C. Circuit will soon have to decide whether any or all of these options are extinguished or limited in the post-*Sabal Trail* world.

It is important to note that it has been argued on Constitutional grounds that FERC, as an independent agency removed from direct presidential control, does not need to comply with NEPA requirements as implemented through CEQ.⁹⁸ However, FERC Order 486 voluntarily complies with such implementation.⁹⁹ This independent acceptance is appropriate: FERC has been traditionally granted broad latitude throughout its existence—even before 1977, when FERC was known as the Federal Power Commission.¹⁰⁰ Congress, through its actions,¹⁰¹ allowed FERC's rules to become the law of the land. This broad latitude granted by Congress combined with the “arbitrary and capricious” standard means that courts rarely override FERC's decisions (including holding the Commission accountable for FERC's own rules).¹⁰² Balancing the need to meet continuing demand for domestic natural gas with potential adverse impacts on landowners and surrounding communities is a challenging task; one ultimately entrusted to the Commission by Congress.¹⁰³ Explored below are some critical legal points that have been used to challenge FERC's review under NEPA of upstream and downstream impact.

96. Brief of Respondent at 22, *Sierra Club et al. v. Fed. Energy Reg. Comm'n*, 867 F.3d 1357 (2017) (No. 16-1329 and 16-1387).

97. *Id.* at 21.

98. James Hoecker, *The NEPA Mandate and Federal Regulation of the Natural Gas Industry*, 13 *ENERGY L.J.* 265, 272 (1992).

99. U.S. Federal Energy Regulatory Commission, Opinion No. 486, 47, 897 (Oct. 19, 2006).

100. Philip L. Cantelon, *The Regulatory Dilemma of the Federal Power Commission, 1920–1977*, 61, 84 (2012) [http://www.shfg.org/resources/Documents/FH%204%20\(2012\)%20Cantelon%202.pdf](http://www.shfg.org/resources/Documents/FH%204%20(2012)%20Cantelon%202.pdf).

101. Department of Energy Organization Act, 42 U.S.C. § 7101 (1979). Public Utilities Regulatory Act, 16 U.S.C. § 791 (1978). Energy Policy Act of 2005, 42 U.S.C.A. § 15801 (2005).

Department of Energy Organization Act in 1977, Public Utilities Regulatory Policy Act of 1978, the Energy Policy Act of 2005, et al.

102. *Ctr. for Env'tl L. & Pol'y v. U.S. Bureau of Reclamation*, 655 F.3d 1000, 1005 (9th Cir. 2011).

103. See Brief of Petitioner at 33, *Sierra Club v. FERC*, 867 F.3d 1357 (D.C. Cir. 2017). (No. 16-1329).

1. Reasonably Foreseeable Effects

As discussed *supra*, in order to determine whether an impact should be studied as an indirect impact, FERC must determine whether the impact: (1) is caused by the proposed action and (2) is reasonably foreseeable. Both prongs have proved sources of a legal challenge.¹⁰⁴ It has been argued that upstream and downstream environmental impacts are reasonably foreseeable effects of a natural gas pipeline or LNG export facility.¹⁰⁵ FERC, since *Sabal Trail*, started and then stopped including downstream impact in its analysis, but however the D.C. Circuit rules on this there are limits. An agency is only required to include “such information as appears to be reasonably necessary under the circumstances for evaluation of the project rather than to be so all-encompassing in scope that the task of preparing it would become either fruitless or well-nigh impossible.”¹⁰⁶ Furthermore, courts have not included the upstream impacts of fracking to be part of the reasonably foreseeable analysis.

It is worth further discussing reasonable foreseeability and the court’s reasoning in *Sabal Trail*, as this was a central issue of contention. Reminding that “indirect effects” in NEPA means “reasonably foreseeable,” the court noted that this, in turn, meant “sufficiently likely to occur that a person of ordinary prudence would take [them] into account in reaching a decision.”¹⁰⁷ Then it stepped away from precedent: “What are the ‘reasonably foreseeable’ effects of authorizing a pipeline that will transport natural gas to Florida power plants?”¹⁰⁸ First, that gas will be burned in those power plants. This is not just “reasonably foreseeable,” it is the project’s entire purpose, as the pipeline developers themselves explain . . . It is just as foreseeable, and FERC does not dispute, that burning natural gas will release into the atmosphere the sorts of carbon compounds that contribute to climate change.”¹⁰⁹

The court addressed whether and to what extent the EIS for this pipeline project needed to discuss these “downstream” effects of the pipelines.¹¹⁰ The court concluded “FERC should have estimated the amount of power-plant

104. Metropolitan Edison Co. v. People Against Nuclear Energy, 460 U.S. 766, 774 (1983).

105. Aaron Flyer, *FERC Compliance Under NEPA: FERC’s Obligation to Fully Evaluate Upstream and Downstream Environmental Impacts Associated with Siting Natural Gas Pipelines and Liquefied Natural Gas Terminals*, 27 GEO. INT’L ENVTL. L. REV. 301, 308 (2016).

106. New York Natural Res. Def. Council, Inc. v. Kleppe, 429 U.S. 1307, 1311 (1976) (citing Natural Res. Def. Council v. Calloway, 524 F.2d 79, 88 (2d Cir. 1975)).

107. EarthReports, Inc. v. FERC, 828 F.3d 949, 955 (D.C. Cir. 2016) (quoting City of Shoreacres v. Waterworth, 420 F.3d 440, 453 (5th Cir. 2005)).

108. See *Sabal Trail*, 867 F.3d at 1371–72.

109. *Id.*

110. *Id.*

carbon emissions that the pipelines will make possible.”¹¹¹ This was a remarkable change in tack. It is also worth noting that the court prescribed this as a “minimum.”¹¹² It remains to be seen if courts will retain or expand this standard, but at least for now this is where the legal landscape stands. FERC’s supplemental EIC appears to have sufficed by simply including GHG emission estimates of downstream impact.¹¹³ That said, subsequent action taken in *New Market* introduces some uncertainty by demonstrating that FERC intends to limit *Sabal Trail*’s EIC as a ‘unique’ scenario.¹¹⁴

Putting aside discussion of whether or not *Sabal Trail*’s holding is incorporated into FERC’s procedures,¹¹⁵ there are limits: NEPA requires “reasonable forecasting,” but an agency need not “engage in speculative analysis” or “to do the impractical, if not enough information is available to permit meaningful consideration.”¹¹⁶ For upstream impacts, the argument discussed in the previous section relating to *Public Citizen* remains valid: because FERC has no legal authority to stop drilling to prevent its environmental effect, there is no decision to inform, and the agency need not analyze the effect in its NEPA review. That said, FERC may—and as discussed, has chosen to for Millennium Pipeline—may choose to do so voluntarily.

2. Cumulative Analysis

As discussed, CEQ’s regulations require agencies to examine the direct, indirect, and cumulative impacts of proposed actions.¹¹⁷ One frequently raised criticism is that the failure to consider upstream and downstream impacts creates an incomplete picture of a project’s cumulative environmental consequences.¹¹⁸ As defined by the CEQ and adopted by

111. *Id.*

112. *Id.*

113. *Sabal Trail Draft Supplemental EIS*, *supra* note 72.

114. Appellee Brief filed by FERC, *Otsego 2000 et al. v. FERC* (January 25, 2018)

(“Contrary to Otsego’s contention, this court’s [*Sabal Trail*] decision did not replace the commission’s obligation to analyze potential impacts on a case-by-case basis with an absolute rule that downstream emissions are always an indirect effect of natural gas transportation projects . . . The unique record in this case — which does not establish any specific end use for the gas transported by the project or what fuels it might displace — does not support a finding that any increase in greenhouse gas emission associated with the end use of gas is reasonably foreseeable.”).

115. FED. ENERGY REG. COMM’N, DOCKET NO. CP16-486-000, ORDER ISSUING CERTIFICATE 111 (2017).

116. *Northern Plain Resources Council, Inc. v. Surface Transportation Board*, 668 F.3d 1067, 1078-79 (9th Cir. 2011).

117. EPA, *Consideration of Cumulative Impacts In EPA Review of NEPA Documents* 1, 2 (1999), <https://www.epa.gov/sites/production/files/2014-08/documents/cumulative.pdf>.

118. Flyer, *supra* note 105, at 307.

FERC, cumulative impacts include the incremental impact of the proposed action when added to past, present, and reasonably foreseeable effects of future actions, regardless of who is responsible for such effects.¹¹⁹ Although, FERC has been criticized for not establishing an adequate baseline prior to determining that federal action will not significantly affect the environment.¹²⁰ The courts have dismissed this criticism, including in *Sabal Trail*: “Perhaps FERC could have said more, but the discussion it undertook of the cumulative impacts of the proposed route fulfilled NEPA’s goal of guiding informed decision-making.”¹²¹

Before *Sabal Trail*, the Second Circuit famously upheld FERC’s decision not to issue an EIS when it authorized the building and operation of the MARC I Hub Line Project’s natural gas pipeline through three counties in Pennsylvania. Focusing on FERC’s reasonableness in determining that overall development of the Marcellus Shale was not sufficiently causally related to the project.¹²² Indeed, it is well beyond FERC’s purview to engage in such a large-scale study. The agency’s focus was and should remain the physical construction and operation of the pipeline itself.¹²³ As discussed below, however, this does not mean that another agency should not take the lead on the environmental review of such projects.

3. Causally Related

As discussed *supra*, when determining whether an impact should be studied as an indirect impact, one of the questions FERC must decide is whether the proposed action caused it: “NEPA requires ‘a reasonably close causal relationship’ between the environmental effect and the alleged cause” in order “to make an agency responsible for a particular effect under NEPA.”¹²⁴ The most powerful argument under this prong against FERC’s practices was that the causally related standard established in *Public Citizen* does not preclude the evaluation of upstream and downstream impacts in environmental reviews.¹²⁵ *Sabal Trail* perhaps dented this understanding, but

119. *Kern River Gas Transmission Co.*, 117 F.E.R.C. ¶ 61,077, 47, 486, 497 (2006).

120. See Brief of Petitioner at 6, *Coal. for Responsible Growth & Res. Conservation v. FERC*, 485 Fed. App’x. 472 (2d Cir. 2012) (No. 12-566) 2012 WL 1667728 (arguing that FERC has been criticized for not having an adequate baseline).

121. See *Sabal Trail*, 867 F.3d at 1357.

122. Brief of Petitioner, *supra* note 6, at 6.

123. FED. ENERGY REG. COMM’N, DOCKET NO. CP16-486-000, ORDER ISSUING CERTIFICATE 159–162 (2017).

124. See *Public Citizen*, *supra* note 752, at 767 (quoting *Metropolitan Edison Co. v. People Against Nuclear Energy*, 460 U.S. 766, 774 (1983)).

125. *Flyer*, *supra* note 103, at 315.

as discussed in previous sections *Public Citizen* remains very much alive: especially in regards to upstream impacts, but also with downstream impacts.

FERC often cites the Supreme Court holding that the agency is not required to “examine everything for which the [Projects] could conceivably be a ‘but-for cause’ in order to satisfy NEPA.”¹²⁶ Thus, “[s]ome effects that are ‘caused by’ a change in the physical environment in the sense of ‘but for’ causation,” will not fall within NEPA if the causal chain is too attenuated.¹²⁷ Such an expansive examination would neither be appropriate nor in the public interest—and is certainly contrary to Congressional intent. In sum,

FERC’s responsibility to study downstream impacts is limited in scope: to estimate the amount of GHG that the pipelines as was required in *Sabal Trail* remains the outer limit.

III. FILLING THE GAP: PROPOSAL FOR A NEW SYSTEM

As discussed, FERC’s current review that provides limited quantified data about upstream and downstream impacts is appropriate and in the public interest and is on stable ground both from a legal and policy standpoint—even in the post *Sabal Trail* world. Whether under NEPA FERC is required to estimate the upstream and downstream impact of pipelines and LNG terminals on the environment is limited only to the *Sabal Trail* pipeline or more broadly is something the D.C. Circuit will have to decide.¹²⁸ Nonetheless, either way the actual impacts themselves remain unaddressed in both scenarios. This section addresses the following issues: (A) the problem with states attempting to resolve this issue individually, and necessity of a national solution; (B) a proposal for a revision of the NGA to designate FERC and EPA joint review for NEPA-mandated review of pipelines and LNG terminals; (C) and why the proposal would be a win-win-win for FERC, EPA, and the public.

A. The Problem with States and Need for a National Solution

In the absence of a comprehensive national regulatory strategy to address, the upstream impacts of pipelines and LNG terminals (i.e. fracking),

126. See *Id.* at 308. See also *Sierra Club v. FERC*, 827 F.3d 36,46 (2016) (citing *DOT v. Pub. Citizen*, 541 U.S. 752,767 (2004)).

127. *Metropolitan Edison Co.*, at 774.

128. FED. ENERGY REG. COMM’N, DOCKET NO. CP16-486-000, ORDER ISSUING CERTIFICATE 159–165 (2017).

states have stepped in with a patch work of different regulations.¹²⁹ Many states passed effective legislation to address concerns about fracking.¹³⁰ However, one major problem is “segmentation;” a strategy to break up a pipeline project into different segments in order to avoid a full environmental impact being measured.¹³¹ Just one example of such practice is the Atlantic Sunrise Project.¹³² This is something that neither state-based regulators nor FERC’s system, as designed, are meant to address.¹³³

Another problem with a local approach is that economic incentives combined with lobbying at the local level militate against broader environmental considerations. Since 2009, the industry has spent more than \$59 million lobbying state legislators, and contributed \$9.5 million to campaigns and political action committees, according to data released in October 2017 by the watchdog group Common Cause, with some estimates running higher.¹³⁴ Furthermore, the debate is divisive and extreme: while some states have been very welcoming of fracking and reluctant to impose any restrictions, others have enacted total bans on drilling.

Therefore, there is a need for the federal government to address this issue. American energy independence and security is too important to be left to the individual states. The government needs to address the environmental issues resulting from fracking nation-wide. The current system by FERC and the states does not address broader cumulative risk or impact for the environment: each project is essentially provided with its own individual analysis.¹³⁵ The time has come for a solution that allows FERC to perform its job of providing reliable, efficient, and sustainable natural gas at a reasonable cost, while ensuring the environmental consequences from fracking are checked.

Why is now the right time to go ahead with this change? Environmental damage caused by fracking and resulting public backlash is a growing problem. Additionally, the recent court decision in *Sabal Trail* is an

129. See Brad Plumer, *How States are Regulating Fracking (In Maps)*, WASHINGTON POST, July 16, 2012, https://www.washingtonpost.com/news/wonk/wp/2012/07/16/how-states-are-regulating-fracking-in-maps/?utm_term=.b3325d90d140.

130. See generally Brad Plumer, *How states are regulating fracking (in maps)*, WASHINGTON POST, July 16, 2012 (demonstrating how states like Ohio and Pennsylvania are states that have passed fracking legislation).

131. Jenny Mandel, *FERC’s Quorum Problem Opens New Lines of Attack*, E&E NEWS, (Mar. 14, 2017), <https://www.eenews.net/stories/1060051393>.

132. *Id.*

133. 40 C.F.R. § 1508.7-1508.8(a)–(b) (2017).

134. See Alexander Kaufman, *This Is What It Looks Like When An Industry Controls A State’s Politics*, HUFFINGTON POST (Oct. 19, 2017, 11:43 AM), https://www.huffingtonpost.com/entry/gas-pennsylvania-severance-tax_us_59e7bd04e4b00905bdae9bfc.

135. Transcript of Proceedings at 78, Federal Energy Regulatory Commission Public Scoping Meeting (Nov. 14, 2007) (relating back to the Palomar Gas Transmission Pipeline Project).

indication of the shift taking place. President Trump's rhetoric on environmental change is significantly different from President Obama. The President's Climate Action Plan, issued in June 2013, was cancelled. On November 3, 2017 the U.S. government published a report prepared by 13 federal agencies clearly stating that humans are the dominant cause of the global temperature rise that has created the warmest period in the history of civilization.¹³⁶

B. Proposal for a Revision of the NGA to Designate FERC and EPA Joint Review for Upstream and Downstream Impact

To address the concerns regarding upstream and downstream impact, this article proposes that the NGA be amended for FERC and EPA to act as co-leads for the purposes of NEPA review of pipelines and LNG terminals. This arrangement would be similar to DOE and FERC sharing authority regarding LNG exports. At present, EPA already is part of the environmental review process for purposes of NGA Section 7 mandate. This simply would be elevating status—but solely for purpose of upstream and downstream impact.¹³⁷ The problem lies in a fundamental conflict of interest in the mission of FERC and goals of NGA versus regulating upstream and downstream impact.¹³⁸ Therefore, upstream and downstream impact analysis should be undertaken jointly by FERC and EPA, an agency beyond FERC's control, with EPA designated as lead—solving the dilemma.

This arrangement would be closer to the original intent of NEPA: "EPA is the day-to-day watchdog of NEPA compliance, responsible for reviewing and commenting upon all federal actions which have significant environmental impact CEQ, in turn, is assigned the task of reviewing problem cases which EPA brings to its attention."¹³⁹ Section 309 of the Clean Air Act requires EPA to review the EIS of other federal agencies and to comment on the adequacy and the acceptability of the environmental impacts of the proposed action.¹⁴⁰ Yet under the current structure, EPA is powerless beyond that.¹⁴¹ For example, in June 2016 EPA said FERC's

136. See *Climate Science Special Report, U.S. Global Change Research Program*, Nov. 3, 2017, <https://science2017.globalchange.gov/>.

137. See *Sierra Club v. FERC (Sabal Trail)*, 867 F.3d 1357, 1364 (D.C. Cir. 2017).

138. *About FERC*, FED. ENERGY REG. COMM'N (Sept 26, 2018), <https://www.ferc.gov/about/about.asp>; see also Natural Gas Act, 15 U.S.C. § 717(n)(b)(1) (2011).

139. See William Andreen, *In Pursuit of NEPA's Promise: The Role of Executive Oversight in the Implementation of Environmental Policy*, 64 *Ind. L.J.* 205, 231 (1989).

140. *What is the National Environmental Policy Act?*, EPA, <https://www.epa.gov/nepa/what-national-environmental-policy-act>.

141. Hannah Northey, *EPA Blasts FERC Reviews, Seeks 'Definitive Resolution'*, E&E NEWS, (Oct. 13, 2016), <https://www.eenews.net/stories/1060044234>.

review of the Leach Xpress project was “insufficient.” The EPA suggested further analysis of alternative routes, ways to protect forested lands and aquatic resources, and environmental justice as well as for the commission to conduct and include an analysis of greenhouse gases and climate change.¹⁴² However, these recommendations were ignored by FERC, leading to a letter containing strong criticism and reiteration of recommendations by the EPA.¹⁴³ This letter was received, but FERC largely disregarded the letter.

EPA already has a lot of authority over fracking (e.g. Clean Water Act), has done a lot of work on the subject, and has a lot of knowledge in this matter, so transition should not be difficult.¹⁴⁴ EPA acting alone, would not do here because the goal is to have both agencies exercising their authority equally on this subject for purposes of NEPA; EPA on the upstream and downstream impact, FERC on the project itself (pipeline or LNG terminal).¹⁴⁵ This review is essentially what FERC already performs. Please note that Congress would have to enact this change. The NGA was amended by the Energy Policy Act of 2005, which provided that FERC shall act as the lead agency for purposes of complying with NEPA for purposes of conducting environmental, safety, and security reviews of LNG plants and related pipeline facilities, including siting natural gas pipelines and LNG terminals.¹⁴⁶ What Congress gives an agency, it can take away (or in this case, redistribute).

C. A Win-Win-Win for the FERC, the Public, and the EPA

Congress and FERC have been at a place of transition before. For example, the passage of NGA in 1938 was meant to fill a gap in how natural gas regulation was being unsuccessfully regulated on a state-level patchwork, without federal supervision.¹⁴⁷ Another example of adjusting to such change in the past was the creation of DOE and FERC (then known as the Federal Power Commission) in 1977 as response to the 1973 oil crisis.¹⁴⁸ Necessity is the mother of invention.

^{142.} *Id.*

^{143.} Letter from Kenneth Westlake, EPA, to Kimberly Bose, FERC, (Oct. 11, 2016), RE: FINAL ENVTL. IMPACT STATEMENT (FEIS) FOR COLUMBIA GAS TRANSMISSION, LLC – LEACH XPRESS PROJECT, AND COLUMBIA GULF TRANSMISSION, LLC – RAYNE XPRESS EXPANSION PROJECT, (FERC Docket Nos. CP15-514-000 and CP15-539-000 Respectively) (CEQ No. 20160203).

^{144.} Mike Soraghan, *The fracking 'loophole' that just keeps growing*, E&E NEWS (Aug. 15, 2015), <https://www.eenews.net/stories/1060023558>.

^{145.} *See id.*

^{146.} *See also* Natural Gas Act, 15 U.S.C. § 717(n).

^{147.} *The History of Regulation*, NATURALGAS.ORG, <http://naturalgas.org/regulation/history/> (last visited May 30, 2019).

^{148.} *Id.*

The delegation of upstream and downstream impact analysis would be good for FERC, the public, and the EPA: a win-win-win. FERC Commissioners and staff are known to undertake significant efforts to prepare detailed reports, such as hearings, solicitation of comments, etc. For the Sabal Trail Project, FERC painstakingly assembled a 477-page EIS developing “a complete record on potential Project impacts to all impacted resource categories: geology; water resources; fisheries and wetlands; vegetation and wildlife; land use and recreation; socioeconomics; cultural resources; air quality; noise; reliability and safety; and cumulative impacts.”¹⁴⁹ This was an outstanding and detailed report, but yet was challenged—with partial success—because it failed to address upstream and downstream impact.

FERC has very competent Commissioners and staff, but environmental review beyond the level at present for upstream/downstream is neither appropriate nor necessary as per NEPA—as affirmed by the courts (especially in *Sabal Trail*). Although the D.C. Circuit will ultimately have to decide following *New Market*, it appears that FERC is fully in compliance with the law and taking action that is appropriate and in the public interest.

This recommended change doesn’t mean that FERC would no longer have to do any NEPA-related work. The direct and indirect environmental impacts on pipelines and LNG terminals would have to still be conducted, that is everything minus upstream/downstream impact. But, the lead for upstream and downstream impacts would fall on EPA. To measure upstream and downstream impact FERC already has experience calculating GHG using EPA’s GHG Equivalencies Calculator-Calculations and References. Allowing EPA to use its own methodology to conduct a broader, in-depth, and cumulative analysis (i.e. combine with different projects) would give the U.S. government a broader picture to make a decision, which would benefit the American public.

With EPA taking the lead in this aspect of reviews, FERC can avoid the massive amount of litigation and legal challenges that fill its dockets and keep its very skilled Office of General Counsel busy. The appellate review process for hearings is proof of the problem of overcrowded dockets.¹⁵⁰ Although the federal Natural Gas Act requires the agency to issue a decision on appeals within 30 days, FERC can extend the deadline indefinitely by

149. Brief of Petitioner, *supra* note 6, at 6.

150. Motion to Dismiss for Lack of Jurisdiction, *Weymouth v. FERC*, Nos. 17-1135, 17-1139, U.S. App. (D.C. Cir. 2017), <https://www.ferc.gov/legal/court-cases/briefs/2017/DC17-1135etalTownofWeymouthMassMotiontoDismiss.pdf>.

issuing what is called a “tolling order.”¹⁵¹ Often, tolling orders are issued at 30 days, granting the agency unlimited time.¹⁵² In some recent cases, FERC issued its decision after the pipes were already in the ground with the gas flowing. Therefore, by the time a challenge makes its way through the court system, the pipeline is operational or close to being operational and will need to be decommissioned, making the point moot or incredibly expensive to correct. This also creates uncertainty for pipeline companies, and was a concern felt by the Sabal Trail and Millennium Pipeline.¹⁵³ Breaking down the division of labor in a predictable manner—like how FERC and DOE divide up responsibility for LNG exports—would make the system more predictable and business-friendly.¹⁵⁴

Finally, a national solution backed by both FERC and the EPA would address public fear of fracking and demolish the rationale behind states banning fracking, which primarily rests on environmental concerns. EPA, with its mission to protect the environment, is well-suited for the task of assessing upstream and downstream impacts. EPA is well-trusted by the public—and environmental groups—in this regard.¹⁵⁵ Having an agency separate and independent from FERC to make this assessment would help build a stronger consensus on the solution.

CONCLUSION

FERC’s mission is to provide a steady source of energy to consumers. The agency additionally has a responsibility under NEPA to evaluate the direct and indirect environmental impacts of natural gas pipelines and LNG terminals. The agency, even before *Sabal Trail*, was in the process of starting to consider indirect downstream impacts. FERC’s actions since the D.C. Circuit Court’s decision—such as the Millennium Pipeline—placed FERC on solid ground. Changes introduced with *New Market* provide some uncertainty, which the D.C. Circuit will have to resolve, but even if the challengers win the victory will be limited: quantifying the downstream environmental effects of GHG emissions from pipeline projects, not actually

151. Susan Phillips, *Lawyers Say FERC Hinders Appeals on Pipeline Projects*, STATE IMPACT PENN., Oct. 20, 2015 at 5, <https://stateimpact.npr.org/pennsylvania/2015/10/20/lawyers-say-ferc-hinders-appeals-on-pipeline-projects/>.

152. Morgan Bettex, *FERC Orders Unlimited Time to Rethink LNG Terminal*, LAW 360, Oct. 21, 2008, <https://www.law360.com/articles/73660/ferc-orders-unlimited-time-to-rethink-lng-terminal>.

153. *Id.*

154. *Liquefied Natural Gas (LNG)*, DEP’T OF ENERGY, <https://www.energy.gov/fe/science-innovation/oil-gas/liquefied-natural-gas> (last visited May 30, 2019).

155. Pew Research Center, *Beyond Distrust: How Americans View Their Government* 58–68 (Nov. 23, 2015), <http://www.pewresearch.org/wp-content/uploads/sites/4/2015/11/11-23-2015-Governance-release.pdf>

addressing the impact. As for indirect effects associated with upstream commercial natural gas activity (i.e. fracking), FERC currently—rightly—does not consider this part of its required assessment under NEPA. FERC started “to provide the public additional information,” based on its “order issuing certificate” from November 2017 for the Millennium Pipeline and then stopped doing so, but even when it did provide such information, the data was minimal. As argued in this paper, the right way to address the legitimate concern of upstream and downstream impacts for pipelines and LNG terminals for the purposes of NEPA is not just FERC alone, but jointly with EPA. This collaboration would be a victory for both agencies as well as the American people they serve, allowing all of us to continue to thrive from our great shale gas revolution.