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—Journal of—
FOOD & LAW
—POLICY—

Volume Thirteen

Number Two

Fall 2017

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LEGAL ACADEMY

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Food Law & Policy: An Essential Part of Today's Legal Academy

Emily M. Broad Leib*
Baylen J. Linnekin**

INTRODUCTION

In 2014, the authors of this article published the first analysis of the development and history of the relatively new academic field of Food Law & Policy (“FL&P”).¹ As we defined the field in that article, FL&P “is the study of the basis and impact of those laws and regulations that govern the food and beverages we grow, raise, produce, transport, buy, sell, distribute, share, cook, eat, and drink.”² FL&P was born out of two pre-existing fields: 1) Food & Drug Law, which focuses on the authority and actions of the Food & Drug Administration (“FDA”), and 2) Agricultural Law, which examines the impacts of laws (including those administered by the U.S. Department of Agriculture (“USDA”)) on the agricultural sector. FL&P differs from its parent fields in that it explores legal and policy issues

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1. See Baylen J. Linnekin & Emily M. Broad Leib, *Food Law & Policy: The Fertile Field's Origins and First Decade*, 2014 WIS. L. REV. 557 (2014).

2. *Id.* at 584.

beyond the scope of both of those areas of law, including the regulation of food by various agencies, at all levels of government, and across the range of agricultural, health, labor, economic, environmental, and other issues that intersect with food. This broader analysis of the food system³ had not previously been part of the legal academy.

As our article described, the field of FL&P came into being roughly in 2004, making the publication of that article in 2014 a celebration of a decade of the life of the field. Even after only ten years, our research found that the state of FL&P was quite strong. For our 2014 article, we developed ten criteria to measure the breadth and depth of a legal-academic field: legal scholarship, law school courses, degree programs, academic centers, casebooks/texts, clinical legal programs, student societies and organizations, dedicated legal journals, relevant professional associations, and academic conferences. According to our detailed analysis, FL&P met seven of the ten criteria. This compared favorably with its much more seasoned parent fields, as FDA Law also met seven of ten, and Agricultural Law met all ten.

Our 2014 article found that as of 2013 (the year when we collected data for the article), twenty of the top 100 law schools had offered FL&P courses; thirty clinics at twenty-three of the top 100 schools had engaged in practice and projects in the field of FL&P; and the field boasted a dedicated legal journal as well as various student Food Law societies, academic centers, and conferences. Our data demonstrated that FL&P scholarship grew exponentially in the years leading up to 2014.

Now, four years later, the field's continued growth has solidified its place in academia. This article endeavors to assess and discuss this growth by reviewing the same ten criteria of a legal-academic field and tracking developments in the four years since we collected our initial data in 2013. As the data we present below details, FL&P's newfound strength within each of our ten criteria demonstrates the field has grown strong roots.

3. Kameshwari Pothukuchi & Jerome L. Kaufman, *The Food System: A Stranger to the Planning Field*, 66 J. AM. PLAN. ASSN. 113, 113 (2000) (explaining that the food system includes "production, processing, distribution, consumption, and waste management").

The field of FL&P is flourishing, and appears now to be a permanent fixture within the American legal academy.

OVERALL FINDINGS

In 2014, we reported that the field of FL&P had evidenced exceptional growth in its first decade, and we predicted continued growth. Data we collected in 2017 has borne out these predictions. In particular, academic offerings in the field have exploded. Of the same 100 law schools we studied in 2014, the number of schools offering FL&P courses increased from 20 using our 2013 data to 34 in our 2017 data. The number of dedicated FL&P clinical programs grew from one to four, and the total number of clinics engaged in FL&P projects and other work more than doubled from 30 clinics at 23 of the top 100 law schools in 2013 to 69 clinics at 48 of the same 100 schools. Student societies have also experienced strong growth. While we did not tabulate the total number of student Food Law societies precisely for our 2014 article, our research at the time suggested that fewer than ten such societies existed then. Today's data shows that number has grown to at least thirty-three nationally. Scholarship is also still increasing in terms of average numbers of articles per year across almost all search terms we used, including ten new ones we developed for this article. While the rate of growth in FL&P publications has slowed for some of those search terms, as we explain below, we believe this continued growth in the *number* of publications in the field, coupled with the slowing *rate* of growth of scholarship in the field, is evidence of the field's maturity.

Importantly, FL&P has now met each of our ten legal-academic criteria, filling out the three criteria the field had not met as of 2013. Most notably, the launch in 2016 of the Academy of Food Law & Policy fulfilled the criterion of a dedicated professional association. Within its first few months of existence, the Academy boasted nearly eighty members, including several international members.⁴ Another previously unmet criterion, degree programs, has now been satisfied by the growth of the Agricultural and Food Law LL.M. program at

4. See THE ACADEMY OF FOOD LAW AND POLICY, FOUNDING MEMBERS, <https://www.academyflp.org/founding-members> (last visited Oct. 18, 2017).

University of Arkansas and the subsequent launch of a similar LL.M. program at Vermont Law School. The last unmet criterion, existence of a casebook or other text, was fulfilled by the publication of the field's first treatise and its first casebook.

The table below provides a broad overview of the growth in each category between data collected in 2013 for our 2014 article and data we collected in 2017 for this article. We break out and present detailed data for each of the ten criteria, respectively, below.

Academic Category	FL&P 2013	FL&P 2017
Academic Scholarship	Explosive growth	Continued strong growth
Law School Courses	20 of top 100 schools	34 of top 100 schools
Degree Programs	0	2
Academic Centers	3	4
Casebooks & Other Texts	0	2 (and at least 2 forthcoming)
Dedicated Legal Journals	1	1
Clinical/Experiential Education	30 clinics at 23 of top 100 schools	69 clinics at 48 of top 100 schools
Student Societies	~ 9	33
Professional Associations/Bar Groups	0	1
Academic Conferences	Regular	Regular & Recurring
Total Criteria Met	7/10	10/10

METHODOLOGY

We researched and obtained the data we use in this article from a variety of sources. As was the case in our 2014 article, we obtained data on FL&P scholarly publications by searching in HeinOnline, one of the leading online repositories of legal scholarship. We obtained information on relevant courses by examining online law school course listings and—in cases where information was unclear or missing from the school websites—by placing phone calls to school registrars. We developed our clinic data by utilizing law school websites to access the websites of individual clinics, with the research team reviewing respective project lists and news releases from those clinics to identify those with FL&P-related projects. We also obtained some data in the article through a survey of members of the Academy of Food Law and Policy.

In order to produce a meaningful comparison for tracking numbers of relevant courses and clinics, we chose to track the same cohort of 100 schools that we analyzed in our 2014 article for two key criteria: courses and clinical projects and offerings. This means the 100 schools we studied in this article are the top 100 schools from the 2013 *U.S. News & World Report* rankings. In addition to collecting data from those 100 schools, we also collected data from 1) eight schools that are in the 2017 top 100 schools, but which were not in the 2013 list and 2) the schools listed in *U.S. News & World Report* as the 2017 schools with the top Environmental Law and Health Law programs. We reference these schools where appropriate in the course of this article but—in order not to skew our earlier data—do not include data from them in the numbers mentioned for course and clinic offerings. Three respective appendices to this article list the top-100 law schools from 2013 (the cohort of 100 schools analyzed in both 2013 and now); the additional law schools ranked in the 2017 top 100; and the schools with the top-ranked Environmental Law and Health Law programs.

I. Academic Scholarship

The research we conducted for the 2014 article “support[ed] the argument that there exist[ed] a ‘large and

growing literature' of FL&P scholarship."⁵ Our updated research demonstrates that the body of scholarly FL&P articles continues to grow. This section discusses our findings pertaining to the numbers of FL&P articles published over a series of time periods and across a range of search terms, as well as the rate of growth of articles featuring those search terms over time. As this section demonstrates, publications in this field have continued to increase almost universally. Most data indicate an increase in the average annual number of search results over the previous four-year period, even if in some cases the rate of growth slowed when compared to the rate of growth during the previous four-year period.

The methodology we used for this present article builds on that we used in our 2014 article,⁶ which relied upon search data we obtained through HeinOnline.⁷ As we did in 2013, we searched the database using terms and phrases scholars associate with FL&P.⁸ As we also did in that article, we began our current research queries in 1950. For the decades prior to 2000, we looked at the total and average number of articles published each year across a given decade (e.g., 1970–79). In order to document more accurately FL&P's growth since 2000—and because we do not yet have the benefit of two complete decades of data this century—our present article looks at the total and average number of articles published each year across four or five-year periods (2000–04; 2005–09; 2010–13; and 2014–17).⁹

5. Linnekin & Broad Leib, *supra* note 1, at 596 (citing Jay A. Mitchell, *Getting into the Field*, 7 J. FOOD L. & POL'Y 69, 76–78 (2011)).

6. The figures included in this section document the results of each search query and its corresponding data points: (1) total number of search results since 1950 by time period; (2) annual average of search results per time period; and (3) the percentage change in the total number of search results from the previous period.

7. While we initially ran searches on both HeinOnline and Westlaw, we relied ultimately on Hein only for two reasons: (1) to maintain a neater comparison with our earlier data; and (2) because the trends in the Westlaw data largely track those of the Hein data.

8. For searches on HeinOnline, we followed the “Core U.S. Journals” hyperlink; entered our search query; then selected “articles;” then selected “United States” as the country published; then viewed results by decade. *See* Linnekin & Broad Leib, *supra* note 1, at 596.

9. Because the searches included in the present article were conducted in early November 2017, there may be relevant articles published in 2017 that are not reflected in the 2014–17 data, including both articles published in November/December 2017 after the

We replicated the four search queries we used previously for purposes of consistency, and then broadened our research by developing new search queries, consisting of ten additional FL&P topics that we identified as emblematic of the field. We based our new search terms on a variety of factors, including FL&P course content, conference topics, mainstream media articles, and our knowledge of and familiarity with the field.¹⁰ The total set of searches contains phrases we and others use to refer to the field itself—for example, “food law and policy”—as well as phrases such as “food justice” and “food waste” that represent a diverse cross-section of themes within the field.

The search terms we included in our 2014 article, which we replicated for this current research, are:

- “agricultural law” and FDA;
- FDA and USDA;
- FDA and “farm subsidies;” and
- “food policy”.

As the charts below and the data in the tables in Appendix D indicate, the rate of growth of articles that feature our original four FL&P search terms—save for “food policy”—continued to rise during the most recent four-year period. Articles featuring the terms FDA and “farm subsidies” grew by more than 115 percent between 2014–17. Articles featuring the terms “Agricultural Law” and “FDA” increased by more than forty-five percent during the same period. And articles featuring both “USDA” and “FDA” grew by more than ten percent.

date of our final search and articles that have been published already but were not yet catalogued by HeinOnline at the time of our searches.

10. Notably, we do not argue that these search queries represent all that FL&P encompasses. The field is far too diverse for any one set of searches to do so, which makes it challenging to formulate a set of searches guaranteed to encompass the whole field.

Figure 1. Average annual number of articles in HeinOnline containing the terms “FDA” and “farm subsidies.”

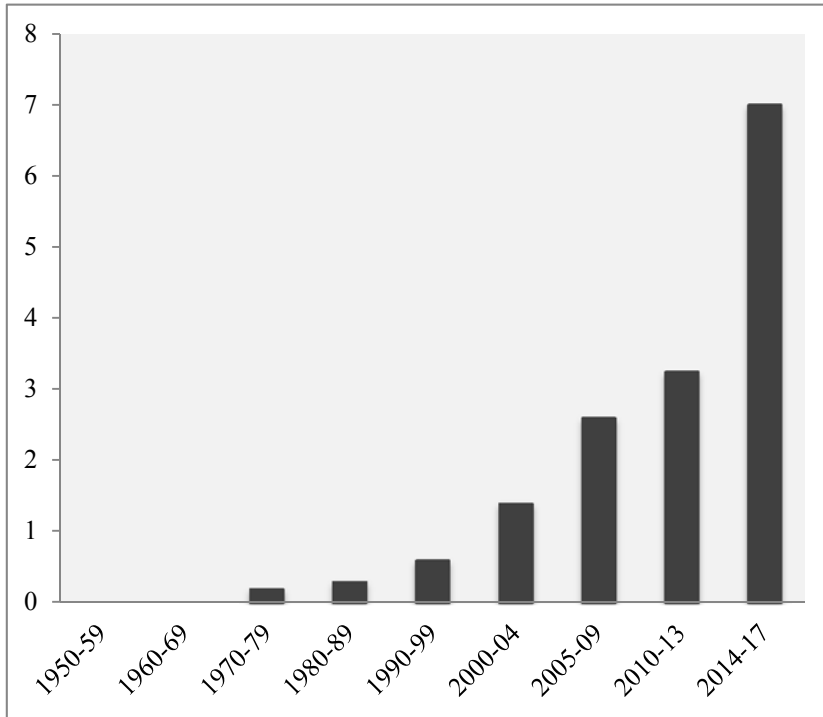


Figure 2. Average annual number of articles in HeinOnline containing the terms “Agricultural Law” and “FDA.”

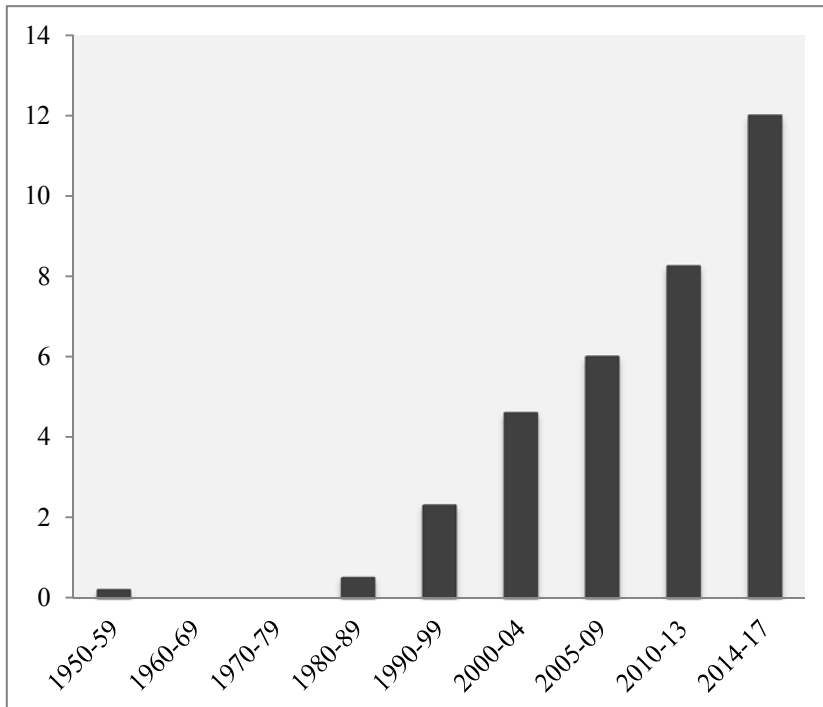


Figure 3. Average annual number of articles in HeinOnline containing the terms “USDA” and “FDA.”

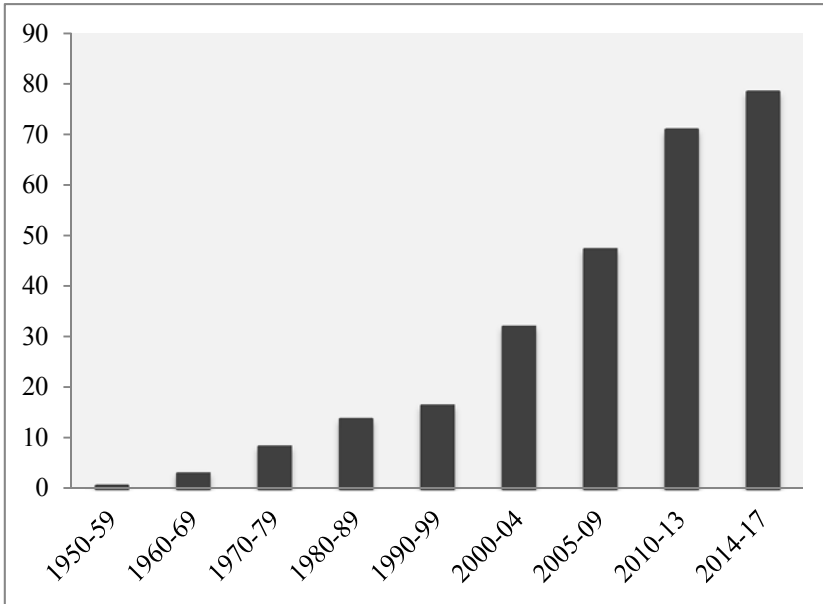
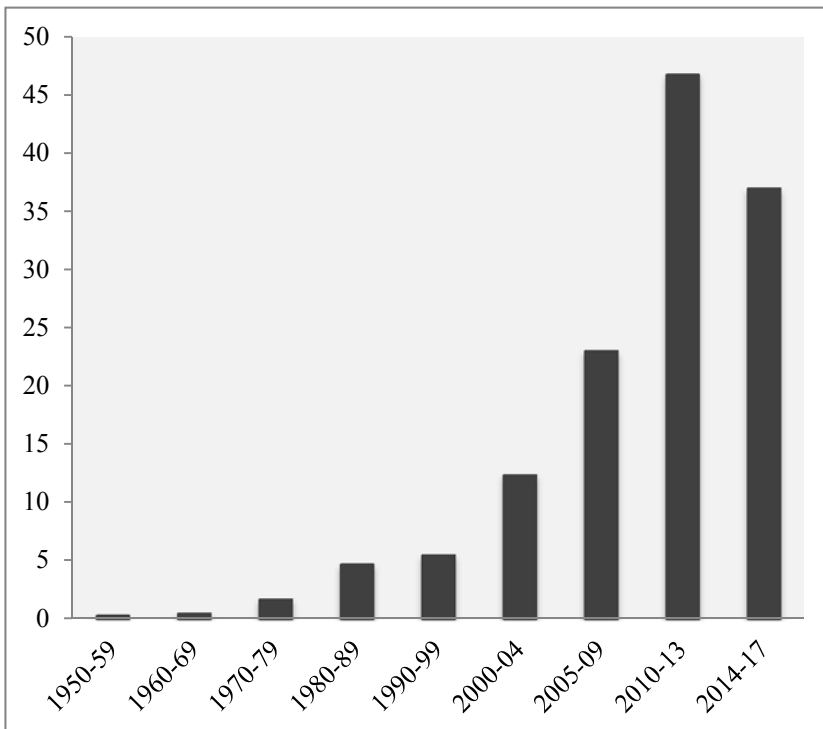


Figure 4. Average annual number of articles in HeinOnline containing the term “food policy.”



Though the rate of growth in law journal articles featuring the term “food policy” decreased greatly from 2014–17, we speculate that this is likely due to the concurrent growth in use of the term “food law and policy” by FL&P scholars, as highlighted below.

The ten new searches that we added and included in our current research are:

- “food law and policy” (or “food law & policy”);
- “food system” (or “food systems”)¹¹
- “food justice;”
- “food access;”
- “food” within five words of “sustainable” (or
- “sustainability”);¹²
- “food sovereignty;”¹³
- “food security;”
- “soda tax” (or “soda taxes”);
- “food waste;” and
- “urban agriculture.”¹⁴

Comparing our search results from 2010–13 with the data we collected for this present article (2014–17), we found tremendous growth, both in terms of the number of articles published and the rate of growth of publications featuring these terms. The search phrases that yielded the greatest total number of articles published during 2014–17—notably, each a new search term—are:

- “food security” (441 articles)
- “food” within five words of “sustainable” or “sustainability” (204 articles);

11. The search query was: “food system,*” in which “*” functions as a wildcard for any one or more characters in HeinOnline searches. With respect to substance, as discussed in the 2014 article, we chose to title the emerging field “Food Law & Policy,” but others have used other names, such as “Food Systems Law,” to refer to the same phenomenon. See Linnekin & Broad Leib, *supra* note 1, at 560 n. 9. The term “food system” encompasses the relationships among each of the nodes in the food chain, including “production, processing, distribution, consumption, and waste management.” *Id.* at 584 n. 252 (citing Kameshwari Pothukuchi & Jerome L. Kaufman, *The Food System: A Stranger to the Planning Field*, 66 J. AM. PLAN. ASS’N 113, 113 (2000)).

12. The search query was: “(“food sustainable” ~5) OR (“food sustainability” ~5)”. “~5” returns results in which the two terms appear within five words of one another.

13. The search query was: (“food sovereignty” ~5). See *infra* note 12 for a description of how “~5” functions.

14. The search query was: “urban agriculture.” See *supra* note 11 for a description of how “*” functions as a wildcard operator.

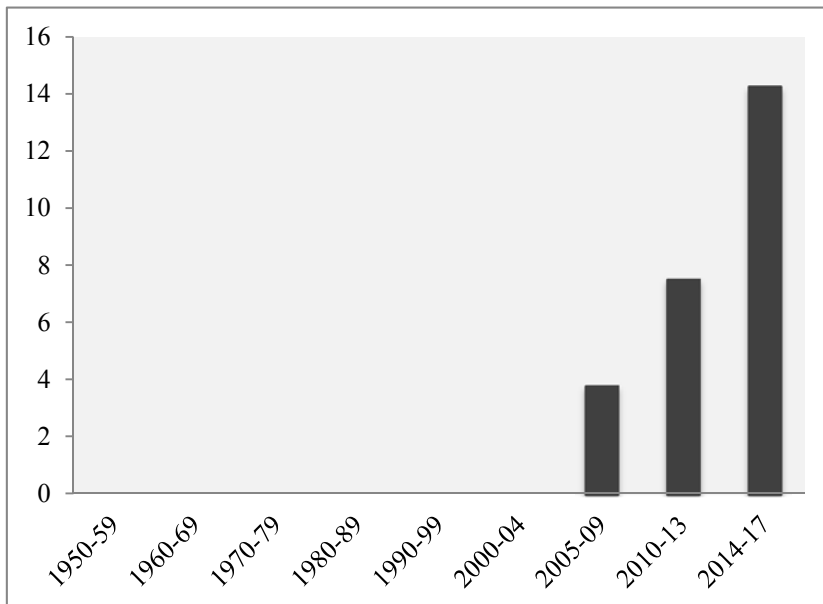
- “urban agriculture” (79 articles)
- “food system” (or “food systems”) (79 articles);
- “food justice” (68 articles); and
- “food law and policy” (or “food law & policy”) (57 articles).

In terms of rate of growth from 2010–13 to 2014–17, the search phrases with the greatest percentage increase are:

- FDA and “farm subsidies” (115.4% increase);
- “food justice” (112.5% increase); and
- “food law and policy” (or “food law & policy”) (90.0% increase).

Notably, as can be seen in Figure 5, the search term “food law and policy” does not appear in even one article published prior to 2005. Since that time, use of the term has grown steadily in each subsequent period. Overall, our data indicate more articles featuring the term “food law and policy” were published between 2014–17 than were published during the previous sixty-four years combined. This fact bolsters not just the conclusion we reached in our earlier article that FL&P’s birth as a field can be traced to the mid-2000s, but also that the field has experienced rapid growth since its birth.

Figure 5. Average annual number of articles in HeinOnline containing the term “food law and policy.”



The figures below show the results for each of these respective new search terms (save for “food law and policy,” which we presented above).

Figure 6. Average annual number of articles in HeinOnline containing the terms “food system” or “food systems.”

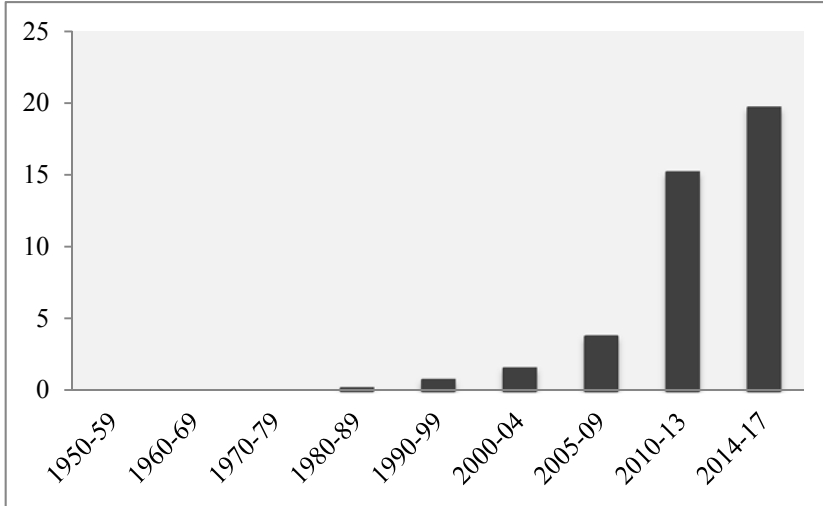


Figure 7. Average annual number of articles in HeinOnline containing the term “food justice.”

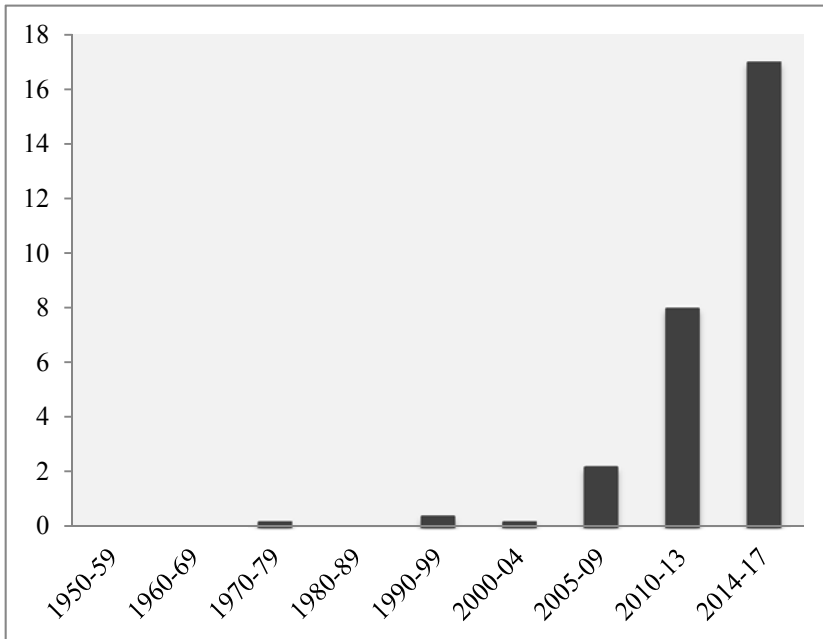


Figure 8. Average annual number of articles in HeinOnline containing the term “food access.”

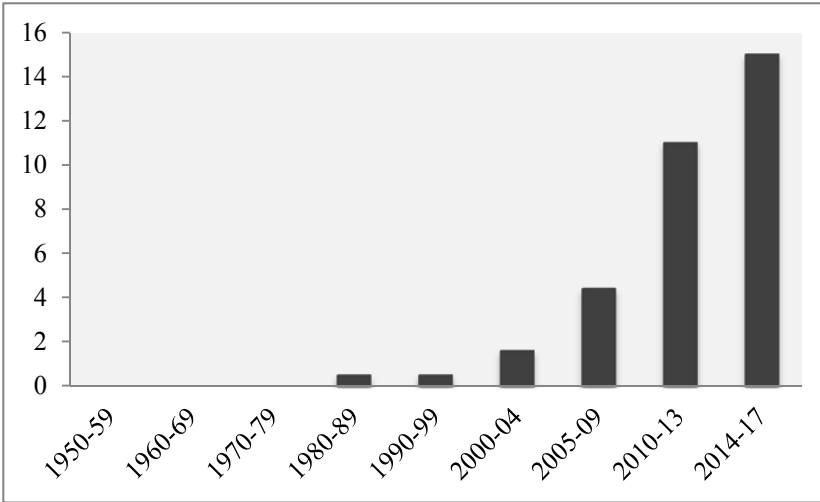


Figure 9. Average annual number of articles in HeinOnline containing the term “food” within five words of “sustainable” (or variations on it, such as “sustainability.”)

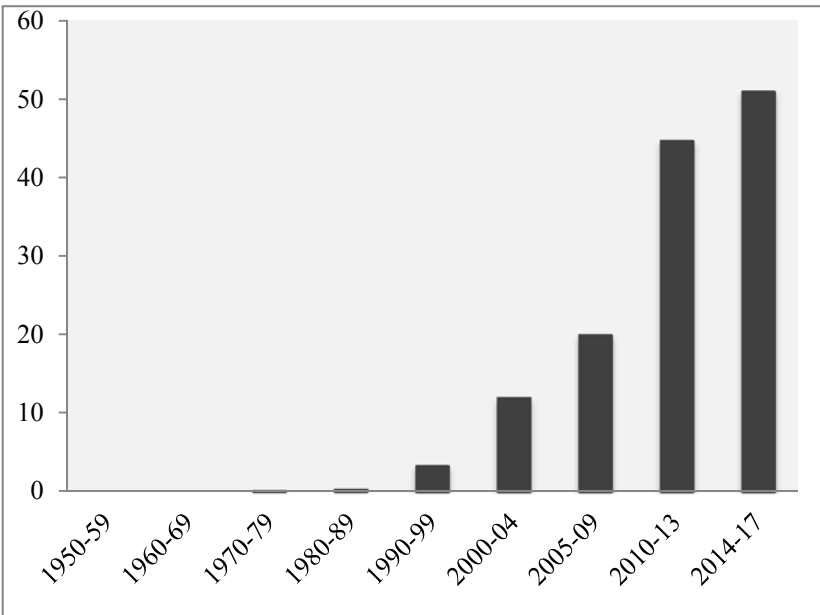


Figure 10. Average annual number of articles in HeinOnline containing the term “food sovereignty.”

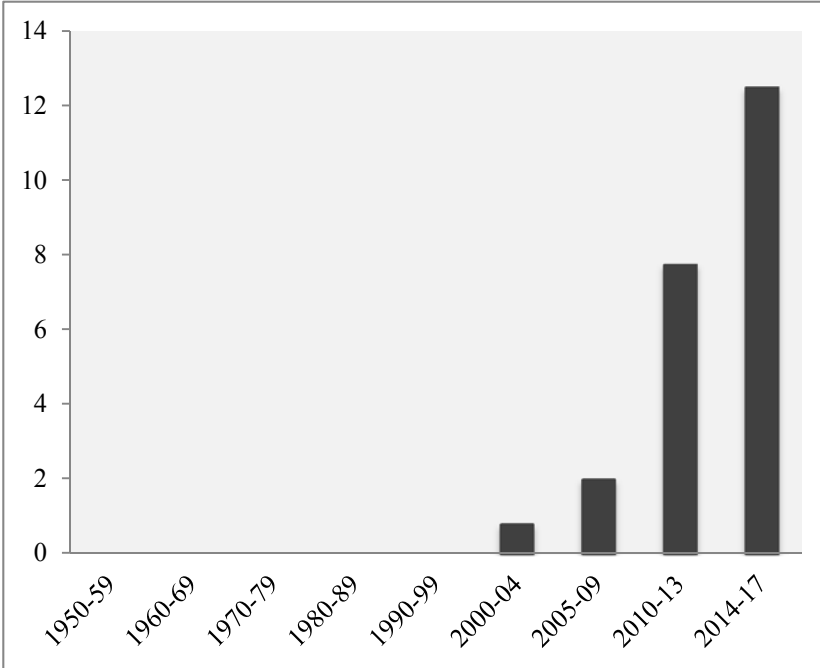


Figure 11. Average annual number of articles in HeinOnline containing the terms “soda tax” or “soda taxes.”

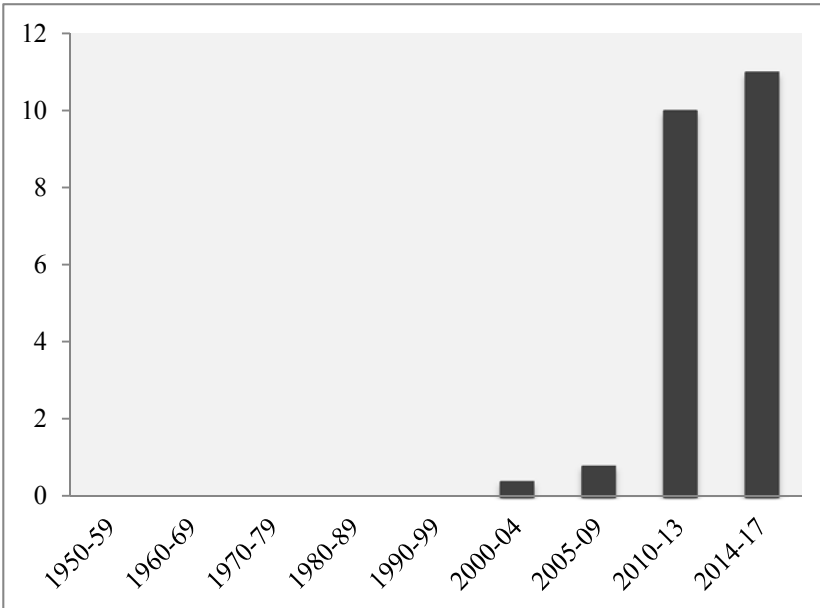


Figure 12. Average annual number of articles in HeinOnline containing the term “food waste.”

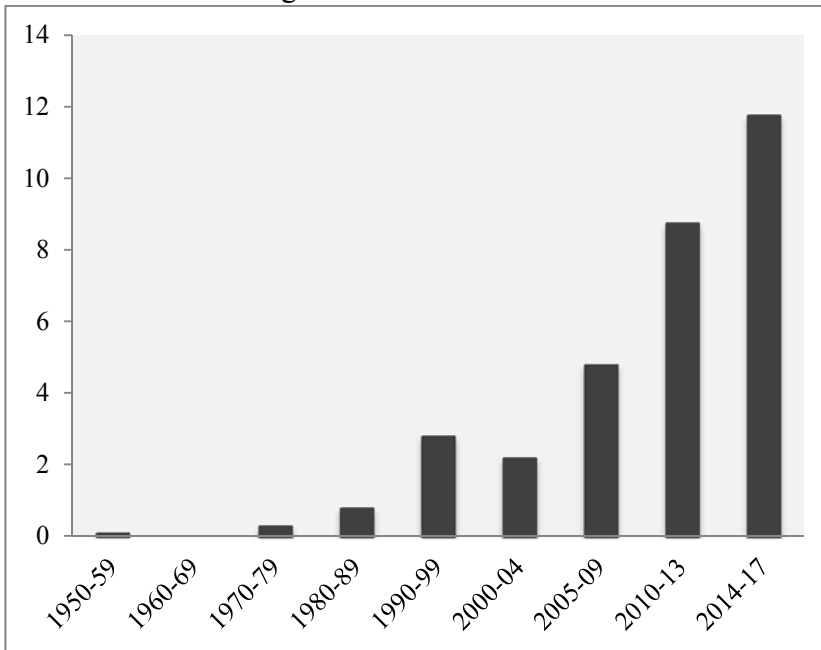
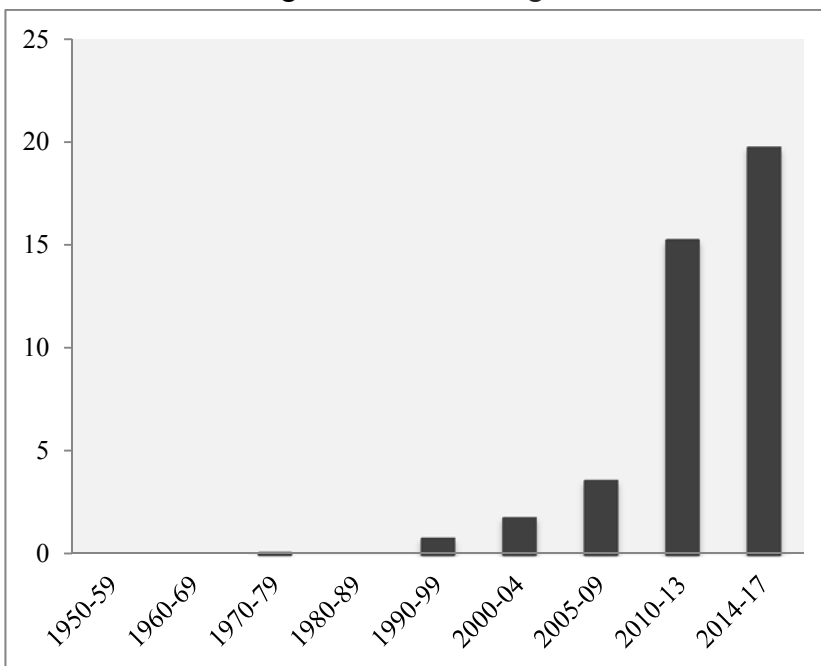
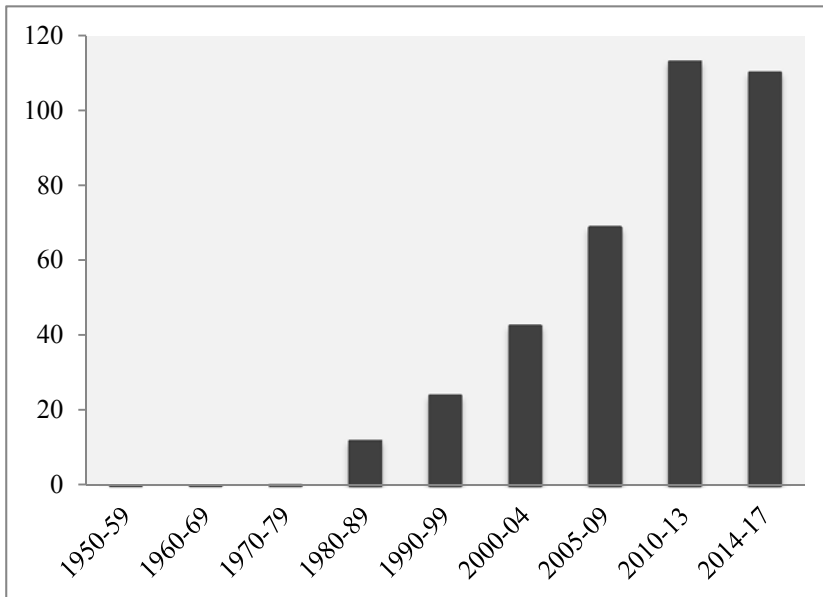


Figure 13. Average annual number of articles in HeinOnline containing the term “urban agriculture.”



Of our ten new search terms, only “food security,” presented in Figure 14 below, saw a decrease (-2.6%) in the total number of articles published between 2010–13 and 2014–17. We theorize this is likely due to the great number of articles on the topic. For example, our data show more than 450 articles published on food security between 2010–13, and nearly 450 articles on the topic between 2014–17. Compare that figure to the 688 total articles published across all of the other nine new FL&P search terms we employed—while also considering the fact that there were nearly 250 articles on “food security” published in the 1990s, even before the birth of the field of FL&P—and it seems apparent that “food security” is a robust area of scholarship that predates the birth of FL&P, while scholarship centering on each our other nine new search terms (e.g., “food sovereignty”) is still in its early days.

Figure 14. Average annual number of articles in HeinOnline containing the term “food security.”



While “food security” numbers decreased slightly—likely for the reasons we state above—a more noteworthy finding from our research is that the rate of increase in many areas of FL&P scholarship slowed between 2014–17. For example, while

articles that focused on “soda taxes” grew by more than 1,000 percent from 2010–13, they grew by only ten percent during the current four-year period. Articles that focused on “FDA” and “USDA” grew by 49.8 percent from 2010–13, but only by 10.6 percent from 2014–17. Articles featuring the term “food system” grew by more than 300 percent during the period 2010–13, but only by slightly less than thirty percent during 2014–17.

This slowing rate of growth, considered in a vacuum, could be misleading. Consider, for example, that even though the growth rate of “food system” articles slowed, there were more articles published containing the search term during 2014–17 (79) than there were during the period 2010–13 (61), even though the *rate* of growth during the former period was far greater than during the latter one. The same is true of articles containing the terms “FDA” and “USDA,” which saw more publications between 2014–17 (314) than during the 2010–13 period (284), even though the rate of growth of scholarship including both “FDA” and “USDA” slowed during the same period.

Why is there a discrepancy between numeric rates of growth and percentage rates of growth? Given the consistent increase in the *number* of FL&P publications across thirteen of our fourteen search areas—with “food security” serving as the exception—rather than evincing a slowing interest in FL&P scholarship, the slowing *rate* of growth of FL&P publications demonstrates that it is a stable and maturing field.¹⁵ As more scholars continue to work and write in the field, we predict we will continue to see growth in the overall number of results within each search, and that the rate of increase in certain FL&P scholarship terms will likely spike again at some future point.

As we look toward that future, prospective FL&P research could benefit from improvements upon methodology and more refined searches, including the use of more complex computational search techniques. Since today’s law students are the FL&P scholars of tomorrow, future research might gather data on and study student FL&P-focused law-journal notes and

15. A population grows when its numbers increase. But in most cases the *rate* of growth slows over time. For example, an increase from “1” to “2” represents a 100-percent increase, while the increase from “2” to “3” is only a fifty-percent increase. Furthermore, the increase from “100” to “101” is only a one-percent increase.

comments. Additionally, future research could assess rates and numbers of citations to FL&P articles over time to assess the strength and connectedness of the field. Finally, future scholars might seek to identify the number of unique articles included in the results of all search phrases or subsets of search phrases.¹⁶ Doing so could provide scholars with greater insight into the characteristics of FL&P articles—including the overlap between articles that mention two or more sets of FL&P issues—and could help scholars, including us, to better track the overall number of articles in the field.

II. Law School Courses

Food Law & Policy courses have proliferated among the top law schools over the past four years. In the 2014 article, we found that twenty of the 2013 top 100 law schools had offered FL&P courses at some point between Fall 2010 and Spring 2014. Since then, from Fall 2014 through Spring 2018, these same 100 schools have offered thirty-four FL&P courses, an increase of more than 150 percent, while the number of FDA Law and Ag Law courses have held approximately stable.

	FL&P	FDA Law	Ag Law
2010–2013	20	41	16
2014–2017	34	40	13

The stability of the number of FDA Law courses masks some turnover among the schools offering those courses. Fordham University School of Law, Louisiana State University Law Center, and University of Wisconsin Law School, for instance, have not again offered the FDA Law courses in this time period. On the other hand, some schools that had ceased offering FDA Law courses prior to 2014 have begun to offer them again: the University of Kansas School of Law stopped offering FDA Law courses in 2009, for instance, but will again offer the course in the 2017–18 academic year.

16. We obtained scholarship data we use in this article from fourteen separate searches. While we believe it is likely that some articles appear in more than one (or perhaps several) of these searches, such research is beyond the scope of this article.

Ag Law has also seen turnover among the offering schools. While NYU no longer offers a course in “Farmed Animal Law & Policy,” for instance, Harvard does. UCLA, too, no longer offers “Animals in Agriculture and the Law,” but Georgetown has added a seminar in “Farm Law and Policy.”

The table below lists the thirty-four top U.S. law schools that offered an FL&P course at least once during the 2014–18 academic years. Notably, several schools offered more than one such course during the relevant period; such schools are marked with a dagger in the table below. Schools that did not offer an FL&P course in the 2013 data but offer one now are marked with an asterisk.

Yale University*†	Harvard University†	Stanford University*
Columbia University*	New York University*†	University of California-Berkeley†
Duke University	Northwestern University*†	Cornell University*
Georgetown University†	Vanderbilt University*	University of California-Los Angeles†
Boston College*	University of Wisconsin†	Wake Forest University*†
University of California-Davis†	George Mason University*	University of Maryland*
University of Colorado–Boulder	Florida State University*	University of California-Hastings*
University of Connecticut*	University of Denver*	Illinois Institute of Technology - Chicago-Kent†
University of Arkansas–Fayetteville†	University of Miami	University of Missouri
Brooklyn Law School*	Lewis and Clark College	Michigan State University†
University of Kansas*	West Virginia University	University of Oregon
University of South Carolina*		

FL&P courses at these law schools generally focus on food laws and policies at all levels of government, looking at federal food safety regulation and agricultural subsidies, efforts by food policy councils to support local food systems, and policy approaches aiming to address diet-related disease or reduce food waste. For example, the first FL&P course at Cornell Law School, “Law and the Policy of Food Systems,” covers topics ranging from production to distribution to consumption, and helps students understand “the specialized language of farmers and food policy specialists and advocates [to better tackle] the difficult technical and policy issues facing food systems today.”¹⁷ Northwestern University’s new “Food Law and Policy Seminar” examines “the local, state, and federal regulation of food, and sample policy topics from among the broad array of health, environmental, social, and cultural issues involving the contemporary food system.”¹⁸

More than a dozen of the schools now offer multiple FL&P courses, which explore more specific or more general topics within the field. Notably, the University of Arkansas–Fayetteville offers more than a dozen FL&P courses, including “Food Law & Policy;” “Federal Nutrition Law & Policy;” “Food Justice: Law & Policy;” “Urban Agriculture: Law & Policy;” and “Agricultural Cooperatives and Local Food Systems,” among many others and a full Agricultural and Food Law LL.M. program, described below. Harvard offered three courses: “Food Law and Policy;” “Law, Development and Global Food Policy;” and the “Food Law Lab” seminar. UCLA offered four courses: “Introduction to Food Law and Policy;” “City Food Policy: Legislation & Advocacy;” “Companies, Food Systems, and Public Health;” and “Rights to Food and Global Food Justice.” University of California-Davis also offered four FL&P courses: “Food and Agricultural Law;” “Food Justice;” “Law and Culture of Food;” and “Wine and the Law.”

17. *Engaged Curriculum Grant: Law and Policy of Food Systems*, CORNELL L. SCH., <http://engaged.cornell.edu/recipient/law-and-policy-of-food-systems/> (last visited Aug. 31, 2017).

18. *Food Law and Policy Seminar*, NORTHWESTERN PRITZKER SCH. OF L., <http://www.law.northwestern.edu/academics/curricular-offerings/coursecatalog/details.cfm?CourseID=1663> (last visited Nov. 11, 2017).

Several schools not among the 2013 top 100 schools list provided notable FL&P course offerings since 2014, as well. Vermont Law School, the number one ranked Environmental Law program in 2017,¹⁹ offers an array of FL&P courses along with its degree and certificate programs (described below). Its courses include “Federal Regulation of Food Safety;” “Food System Justice and Sustainability;” “The Farm Bill;” “Public Health Implications of US Agriculture and Policy;” and “Global Food Security.” Elisabeth Haub School of Law, too, offers courses in “Food & Agriculture Law;” “Food Systems Law;” and “Agriculture Law & the Environment;” and also launched a food law program and clinic. Drake University Law School has expanded its strong agricultural law program into the FL&P space, too, and offers courses including “Food and the Law;” “Current Issues in Food & Agricultural Law;” “Environmental Regulation of Agriculture;” and “Sustainability and the Law.”

III. Degree Programs

The last four years have seen the maturing of existing degree programs into dedicated FL&P programs, alongside the launch of new FL&P degree programs. We wrote in 2014 that no such programs were in existence at that time.²⁰ Before 2014, University of Arkansas and Drake Law School were each home to degree programs historically grounded in Ag Law but which also engaged with FL&P issues.²¹ In particular, the University of Arkansas changed the name of its Master of Laws program in 2009 from an LL.M. in Agricultural Law to an LL.M. in Agricultural *and Food* Law.²² While the program began to slowly increase its FL&P course offerings prior to 2014, the years from 2014 to present have evidenced its strong commitment to FL&P, including dozens of new FL&P courses

19. *Best Environmental Law Programs 2017*, U.S. NEWS AND WORLD REPORT, <https://www.usnews.com/best-graduate-schools/top-law-schools/environmental-law-rankings> (last visited Nov. 11, 2017).

20. See Linnekin & Broad Leib, *supra* note 1, at 601.

21. See *id.* at 602-03.

22. See *id.* at 602 (citing *History of the LL.M. Program*, U. ARK. SCH. L., <http://law.ark.edu/academics/llm/history-of-the-ll-m-program/> (last visited Dec. 17, 2013)) (emphasis added).

and new practicum placements with FL&P organizations.²³ Drake Law School's Agricultural Law Center has also increased FL&P course offerings available to students through its Food and Agricultural Law Certificate Program.²⁴

In 2014, Vermont Law School's Center for Agriculture and Food Systems²⁵ established two dedicated degree programs and a certificate program in Food & Agriculture Law.²⁶ The Master of Food and Agriculture Law and Policy ("MFALP") program is offered as both a standalone degree program and a dual-degree option for law students. The program provides students with an opportunity to participate in summer courses with practicing lawyers and national experts in various areas of law and policy, in addition to academic year FL&P courses and the Food and Agriculture Clinic at Vermont Law School.²⁷ Along with the MFALP program, Vermont Law School offers an LL.M. program both on-campus and online in Food & Agriculture Law,²⁸ and enables law students to obtain a certificate in Food and Agriculture Law.²⁹

Other degree and certificate programs are grounded in Food and Drug Law or related areas of the regulation of food, which overlap with FL&P. Georgetown University Law Center offers LL.M. students the opportunity to obtain a certificate in Food and Drug Law.³⁰ Michigan State University's Institute for Food Laws and Regulations runs an online LL.M. program in Global

23. *Food and Agricultural Law Courses*, UNIV. OF ARKANSAS SCH. OF L., <https://law.uark.edu/academics/llm-food-ag/llm-courses.php> (last visited Nov. 11, 2017).

24. *Food and Agricultural Law Certificate Program*, DRAKE L. SCH., <http://www.drake.edu/law/students/academics/certificate/food-ag/> (last visited Nov. 11, 2017).

25. See *infra* "Academic Centers."

26. VERMONT L. SCH., THE CTR. FOR AGRIC. AND FOOD SYSTEMS: THE FIRST THREE YEARS 6 (2015), https://www.vermontlaw.edu/sites/default/files/Assets/cafs/CAFS_First3Years_REV.pdf.

27. *Master of Food and Agriculture Law and Policy (MFALP)*, VT. L. SCH., [https://www.vermontlaw.edu/academics/degrees/masters/master-of-food-and-agriculture-law-and-policy-\(mfalp\)](https://www.vermontlaw.edu/academics/degrees/masters/master-of-food-and-agriculture-law-and-policy-(mfalp)) (last visited Aug. 29, 2017).

28. See *LLM Programs*, VT. L. SCH., <https://www.vermontlaw.edu/academics/degrees/llm> (last visited Aug. 29, 2017).

29. See *Certificate in Food and Agriculture Law*, VT. L. SCH., <https://www.vermontlaw.edu/academics/certificates/certificate-in-food-and-agriculture-law> (last visited Nov. 11, 2017).

30. See *Food and Drug Law*, GEORGETOWN UNIV. L. CTR., <https://www.law.georgetown.edu/academics/academic-programs/graduate-programs/certificate-programs/food-and-drug-law.cfm> (last visited Aug. 29, 2017).

Food Law, with a curriculum focused on the global context and on regulatory frameworks governing food production, marketing, labeling, and Food and Drug Law.³¹ The Institute also offers a Certificate in International Food Law and a Certificate in United States Food Law.³²

IV. Academic Centers

In 2014, noting the recent launches of UCLA's Resnick Program for Food Law and Policy, Vermont Law School's Center for Agriculture and Food Systems, and Harvard's Food Law Lab, we predicted "a proliferation of similar FL&P-focused centers."³³ Though FL&P-focused academic centers have not increased at a comparable rate to FL&P courses offered around the country, several new centers have been established. For example, the Elisabeth Haub School of Law at Pace University's Pace-NRDC Food Law Initiative was established in 2015 "to address the direct legal service needs of food justice organizations, farmers, and food entrepreneurs" through education of law students and lawyers.³⁴

The following list highlights four FL&P-focused academic centers among the top 100 law schools. Several other schools also host relevant academic centers, including Drake Law School's Agricultural Law Center,³⁵ Michigan State University's Institute for Food Laws and Regulations,³⁶ and Howard University's World Food Law Institute.³⁷

31. See *The Curriculum*, MICH. ST. UNIV. SCH. L., <http://www.law.msu.edu/llm/globalfoodlaw/curriculum.html> (last visited Aug. 29, 2017).

32. *Institute for Food Laws and Regulations: Certificate Programs*, MICHIGAN STATE UNIV., <http://www.canr.msu.edu/iflr/certificate-programs/> (last visited Nov. 11, 2017).

33. Linnekin & Broad Leib, *supra* note 1, at 603.

34. See *Pace-NRDC Food Law Initiative*, ELISABETH HAUB SCH. L. AT PACE UNIV., <http://law.pace.edu/pace-nrdc-food-law-initiative> (last visited Aug. 27, 2017).

35. *Agricultural Law Center*, DRAKE UNIV., <http://www.drake.edu/law/clinics-centers/aglaw/> (last visited Aug. 27, 2017).

36. *Institute for Food Laws and Regulations*, MICHIGAN STATE UNIV., <http://www.canr.msu.edu/iflr/> (last visited Nov. 11, 2017).

37. *World Food Law Institute*, HOWARD UNIV. SCH. L., <http://law.howard.edu/content/world-food-law-institute> (last visited Aug. 27, 2017).

Law School	Academic Center
Harvard University	Food Law Lab (est. 2013)
University of California-Los Angeles	Resnick Program for Food Law & Policy (est. 2013)
Vermont Law School	Center for Agriculture and Food Systems (est. 2012)
Elisabeth Haub School of Law at Pace University	Pace-NRDC Food Law Initiative (est. 2015)

V. Casebooks & Other Texts

As of early 2014, we noted that the first true FL&P text had yet to be written. Relevant works that had by then been published focused primarily on either FDA Law or Ag Law, though these works did touch on FL&P issues.³⁸ The authors of some of those works have been instrumental to developing the field of FL&P. Now, the field can count several dedicated casebooks and texts published or under development that engage with a broad cross-section of FL&P issues.

In 2014, Lisa Heinzerling of Georgetown University Law Center published the first dedicated FL&P casebook, *Food Law: Cases and Materials*.³⁹ In 2016, Michael T. Roberts of UCLA's Resnick Program on Food Law & Policy published the field's first treatise, *Food Law in the United States*, which "lays out the national legal framework for the regulation of food and the legal tools that fill gaps in this framework, including litigation, state law, and private standards [and addresses] topics including commerce, food safety, marketing, nutrition, and emerging food-systems issues such as local food, sustainability, security, urban agriculture, and equity[.]"⁴⁰ University of Arkansas

38. See Linnekin & Broad Leib, *supra* note 1, at 603-04.

39. See *Food Law: Cases and Materials*, LULU, <http://www.lulu.com/us/en/shop/lisa-heinzerling/food-law-cases-and-materials/paperback/product-22283467.html> (last visited Oct. 14, 2017).

40. *Food Law in the United States*, UCLA LAW SCH., <https://law.ucla.edu/centers/social-policy/resnick-program-for-food-law-and-policy/publications/food-law-in-the-united>

Professor Susan Schneider's text *Food, Farming, and Sustainability: Readings in Agricultural Law*, first published in 2011, included several FL&P issues within its Agricultural Law focus, and the second edition in 2016 provided expanded integration of FL&P issues.⁴¹ 2016 also saw the release of the second edition of Michigan State University Professor Neil Fortin's text *Food Regulation* (originally published in 2008). The text focuses mostly on FDA Law as it pertains to food, but the second edition appears more oriented toward a broader set of FL&P issues, as it addresses new "policy questions[] and emerging issues."⁴²

UCLA's Roberts, along with Jacob Gersen of Harvard Law School and Margot Pollans of the Pace University Elizabeth Haub Law School, is currently developing a FL&P casebook,⁴³ as is University of Arkansas's Susan Schneider.⁴⁴ Finally, outside of the U.S. at least seven texts that address FL&P issues in the European and international contexts have been published since 2014.⁴⁵

VI. Dedicated Legal Journals

-states/ (last visited Aug. 28, 2017); see also MICHAEL T. ROBERTS, *FOOD LAW IN THE UNITED STATES* i (2017).

41. See SUSAN A. SCHNEIDER, *FOOD FARMING AND SUSTAINABILITY: READINGS IN AGRIC. L.*, (California Press 2d ed. 2016).

42. See generally NEIL FORTIN, *FOOD REGULATION: LAW, SCIENCE, POLICY, AND PRACTICE* (Wiley 2d ed. 2016).

43. See Michael T. Roberts, UCLA LAW SCH., <https://www.law.ucla.edu/faculty/faculty-profiles/michael-t-roberts/#/> (last visited Aug. 28, 2017); see Jacob Gersen, HARV. L. SCH., <https://hls.harvard.edu/faculty/directory/10302/Gersen/> (last visited Aug. 30, 2017); see Margot J. Pollans, ELISABETH HAUB SCH. L. AT PACE UNIV., <http://www.law.pace.edu/faculty/margot-j-pollans> (last visited Oct. 18, 2017).

44. Email from Susan A. Schneider, Professor, Univ. of Arkansas School of Law, to Emily Broad Leib & Baylen Linnekin (Nov. 7, 2017) (on file with authors).

45. See RETHINKING FOOD SYSTEMS: STRUCTURAL CHALLENGES, NEW STRATEGIES, & THE LAW (Nadia C.S. Lambek et al. eds., 2014); see EU FOOD LAW HANDBOOK (Bernd van der Meulen ed., 2d ed. 2014); see FOUNDATIONS OF EU FOOD LAW & POLICY: FOUNDATIONS OF THE EUROPEAN FOOD SAFETY AUTHORITY (Alberto Alemanno & Simone Gabbi eds., 2014); see VICENTE RODRIGUEZ FUENTES, FROM AGRICULTURAL TO FOOD LAW: THE NEW SCENARIO (2014); CAOIMHÍN MACMAOLÁIN, *FOOD LAW: EUROPEAN, DOMESTIC AND INTERNATIONAL FRAMEWORKS* (2015); see INTERNATIONAL FOOD LAW AND POLICY (Gabriela Steier & Kiran Patel, eds., 2016); see EUROPEAN AND GLOBAL FOOD LAW (Luigi Costato & Ferdinando Albisinni eds., 2d ed. 2016).

As in 2014, the field of FL&P has one dedicated legal journal, the *Journal of Food Law & Policy*, hosted at the University of Arkansas School of Law.⁴⁶ FDA Law, too, has one dedicated journal, the *Food and Drug Law Journal*, published by the Food and Drug Law Institute and Georgetown University Law Center.⁴⁷ In recent years, the *Food and Drug Law Journal* has begun to publish more FL&P articles.⁴⁸ Agricultural Law, meanwhile, continues to have multiple legal journals focused on the field: *Drake Journal of Agricultural Law*,⁴⁹ *San Joaquin Agricultural Law Review*,⁵⁰ and *Kentucky Journal of Equine, Agriculture, & Natural Resources Law*;⁵¹ all of these journals also publish FL&P articles in addition to their traditional agricultural law content.⁵²

VII. Clinical/Experiential Education

Clinical and experiential education in FL&P has grown tremendously over the past four years. The number of dedicated FL&P clinics has increased, and we have seen a doubling in the number of clinics in other domains that work on, or have worked on, projects implicating FL&P issues.

In early 2014, only one dedicated FL&P clinic existed: the Food Law and Policy Clinic at Harvard Law School,⁵³ which “provides legal and policy guidance to a range of clients seeking to increase access to healthy foods, assist small and sustainable

46. *Journal of Food Law & Policy*, UNIV. ARK. SCH. L., <https://law.uark.edu/academics/journals/journal-food-law-policy.php> (last visited Aug. 27, 2017).

47. *Food and Drug Law Journal*, FOOD & DRUG L. INST., <https://www.fldi.org/resources/food-drug-law-journal/> (last visited Aug. 27, 2017).

48. See, e.g., Laurie Beyranevand & Emily Broad Leib, *Making the Case for a National Food Strategy in the United States*, 72 FOOD & DRUG L. J. 225 (2017); Melanie Pugh, *A Recipe for Justice: Support for a Federal Food Justice Interagency Working Group*, 72 FOOD & DRUG L. J. 341 (2017).

49. *Drake Journal of Agricultural Law*, DRAKE J. AGRIC. L., <https://aglawjournal.wp.drake.edu/> (last visited Aug. 27, 2017).

50. *San Joaquin Agricultural Law Review*, SAN JOAQUIN C. L., <http://www.sjcl.edu/index.php/sjalr> (last visited Aug. 27, 2017).

51. *Kentucky Journal of Equine, Agriculture, & Natural Resources Law*, KY. J. EQUINE, AGRIC., & NAT. RES. L., <http://www.kjeanrl.com/> (last visited Aug. 27, 2017).

52. See, e.g., Nicole M. Civita, *2012 Developments in Food Law & Policy*, 18 DRAKE J. AGRIC. L. & POL'Y 39 (2012); Comment, Carmen Kalashian, *Out of Sight, Out of Mind: Finding a Solution to Food Waste in America*, 23 SAN JOAQUIN AGRIC. L. REV. 103 (2014).

53. Linnekin & Broad Leib, *supra* note 1, at 605.

farmers in breaking into new commercial markets, and reduce waste of healthy, wholesome food.”⁵⁴ Since then, FL&P clinics have been established at the Pace University’s Elisabeth Haub School of Law, UCLA Law School, and Vermont Law School. The Food and Beverage Law Clinic at Pace University offers “transactional legal services” to various types of clients, including “small- and medium-sized farmers implementing innovative and sustainable farming practices, mission-oriented food entrepreneurs, and food justice nonprofit organizations.”⁵⁵ At the Food Law and Policy Clinic at UCLA Law School, students engage with multiple “policy advocacy strategies,” including working with food system stakeholders to develop policy initiatives, educating food innovators about law and policy, and promoting food equity via social change campaigns and legal needs assessments.⁵⁶ The Food and Agriculture Clinic at Vermont Law School similarly targets a broad range of clients in the food system, though sustainable food production and equitable access are particular areas of emphasis. The Clinic “focus[es] on creating legal resources that are meant to put the law in the hands of food system constituencies (farmers, laborers, food entrepreneurs, consumers, legislators, advocates, etc.) so that they may achieve their law, policy and business goals” on a range of issues, from launching farm-to-school initiatives to developing sustainable food and farm businesses.⁵⁷ In addition, beginning in the 2017–18 academic year, Yale Law School has hired a Farm and Food Legal Fellow to work at the intersection of its Environmental Protection and Community and Economic Development clinics.⁵⁸

Further, the number of clinics in other areas of the law that are taking on projects that implicate FL&P issues has more than

54. *Food Law and Policy Clinic*, CTR. FOR HEALTH L. AND POL. INNOVATION, HARV. L. SCH., <https://www.chlpi.org/food-law-and-policy/about/> (last visited Nov. 11, 2017).

55. *Food and Beverage Law Clinic*, ELISABETH HAUB SCH. L., <http://law.pace.edu/food-and-beverage-law-clinic> (last visited Aug. 31, 2017).

56. *LAW 775 - Food Law and Policy Clinic*, UCLA LAW SCH., <https://law.ucla.edu/academics/curriculum/course-list/law-775/> (last visited Aug. 31, 2017).

57. *Food and Agriculture Clinic*, VT. L. SCH., <https://www.vermontlaw.edu/academics/clinics-and-externships/food-and-agriculture-clinic> (last visited August 31, 2017).

58. Email from Joshua Galperin, Professor, Yale Law School, to Emily Broad Leib, (Oct. 17, 2017) (on file with the authors).

doubled. The research we conducted for the 2014 article found that 30 different clinics at 23 of the top 100 law schools either were working on or had worked on at least one project with a connection to FL&P issues.⁵⁹ As of the time of this writing, these numbers have grown to 69 clinics at 48 of those 100 schools. Some of these clinics have increased the number of projects they undertake that are pertinent to FL&P. For example, one clinic highlighted in the 2014 article was the Harrison Institute for Public Law at Georgetown Law. Prior to 2014, the Harrison Institute had engaged in a project related to improving school meals.⁶⁰ That project continues, and has broadened to include efforts change how both school districts, and hospital systems, conduct food procurement.⁶¹ Additionally, during the last four years the Harrison Institute clinic added a food and sustainability project to its roster.⁶²

Of the nearly seventy clinics now working on FL&P projects, many engage in projects focused on the intersection of food and Environmental Law, such as the environmental law clinics at Yale Law School, Emory Law School, Washington University in St. Louis, and University of Connecticut.⁶³ Others clinics engage in projects focused on economic opportunities for farmers and food producers in both rural and urban settings, such as community economic development clinics at University of Michigan, University of California-Berkeley, University of Chicago, Stanford University, Yale University, University of Colorado-Boulder, University of Maryland, and Penn State Law.⁶⁴ The Organizations and Transactions Clinic at Stanford

59. See Linnekin & Broad Leib, *supra* note 1, at 605.

60. See *id.* at 606-07.

61. *Health and Food Policy*, GEORGETOWN L. SCH., <https://www.law.georgetown.edu/academics/academic-programs/clinical-programs/our-clinics/HIP/health-food-work.cfm> (last visited Aug. 31, 2017).

62. See *id.*

63. See *Environmental Protection Clinic*, YALE L. SCH., <https://law.yale.edu/studying-law-yale/clinical-and-experiential-learning/our-clinics/environmental-protection-clinic> (last visited Aug. 31, 2017); *Turner Environmental Law Clinic*, EMORY L. SCH., <http://law.emory.edu/academics/clinics/turner-environmental-clinic.html> (last visited Aug. 31, 2017); *Interdisciplinary Environmental Clinic News*, WASHINGTON UNIV. ST. LOUIS L. SCH., <https://law.wustl.edu/intenv/pages.aspx?id=431> (last visited Aug. 31, 2017); *Environmental Law Clinic*, <https://www.law.uconn.edu/academics/clinics-experiential-learning/environmental-law-clinic> (last visited Aug. 31, 2017).

64. *Examples of Our Work*, UNIV. MICHIGAN LAW SCH., <https://www.law.umich.edu/clinical/CEDC/Pages/caseexamples.aspx> (last visited Aug. 31, 2017); *Clinics Help Co-*

Law School, which has a longstanding history of working with food and agricultural clients, recently released a publicly-accessible library of transactional document templates for a variety of food and agriculture nonprofit enterprises, including farmers' markets, gleaning programs, community gardens, and food banks.⁶⁵

VIII. Student Societies

Student-led FL&P societies have continued to emerge since 2013, when we counted fewer than ten such societies in law schools across the country.⁶⁶ Today, at least thirty-three student-led FL&P societies now exist in law schools across the country,⁶⁷ including at Fordham,⁶⁸ Harvard,⁶⁹ Michigan State,⁷⁰ Northeastern,⁷¹ NYU,⁷² Pace,⁷³ UCLA,⁷⁴ Wisconsin,⁷⁵ Vermont,⁷⁶ and Yale.⁷⁷

Ops Set Up Shop, UNIV. OF CALIFORNIA: BERKLEY LAW, <https://www.law.berkeley.edu/article/clinic-helps-co-ops-set-shop/> (last visited Aug. 31, 2017); *IJ Clinic on Entrepreneurship*, INST. FOR JUSTICE, <http://ij.org/ij-clinic-on-entrepreneurship/> (last visited Aug. 31, 2017); *Sustainable Community Development Clinic*, UNIV. OF COLORADO: BOULDER SCHOOL OF LAW, <http://www.colorado.edu/law/academics/clinics/sustainable-community-development-clinic> (last visited Aug. 31, 2017); *About*, UNIV. OF MARYLAND AGRIC. LAW AND EDUCATION INITIATIVE, <http://umaglaw.org/> (last visited Aug. 31, 2017); *Rural Economic Development Clinic*, PENN STATE LAW, <https://pennstatelaw.psu.edu/practice-skills/clinics/rural-economic-development-clinic> (last visited Aug. 31, 2017).

65. *Documents*, NONPROFIT CORPORATIONS: FORM AND SAMPLE DOCUMENTS, <https://nonprofitdocuments.law.stanford.edu/documents/> (last visited Oct. 13, 2017).

66. See Linnekin & Broad Leib, *supra* note 1, at 607-08.

67. This number includes food law societies at both the 100 school cohorts, as well as the other schools examined in our 2017 research.

68. *Farm to Fordham*, FORDHAM U. SCH. L., https://www.fordham.edu/info/24772/student_groups/7753/farm_to_fordham (last visited Aug. 23, 2017).

69. *Harvard Food Law Society*, HARV. L. SCH., <https://orgs.law.harvard.edu/foodlaw/> (last visited Aug. 23, 2017).

70. *Environmental & Agriculture Law Society*, MICH. ST. C. L., <http://www.law.msu.edu/students/student-org-profile.php?id=43> (last visited Aug. 23, 2017); *Food Law Society at MSU*, FACEBOOK, https://www.facebook.com/pg/The-Food-Law-Society-at-MSU-Law-1681300942152620/about/?ref=page_internal (last visited Aug. 23, 2017).

71. *Student Organizations*, NORTHEASTERN. SCH. L., <https://www.northeastern.edu/law/student-life/organizations.html> (last visited Aug. 23, 2017).

72. *Food & Agriculture Law Society*, N.Y.U. SCH. L., <http://www.law.nyu.edu/studentorganizations/foodlaw> (last visited Aug. 23, 2017).

73. *Environmental Student Organizations*, PACE L., <http://www.law.pace.edu/environmental-student-organizations> (last visited Aug. 23, 2017).

74. *The Food Law Society at UCLA*, FOOD L. SOC'Y AT UCLA, <http://foodlawsociety.webs.com/> (last visited Aug. 23, 2017).

Law students have also begun to organize and collaborate across schools. In 2015, Harvard Law School's Food Law and Policy Clinic hosted the first annual Food Law Student Leadership Summit, which featured 100 invited law-student participants representing 50 law schools in 30 states across the country.⁷⁸ Shortly after that three-day event, the Summit's student participants launched the Food Law Student Network to "exchange ideas, knowledge, and practical skills, while building enduring connections among students and professionals" in the growing FL&P field.⁷⁹ The summit is now in its third year, with Drake Law School and UCLA Law School playing host in 2016 and 2017, respectively, and student interest and application numbers increasing each year.⁸⁰

IX. Professional Associations/Bar Groups

In 2013, unlike FDA Law and Ag Law, FL&P had no professional membership association to foster and promote the field in either academia or legal practice. Faculty and scholars in the field, including the authors of this article, established the Academy of Food Law & Policy in 2016 to fill this role.⁸¹ The Academy connects FL&P faculty and scholars from schools across the United States, as well as several global members, and aims "to stimulate intellectual discourse, encourage and recognize scholarship, enhance teaching, support student interest, and promote the academic field of food law and policy."⁸²

75. *Wisconsin Agriculture & Food Law Society*, WISC. AGRIC. & FOOD L. SOC'Y, <https://wafslaw.wordpress.com/> (last visited Aug. 23, 2017).

76. *Student Groups*, VT. L. SCH., <http://vermontlaw.edu/community/student-groups> (last visited Aug. 23, 2017).

77. *Yale Food Law Society*, YALE L. SCH., <https://law.yale.edu/student-life/studentjournals-organizations/student-organizations/yale-food-law-society> (last visited Aug. 23, 2017).

78. Student and school list on file with the authors.

79. *About, FLSN*, FOOD L. STUDENT NETWORK, <http://foodlawstudentnetwork.org/about/> (last visited Aug. 23, 2017).

80. Student applications on file with the authors.

81. *The Academy of Food Law & Policy*, ACAD. FOOD L. & POL'Y, <https://www.academyflp.org/> (last visited Aug. 23, 2017).

82. *Mission*, ACAD. FOOD L. & POL'Y, <https://www.academyflp.org/mission> (last visited Oct. 9, 2017).

Just over a year into its existence, the Academy has recruited nearly 80 members, mostly domestic but with several global members as well.⁸³ FL&P professional associations have also spread beyond the United States, with the launch of Food Lawyers of Canada, which hosted its second annual conference in November 2017.⁸⁴

X. Academic Conferences

The number of Food Law & Policy conferences and symposia around the country has continued to grow. In our 2014 article, we reported that recent FL&P conferences and symposia had been held at many law schools across the country—including Chapman, Duke, Fordham, Harvard, Northeastern, Oregon, Stanford, Wisconsin, and Yale.⁸⁵ The frequency of these scholarly FL&P events has grown in recent years. Notably, several conferences and symposia have become important annual gatherings that showcase a host of leading FL&P scholars and issues.

Conferences hosted in recent years by law reviews, journals, and law schools include those at Fordham University Law School,⁸⁶ Seattle University Law School;⁸⁷ University of Kentucky Law School,⁸⁸ Duke University Law School,⁸⁹ Northwestern University Law School;⁹⁰ Lewis & Clark

83. *Founding Members*, ACAD. FOOD L. & POL'Y, <https://www.academyflp.org/founding-members> (last visited Oct. 18, 2017).

84. *Taking Stock: The State of Food Law and Policy in Canada*, FOOD LAWYERS OF CANADA, <http://foodlaw.ca/takingstock> (last visited Aug. 23, 2017).

85. Linnekin & Broad Leib, *supra* note 1, at 610.

86. *Cooper-Walsh Colloquium*, FORDHAM URB. L.J., (2017).

87. Symposium, *Re-Tooling Food Law: How Traditional Legal Models Can Be Re-Tooled For Food System Reform*, SEATTLE U. L. REV. (2015), http://digitalcommons.law.seattleu.edu/sultr/su_2015_symposium_flyer.pdf.

88. Symposium, *Improving or Impeding? The Local & National Effects of State & Federal Regulation*, KENTUCKY J. EQUINE, AGRIC. & NAT. RES. L. (2015).

89. *Carrots and Sticks: Moving the U.S. National Food System Toward a Sustainable Future*, DUKE ENV. LAW & POL'Y FORUM (2015), scholarship.law.duke.edu/delpf_symposium/2015/.

90. Symposium, *Third Annual Research Roundtable on Animal Law and Regulation: Local Food Law, Animal Welfare, and Sustainability*, NORTHWESTERN U. L. SCH. (2017), www.law.northwestern.edu/research-faculty/searlecenter/events/roundtable/index.html#animal2017.

University Law School,⁹¹ Boston University Law School,⁹² University of Colorado-Boulder Law School,⁹³ and Wake Forest Law School.⁹⁴

Annual events include Harvard Law School's "Just Food?" conference, sponsored by Harvard Law School's Food Law Society and Food Law & Policy Clinic (which has been held three times),⁹⁵ along with other FL&P conferences held at Harvard Law School under different names,⁹⁶ the Harvard-UCLA Food Law and Policy Conference, co-sponsored by the Food Law Lab at Harvard Law School and the Resnick Program for Food Law and Policy at UCLA Law School (now in its fourth year),⁹⁷ the Yale Food Systems Symposium (in its fifth year),⁹⁸ the Southern Methodist Law School's Food Law Forum (now in its third year),⁹⁹ the Food Law Student Leadership Summit, which is sponsored by the Food Law and Policy Clinic at Harvard Law School in partnership with the Food Law Student Network and a rotating host school (now in its third year),¹⁰⁰ and the periodic Food-Law Faculty Scholarship

91. Symposium, *21st Century Food Law: What's on our Plates?*, LEWIS & CLARK ENV. L.J., (2017), <https://law.lclark.edu/live/events/229834-21st-century-food-law-whats-on-our-plates>.

92. Symposium, *The Iron Triangle of Food Policy*, AM. J.L. MED. & ETHICS (2015), <https://www.bu.edu/law/2015/02/09/the-iron-triangle-of-food-policy-ajlms-2015symposium/>.

93. *Food Law Workshop Highlights Colorado's Innovations in the Field*, UNIV. OF COLORADO: BOULDER SCHOOL OF LAW (May 23, 2017), <https://www.colorado.edu/law/2017/05/23/food-law-workshop-highlights-colorados-innovations-field>.

94. Symposium, *Keeping in Fresh? Exploring the Relationship Between Food Laws & Their Impact on Public Health & Safety*, WAKE FOREST UNIV. SCH. L. (2014), http://events.wfu.edu/event/keeping_it_fresh_exploring_the_relationship_between_food_laws_their_impact_on_public_health_safety_symposium#.WeNUm0yZPEY.

95. See, e.g., Symposium, *Just Food? Forum on Justice in the Food System*, HARV. L. SCH. (2015), <https://green.harvard.edu/events/just-food-forum-justice-food-system>.

96. See, e.g., *Reduce and Recover: Save Food For People*, HARV. L. SCH.: CTR. FOR HEALTH LAW & POL'Y INNOVATION (2016), <https://www.chlpi.org/food-law-and-policy/reduce-and-recover-save-food-for-people/>.

97. See, e.g., *4th Annual Harvard-UCLA Food Law and Policy Conference*, HARV. L. SCH. (2017), <https://green.harvard.edu/events/4th-annual-harvard-ucla-food-law-and-policy-conference>.

98. See *Yale Food Systems Symposium*, YALE L. SCH. (2018), <https://yalefoodsymposium.org>.

99. See, e.g., *2015 Food Law Forum: The New "Normal" for the Food Industry*, SMU DEDMAN L. SCH. (2015), <http://www.strasburger.com/wp-content/uploads/2015/02/Updated-Food-Law-Forum-Overview-and-Agenda.pdf>.

100. See *Food Law Student Leadership Summit*, FOOD L. STUDENT NETWORK (2017), foodlawstudentnetwork.org/summit/.

Workshop, hosted by University of Colorado-Boulder Law School.¹⁰¹

CONCLUSION

Food Law & Policy, nearing the midpoint of its second decade, is now firmly rooted as a growing and thriving legal field. As the data demonstrates, the field continues its impressive development in nearly every one of the ten key metrics measured.

FL&P courses—and the faculty who teach them—are now the norm at many of America’s top schools, with more than a dozen schools offering two or more such courses each year. The number of dedicated FL&P clinics and centers at law schools, and clinics in other areas that address FL&P matters, has more than doubled, and continues to expand each year. Degree programs have proliferated. FL&P conferences and symposia continue to expand, with several now featured as annual events. The birth of the Academy of Food Law & Policy in 2016 has provided the field with a vital means of fostering the field’s continued growth, and offers a forum to cultivate many of the up-and-coming young faculty who will lead the field’s growth over the next decade. Student-led food-law societies have spread to law schools in every corner of the nation, and these students are now connected to one another through the Food Law Student Network. And while the frenetic pace of scholarly FL&P articles has stabilized—as befits a maturing field that experienced explosive growth in a short period of time—the overall growth in the number of publications continues in nearly every FL&P subject area (including in more than ninety percent of the search terms from which we obtained data for this article).

Whereas in 2014 we characterized FL&P as “a timely and vibrant addition to the legal academy,”¹⁰² today the field might best be characterized as an essential feature of today’s legal academy. We are confident that FL&P’s continued growth during the four years since our first in-depth study of the field is a firm indicator that FL&P is flourishing, and that the future of

101. *Food Law Workshop Highlights Colorado’s Innovations in the Field*, *supra* note 93.

102. Linnekin & Broad Leib, *supra* note 1, at 612.

FL&P is as bright as the students and faculty who have committed themselves to this important area of law.

I. Appendices

A. Cohort of 100 Law Schools Studied (Top 100 Law Schools From 2013 U.S. News & World Report Rankings)

Yale University	University of Washington
Harvard University	Arizona State University
Stanford University	Boston University
Columbia University	Boston College
University of Chicago	University of North Carolina–Chapel Hill
New York University	College of William and Mary
University of Pennsylvania	University of Georgia
University of Virginia	University of Wisconsin–Madison
University of California–Berkeley	Ohio State University
University of Michigan–Ann Arbor	Wake Forest University
Duke University	Fordham University
Northwestern University	University of Arizona
Cornell University	University of California–Davis
Georgetown University	George Mason University
University of Texas–Austin	University of Maryland
Vanderbilt University	University of Utah
University of California–Los Angeles	Brigham Young University
University of Southern California	University of Colorado–Boulder
University of Minnesota	University of Florida
Washington University	University of Illinois–Urbana-Champaign
George Washington University	Florida State University
University of Alabama	Southern Methodist University
Emory University	Tulane University
University of Notre Dame	University of California
Indiana University–Bloomington	University of Houston
University of Iowa	University of Richmond
Washington and Lee University	Baylor University

Georgia State University	Louisiana State University–
American University	Baton Rouge
Temple University	Loyola University Chicago
University of Connecticut	University of Miami
University of Kentucky	University of Missouri
Yeshiva University	Brooklyn Law School
Pepperdine University	Catholic University
University of Nebraska–	Lewis & Clark College
Lincoln	Michigan State University
University of Tennessee–	University of Cincinnati
Knoxville	University of Hawaii
Pennsylvania State	Northeastern University
University–Carlisle	Rutgers University
Seton Hall University	University of Buffalo
University of Denver	University of Kansas
University of New Mexico	University of Tulsa
Case Western Reserve	Rutgers, Camden
University	University of Pittsburgh
Illinois Institute of	West Virginia University
Technology	Marquette University
Loyola Marymount	University of Oregon
University	Santa Clara University
University of Arkansas–	Syracuse University
Fayetteville	Indiana University–
University of Louisville	Indianapolis
University of Nevada–Las	St. John’s University
Vegas	University of South
University of Oklahoma	Carolina
University of San Diego	Villanova Universit

**B. Additional Schools (Schools Currently Ranked in
U.S. New & World Report Top 100 Rankings That
Were not so Ranked in 2013)**

University of California–Irvine

Pennsylvania State University–University Park

St. Louis University

Texas A&M University

Stetson University

Florida International University

University of New Hampshire

Wayne State University

C. Schools Ranked in the Top 11 for Environmental Law & Health Law

Environmental Law:

Vermont Law School
Lewis & Clark College
Pace University
University of California–
Berkeley
University of California–
Los Angeles
Georgetown University Law
Center
University of Colorado–
Boulder
Duke University
University of Utah
New York University
Harvard University

Health Law:

St. Louis University
University of Maryland
Boston University
University of Houston
Harvard University
Loyola University Chicago
Georgia State University
Georgetown University
Case Western Reserve
University
Seton Hall University
Mitchell Hamline School of
Law

D. Raw Data From Scholarship Search Terms

FDA & “Farm Subsidies”			
Date Range	Articles	Annual Average	Percent Change
1950–59	0	0	
1960–69	0	0	0
1970–79	2	0.2	0
1980–89	3	0.3	50.00%
1990–99	6	0.6	100.00%
2000–04	7	1.4	133.33%
2005–09	13	2.6	85.71%
2010–13	13	3.25	25.00%
2014–17	28	7	115.38%
Total	72		

“Agricultural Law” & FDA			
Date Range	Articles	Annual Average	Percent Change
1950–59	2	0.2	
1960–69	0	0	-100.00%
1970–79	0	0	0
1980–89	5	0.5	0
1990–99	23	2.3	360.00%
2000–04	23	4.6	100.00%
2005–09	30	6	30.43%
2010–13	33	8.25	37.50%
2014–17	48	12	45.45%
Total	164		

FDA & USDA			
Date Range	Articles	Annual Average	Percent Change
1950–59	7	0.7	

1960–69	32	3.2	357.14%
1970–79	85	8.5	165.63%
1980–89	139	13.9	63.53%
1990–99	166	16.6	19.42%
2000–04	161	32.2	93.98%
2005–09	237	47.4	47.20%
2010–13	284	71	49.79%
2014–17	314	78.5	10.56%
Total	1425		

“Food Policy”			
Date Range	Articles	Annual Average	Percent Change
1950–59	3	0.3	
1960–69	5	0.5	66.67%
1970–79	17	1.7	240.00%
1980–89	47	4.7	176.47%
1990–99	55	5.5	17.02%
2000–04	62	12.4	125.45%
2005–09	115	23	85.48%
2010–13	187	46.75	103.26%
2014–17	148	37	-20.86%
Total	639		

“Food Law and Policy”			
Date Range	Articles	Annual Average	Percent Change
1950–59	0	0	
1960–69	0	0	0
1970–79	0	0	0
1980–89	0	0	0
1990–99	0	0	0
2000–04	0	0	0

2005–09	19	3.8	0
2010–13	30	7.5	57.89%
2014–17	57	14.25	90.00%
Total	106		

“Food System” or “Food Systems”			
Date Range	Articles	Annual Average	Percent Change
1950–59	0	0	
1960–69	0	0	0
1970–79	0	0	0
1980–89	2	0.2	0
1990–99	8	0.8	300.00%
2000–04	8	1.6	100.00%
2005–09	19	3.8	137.50%
2010–13	61	15.25	301.32%
2014–17	79	19.75	29.51%
Total	177		

“Food Justice”			
Date Range	Articles	Annual Average	Percent Change
1950–59	0	0	
1960–69	0	0	0
1970–79	2	0.2	0
1980–89	0	0	-100.00%
1990–99	4	0.4	0
2000–04	1	0.2	-50.00%
2005–09	11	2.2	1000.00%
2010–13	32	8	263.64%
2014–17	68	17	112.50%
Total	118		

“Food Access”			
Date Range	Articles	Annual Average	Percent Change
1950–59	0	0	
1960–69	0	0	0
1970–79	0	0	0
1980–89	5	0.5	0
1990–99	5	0.5	0.00%
2000–04	8	1.6	220.00%
2005–09	22	4.4	175.00%
2010–13	44	11	150.00%
2014–17	60	15	36.36%
Total	144		

“Food” & “Sustainable” or “Sustainability” (within 5 words)			
Date Range	Articles	Annual Average	Percent Change
1950–59	0	0	
1960–69	0	0	0
1970–79	1	0.1	0
1980–89	3	0.3	200.00%
1990–99	33	3.3	1000.00%
2000–04	60	12	263.64%
2005–09	100	20	66.67%
2010–13	179	44.75	123.75%
2014–17	204	51	13.97%
Total	580		

“Food Sovereignty”			
Date Range	Articles	Annual Average	Percent Change
1950–59	0	0	
1960–69	0	0	0

1970–79	0	0	0
1980–89	0	0	0
1990–99	0	0	0
2000–04	4	0.8	0
2005–09	10	2	150.00%
2010–13	31	7.75	287.50%
2014–17	50	12.5	61.29%
Total	95		

“Soda Tax” or “Soda Taxes”			
Date Range	Articles	Annual Average	Percent Change
1950–59	0	0	
1960–69	0	0	0
1970–79	0	0	0
1980–89	0	0	0
1990–99	0	0	0
2000–04	2	0.4	0
2005–09	4	0.8	100.00%
2010–13	40	10	1150.00%
2014–17	44	11	10.00%
Total	90		

“Food Waste”			
Date Range	Articles	Annual Average	Percent Change
1950–59	1	0.1	
1960–69	0	0	-100.00%
1970–79	3	0.3	0
1980–89	8	0.8	166.67%
1990–99	28	2.8	250.00%
2000–04	11	2.2	-21.43%
2005–09	24	4.8	118.18%

2010–13	35	8.75	82.29%
2014–17	47	11.75	34.29%
Total	157		

“Urban Agriculture”			
Date Range	Articles	Annual Average	Percent Change
1950–59	0	0	
1960–69	0	0	0
1970–79	1	0.1	0
1980–89	0	0	-100.00%
1990–99	8	0.8	0
2000–04	9	1.8	125.00%
2005–09	18	3.6	100.00%
2010–13	61	15.25	323.61%
2014–17	79	19.75	29.51%
Total	176		

“Food Security”			
Date Range	Articles	Annual Average	Percent Change
1950–59	2	0.2	
1960–69	2	0.2	0.00%
1970–79	3	0.3	50.00%
1980–89	121	12.1	3933.33%
1990–99	242	24.2	100.00%
2000–04	214	42.8	76.86%
2005–09	345	69	61.21%
2010–13	453	113.25	64.13%
2014–17	441	110.25	-2.65%
Total	1823		

The FDA's Guidance on Dietary Supplement Naming and the Emperor's New Clothes

Neal D. Fortin*

I. Introduction

What do a Food and Drug Administration (FDA) guidance document and a Hans Christian Andersen fable have in common? Unfortunately, more than one might hope.

The fable of the emperor's new clothes is iconic for the human tendency towards collective avoidance of speaking truth to power. The fable is also a metaphor for smooth-talking tricksters hoodwinking a government leader.

A recent FDA guidance document indicates one or both of these failings. On March 7, 2016, FDA published a notice in the *Federal Register*, stating that it was revising the agency's guidance on dietary supplement labeling.¹ The reason for the revision, FDA declared, was that the agency was, "made aware that the guidance was inaccurate in one detail."² FDA's modification of this detail—the new clothes—permits dietary supplements to be generically labeled. Specifically, FDA states, "the term 'dietary supplement' may be used as the *entire* statement of identity for a dietary supplement".³

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1. A Dietary Supplement Labeling Guide: Chapter II. Identity Statement; Guidance for Industry; Availability, 81 Fed. Reg. 11,813, 11,814 (Mar. 7, 2016).

2. *Id.* at 11,814.

3. *Id.* (emphasis added).

Who the smooth-talking weavers were who sold FDA this invisible garment is not transparent. Nonetheless, it is transparent that the FDA's "correction" is in clear error. The original 2005 guidance language was accurate based on the following:

- the plain language of the Food, Drug, and Cosmetic Act;
- the plain language of 21 C.F.R. § 101.3(g); and
- even if one accepts, *arguendo*, that the law is ambiguous, the new interpretation does not comport with numerous rules of statutory interpretation.

Moreover, this change violates the Administrative Procedures Act and the FDA's rules on notice and comment. This change is a disguised rescission of 21 C.F.R. § 101.3(g) without a proper opportunity for the public to be heard under notice and comment rulemaking.

II. Interpretation of the Law on Dietary Supplement Naming

A. The 2005 Guidance Accurately Interpreted the Plain Language of the Statute

The starting point for analysis is the text of the statute.⁴ The Federal Food, Drug, and Cosmetic Act states that a dietary supplement is misbranded if: "the label or labeling of the dietary supplement fails to identify the product by using the term 'dietary supplement', which term may be modified with the name of such an ingredient."⁵ Thus, the term "dietary supplement" or the modification must be included in the identification of a dietary supplement. This is how dietary supplements are distinguished from conventional foods.

Nothing in the wording indicates that "dietary supplement" is or can be the entire statement of identity for the entire diverse category of dietary supplements. Note the sleight of hand. The requirement to *identify* dietary supplements as dietary supplements disappears. In its place is substituted the creation of

4. *See, e.g.*, *Desert Palace, Inc. v. Costa*, 539 U.S. 90, 98 (2003) ("Our precedents make clear that the starting point for our analysis is the statutory text.")

5. Federal Food, Drug, and Cosmetic Act 21 U.S.C.A. § 343(s)(2)(B) (2010) [hereinafter FDCA or Act].

a *statement of identity* requirement for dietary supplements. By way of illustration, with a category of conventional food, all cheeses must be identified as cheese, but “cheese” is not the complete statement of identity for all cheeses.

Because the meaning of the language of the statute is unambiguous, further construction of the language is normally neither necessary nor permitted.⁶ Any deference to the agency interpretation of the statute is lost when that interpretation is contrary to the plain meaning of the statute or is unreasonable.⁷ The plain meaning of the Food, Drug, and Cosmetic Act is that the term “dietary supplement” or a modification must be included within the identification of a dietary supplement, but nothing in the Act’s wording indicates that the term may be a complete statement of identity.

B. The 2005 Guidance Accurately Interpreted the Plain Language of the Regulation

The plain language in FDA regulation 21 C.F.R. § 101.3(g) is clear that the term “dietary supplement” or a modification must be included in the identity of a dietary supplement. Also clear from the regulation is that the term “dietary supplement,” is not a complete statement of identity. The FDA rule, 21 C.F.R. § 101.3(g), reads:

(g) Dietary supplements shall be identified by the term “dietary supplement” *as a part of* the statement of identity, except that the word “dietary” may be deleted and replaced by the name of the dietary ingredients in the product (e.g., calcium supplement) or an appropriately descriptive term indicating the type of dietary ingredients that are in the product (e.g., herbal supplement with vitamins).⁸

The language of the regulation plainly contradicts the FDA’s “correction” in the March 7, 2016, *Federal Register*. The “dietary supplement” *is a part of* the statement of identity and therefore cannot be the entire statement of identity. Even the

6. *See, id.*; *Connecticut Nat. Bank v. Germain*, 503 U. S. 249, 253-254 (1992) (“When the words of the statute are unambiguous, the ‘judicial inquiry is complete.’” (quoting *Rubin v. United States*, 449 U. S. 424, 430 (1981))).

7. *See Sullivan v. Everhart*, 494 U.S. 83, 88-89 (1990) (citing *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-43 (1984)).

8. 21 C.F.R. § 101.3(g) (emphasis added).

most tortuous reading of the regulation cannot support the FDA's erroneous "correction."

C. Even if One Accepts, *Arguendo*, That the Phrase is Ambiguous, the New Interpretation Does not Comport With the Rules of Statutory Interpretation

1. *Interpret the Language Within the Context of the Provision*

Any exercise of statutory construction must be made within the context of the whole statute.⁹ Statutory interpretation is a "holistic endeavor".¹⁰

The context for the provision in question in the Federal Food, Drug, and Cosmetic Act (FDCA) § 403(s), states that a dietary supplement is misbranded if:

- (1) it is a dietary supplement; and
- (2)(A) the label or labeling of the supplement fails to list—
 - (i) the name of each ingredient of the supplement that is described in section 321(ff) of this title; and
 - (ii)(I) the quantity of each such ingredient; or (II) with respect to a proprietary blend of such ingredients, the total quantity of all ingredients in the blend;
- (B) the label or labeling of the dietary supplement fails to identify the product by using the term "dietary supplement", which term may be modified with the name of such an ingredient.¹¹

This part of the FDCA describes certain details that must be included on a dietary supplement label or the product will be misbranded. These details are not the beginning and end of the labeling requirements for dietary supplements; there are many other labeling requirements elsewhere in the FDCA that apply to

9. See *John Hancock Mut. Life Ins. Co. v. Harris Trust & Sav. Bank*, 510 U.S. 86, 94-95 (1993); see also *Massachusetts v. Morash*, 490 U.S. 107, 115 (1989) ("[I]n expounding a statute, we [are] not . . . guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy.").

10. See *Smith v. United States*, 508 U.S. 223, 233(1993) (quoting *United Sav. Assn. v. Timbers of Inwood Forest Assocs., Ltd.*, 484 U.S. 365, 371 (1988)).

11. 21 U.S.C.A § 343(s) (2010).

dietary supplements.¹² Clearly, this unique dietary supplement requirement is intended to be read in conjunction with other general labeling requirements in the Food, Drug, and Cosmetic Act. Specifically, the above provision relates to some unique aspects of the dietary supplement label that distinguish it from conventional foods.

Nothing in the context concerns overall naming of dietary supplements. Nowhere does the language even use the term “statement of identity.” Within this context, there is no ambiguity in the language in the Act. The plain language indicates terms that, if absent from the label, will result in a misbranded product. Nothing more.

2. If Need be, Interpret the Language Within the Overarching Purpose of the Act

The 1938 Food, Drug, and Cosmetic Act’s primary purpose is to protect consumer’s health, as well as their pocketbooks. The latter purpose included a provision requiring that food “bear its common or usual name,” which was added in 1938 in large part so that consumers could make value comparisons in the marketplace. Allowing a generic statement of identity for all countless, varied dietary supplements is contrary to the purpose of the Act.¹³ Clearly, Congress never intended § 403(s)(2)(B) to limit the FDA’s ability to require truthful, informative labeling of the statement of identity of dietary supplements. Statutes, when ambiguous, should be interpreted so as best to carry out their statutory purpose.¹⁴

3. Reconcile With Other Provisions of the Act to Produce a Harmonious Whole

Any interpretation must be read in the context of the entire statute so as to produce a harmonious whole.¹⁵ Section 403(i)(1)

12. See, e.g., 21 U.S.C.A. § 343-2(a); 21 U.S.C.A. § 342(g); 21 U.S.C.A. § 379aa-1(b).

13. See NEAL FORTIN, *FOOD REGULATION: LAW, SCIENCE, POLICY, AND PRACTICE* 31 (Wiley, 2d ed. 2017).

14. See *Reves v. Ernst & Young*, 494 U.S. 56, 60-61 (1990).

15. See *United Sav. Assn. v. Timbers of Inwood Forest Assocs., Ltd.*, 484 U.S. 365, 371 (1988) (favors a meaning that produces a substantive effect compatible with the rest of the law).

of the Act requires that a food label must bear the common or usual name of the food.¹⁶ The generic term, “dietary supplement,” is not the common or usual name of all dietary supplements.¹⁷ “Dietary supplement” is the name of the entire regulatory category rather than the common or usual name or any specific food.¹⁸

4. *The Rule of Continuity*

Similar to the favoring of harmonious interpretation, the rule of continuity directs us to assume that Congress does not discontinue duties or obligations without some clear statement.¹⁹ Nothing in the statute or the legislative history indicates that Congress intended to repeal the obligation that dietary supplements be labeled under the general requirements for a statement of identity for packaged food (including dietary supplements, which are a subcategory of “food” under the Act). In particular, exemptions from other statutory requirements should be read narrowly.²⁰

5. *Repeal by Implication Disfavored*

To reconcile FDA’s current interpretation with other provisions of the Act would require negating the FDCA requirement for a statement of identity for dietary supplements.²¹ If Congress had intended such major change in the law, the language of the statute would have indicated it. It is absurd to believe that Congress *sub silentio* suspended section 403(i)(1) of the Food, Drug, and Cosmetic Act from application

16. FDCA 21 U.S.C. § 403(i)(1).

17. Brian Scarbrough, *Dietary Supplements: A Review of United States Regulation with Emphasis on the Dietary Supplement Health and Education Act of 1994 and Subsequent Activity*, DIGITAL ACCESS TO SCHOLARSHIP AT HARV. (Nov. 14, 2017), <https://dash.harvard.edu/bitstream/handle/1/8852160/scarbrough.pdf?sequence=1>.

18. *Id.*

19. *See* Green v. Bock Laundry Mach. Co., 490 U.S. 504, 521 (1989) (“A party contending that legislative action changed settled law has the burden of showing that the legislature intended such a change.”); *see also* Finley v. United States, 490 U.S. 545, 554 (1989) (“Under established canons of statutory construction, ‘it will not be inferred that Congress, in revising and consolidating the laws, intended to change their effect unless such intention is clearly expressed.’” (quoting Anderson v. Pacific Coast S.S. Co., 225 U.S. 187, 199 (1912))).

20. *See, e.g.*, Commissioner v. Clark, 489 U.S. 726, 739 (1989).

21. FDCA § 403(i)(1).

to dietary supplements. As a rule, exemptions or exceptions to the general requirements of an act are not created unless specified by Congress.²²

6. *The “Dog Didn’t Bark” Canon*

Similar to the rule disfavoring repeal of requirements, without express statutory language is the “dog didn’t bark” canon. The presumption is that a prior legal rule should be retained if no one in legislative deliberations discussed any changes in the rule.²³

7. *Avoid Unreasonable Results*

Under the FDA revised guidance, statements of identity on dietary supplement labels could be changed as follows:

Current statement of identity	Permitted statement of identity under FDA’s new guidance
Garlic 1000 mg Supplement	dietary supplement
Fiber Supplement	dietary supplement
Iron Supplement 65 mg	dietary supplement
Multivitamin Supplement	dietary supplement
Ginger root dietary supplement	dietary supplement
D3 1000 IU dietary supplement	dietary supplement
Lutein 20 mg dietary supplement	dietary supplement
Fish Oil 1200 mg dietary supplement	dietary supplement

Statutory language should be construed reasonably. The new FDA interpretation is unreasonable.

8. *Apply Common Sense*

An interpretation of the statute should comport with common sense. FDA’s new guidance creates an absurd result.

22. See *United States v. Smith*, 499 U.S. 160, 166-67 (1991).

23. See *Chisom v. Roemer*, 501 U.S. 380, 396 n.23 (1991) (“Congress’ silence in this regard can be likened to the dog that did not bark.” See A. DOYLE, *SILVER BLAZE*, in *THE COMPLETE SHERLOCK HOLMES* 335 (1927)).

9. Review the Legislative History and Contemporaneous Interpretation

The primary goal of judicial interpretation of statutes is to ascertain and give effect to the intent of the legislature. In 1996, the FDA received numerous comments on its proposed new rule 21 C.F.R. § 101.3(g).²⁴ Nowhere in the legislative history did anyone construe the meaning of section 403(s)(2)(B) of the FDCA as supplying the complete statement of identity. All 1996 discussion revolved around including “dietary supplement” *as part of* the statement of identity. For example, “The agency has carefully reviewed these comments but concludes that the best reading of the act, as well as the agency’s longstanding regulations that implement the act, require that the term ‘dietary supplement,’ or some form of this term, appear as part of the statement of identity.”²⁵

III. FDA’s Violation of the Administrative Procedures Act

A. Failure to Give Notice and Comment

This change violates the Administrative Procedures Act and FDA’s rules on notice and comment.

B. Disguised Rescission of a Rule Without Proper Notice and Comment

FDA’s change is a disguised rescission of 21 C.F.R. § 101.3(g) without a proper opportunity to be heard under notice and comment rulemaking in violation of the Administrative Procedures Act section 553. The FDA rule 21 C.F.R. § 101.3(g) clearly identifies that the term “dietary supplement” is only a part of the statement of identity for a dietary supplement. The FDA’s new guidance statement effectively negates 21 C.F.R. § 101.3(g) without the required rescission or amendment of the rule.

24. Food Labeling: Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements; Compliance Policy Guide, Revocation, 62 Fed. Reg. 49,826 (Sept. 23, 1997) (to be codified at 21 C.F.R. pt. 101).

25. *Id.* at 49,827.

In addition, this was a major change that should have had public participation—in accordance with FDA rule 21 C.F.R. § 10.115(g)(2)—before it was instituted. Changing the longstanding meaning of the guidance and effectively negating the plain language of the FDA’s rule of 21 C.F.R. § 101.3(g) was a major change that required public participation through notice and comment before it could be effectuated.

The April 2005 FDA guidance for industry, “A Dietary Supplement Labeling Guide,” was accurate. Therefore, FDA should immediately reinstate the April 2005 guidance language on this detail. Specifically, in Chapter II, Identity Statement, question 3 asked, “Can the term ‘dietary supplement’ by itself be considered the statement of identity?” The 2005 response to the question said that it could not. This interpretation is consistent with the plain meaning of section 403(s)(2)(B) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 101.3(g).

IV. Conclusion

To be candid, no one wants to see the emperor naked. It is unseemly, undermines respect, and is, frankly, more than a little disturbing. FDA must remedy this situation immediately. No matter how humiliating it might be for FDA to admit it has no clothes, recognizing the truth beats walking around naked.

The truth of the law regarding the naming of dietary supplements is clear. The FDA’s new guidance regarding the statement of identity for dietary supplements leaves the agency naked with not even a fig leaf to cover itself. Moreover, FDA is breaking the law on notice and comment rulemaking.

What is not clear is why FDA made such a blatant and obvious error of law. How much of the metaphor of the emperor’s new clothes applies? Is FDA collectively avoiding speaking truth regarding the new guidance? Or did FDA get hoodwinked by a smooth-talking trickster? More troubling than naked leadership on a small matter is what the mistake might reveal about the state of this important federal agency.

The Role of Non-Profit Organizations in Shaping Food Law and Corporate Responsibility in the United States

Melissa M. Card*

INTRODUCTION

Disputes between Europe and the United States over real and perceived concerns about food safety demonstrate different perspectives on corporate responsibility and different institutional processes for settling those differences.¹ For example, in the United States, a bill concerning genetically engineered labeling was sponsored and drafted by the Senate Agriculture Committee focusing on industry needs.² However, Europe adopted a labeling approach for genetically engineered products based on input from various non-profit organizations focusing on consumers' concerns.³

Non-governmental organizations ("NGOs") are assumed to be counterweight to capitalism and globalization.⁴ NGOs promote what they perceive to be more ethical and socially

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1. *Compare* *Liebeck v. McDonald's Restaurants, P.T.S., Inc.*, No. CV-93-02419, 1995 WL 360309, at *1 (N.M. Dist. Aug. 18, 1994), *vacated sub nom. Liebeck v. Restaurants* (N.M. Dist. Nov. 28, 1994) (exemplifying the litigious society of the United States, in which consumers hold corporations responsible), *with* DAVID VOGEL, *THE MARKET FOR VIRTUE: THE POTENTIAL AND LIMITS OF CORPORATE SOCIAL RESPONSIBILITY* 8 (2006) (declaring that interest in Corporate Social Responsibility exists on the European continent).

2. Agricultural Marketing Act of 1946 § 202, 7 U.S.C.A. § 1621 (1946).

3. Commission Regulation 1829/2003, 2003 O.J. (L 268) 24 (EU).

4. *See* Jonathan P. Doh & Terrence R. Guay, *Corporate Social Responsibility, Public Policy, and NGO Activism in Europe and the United States: An Institutional-Stakeholder Perspective*, 43 *J. OF MANAGEMENT STUDIES* 47, 47, 51 (2006) (stating that others suggest that NGOS may cause risks of 'privatizing' public policies that deal with environmental, labor, and social issues, thereby leading to a loss in democratic accountability).

responsible business practices.⁵ In addition, NGOs create and institutionalize new norms in society. With the use of social media and dynamic documentaries, non-profit organizations are able to successfully network and influence public opinion about various food safety topics.⁶ But is it advantageous for the United States to adopt an institutional process similar to Europe's, where non-profit organizations provide input on food law and corporate responsibility?

This article will assess whether the United States should adopt an institutional process similar to Europe's by giving non-profit organizations a role in shaping food law and corporate responsibility. Part I provides a comparative analysis of genetically engineered product regulations in the United States and European Union (EU). Part II explains how the institutional processes of the United States and Europe led to the varying regulations, and demonstrates that the United States institutional structure is too different from Europe's to allow NGO's to have a role in shaping food law and corporate responsibility. Finally, Part III asserts that the United States should change its institutional process by allowing public universities and private colleges to influence food law and corporate responsibility. This article concludes that public universities and private colleges afford collaboration from a diverse group of individuals who are likely to have both the industry's needs and consumers' concerns in mind.

I. The Comparative Analysis of the Institutional Processes of the United States and Europe Through the Regulation of Genetically Modified Foods

Genetically engineered ("GE"), more commonly genetically modified, refers to the genetic modification through the use of recombinant deoxyribonucleic acid ("rDNA") techniques to express desired traits.⁷ The food industry often

5. *E.g.*, Cristina Brandão, et al., *Social Responsibility: A New Paradigm of Hospital Governance?*, 21 HEALTH CARE ANAL., 390, 391 (2013) (explaining that a number of organizations embrace a socially responsible conduct, meaning that citizens, and investors, are deeply aware that profit and ethical values are not incompatible).

6. *E.g.*, WHAT THE HEALTH (Vimeo 2017).

7. NEAL D. FORTIN, *FOOD REGULATION: LAW, SCIENCE, POLICY, AND PRACTICE* 277 (Wiley ed., 2d ed. 2017) (asserting that genetically modified, or more precisely genetically engineered, indicates that humans have directly engineered the DNA). *Cf. id.*

creates genetically modified organisms and genetically modified plants to produce a target trait of a nonrelated species.⁸ For example, Calgene, Inc. modified its FLAVR SAVR™ tomatoes to contain lower levels of a naturally occurring enzyme, resulting in ripe fruit remaining firm for an extended period of time and allowing fresh market tomatoes to remain on the vine longer for enhanced flavor.⁹ While the technology concerning GE foods is identical, GE food regulations in the U.S. and EU vary considerably.¹⁰ The United States focuses on the end product, and the EU focuses on the process.¹¹ This section delves into the regulatory and labeling requirements for GE foods in the U.S. and the EU.

(defining conventional plant breeding to mean all breeding methods other than by rDNA techniques). See generally Rachele B. Bailey, *A Tale of Two Systems: A Comparison Between U.S. and EU Labeling Policies of Genetically Modified Foods*, 15 SAN JOAQUIN AGRIC. L. REV. 193, 197 (2006) (stating that genetically modified organisms have been altered in a way that would not occur naturally, allowing selected genes to be transferred between non-related species).

8. See Debra M. Strauss, *Feast or Famine: The Impact of the WTO Decision Favoring the U.S. Biotechnology Industry in the EU Ban of Genetically Modified Foods*, 45 AM. BUS. L.J. 775, 777 (2008) (considering the implications of the precautionary principle, the role of multilateral environmental agreements, the ability of nations to apply safeguard measures, and ultimately the appropriateness of the WTO as a body for determining environmental and food policy). As it relates to food, genetically modified organisms and genetically modified plants are created when the genes of one organism are inserted into the DNA of another organism to produce the target trait in that nonrelated species. *Id.*

9. *Agency Summary Memorandum Re: Consultation with Calgene, Inc., Concerning FLAVR SAVR™ Tomatoes*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Food/IngredientsPackagingLabeling/GEPlants/Submissions/ucm225043.htm#out2> (last updated Oct. 13, 2015). When developing the FLAVR SAVR™ tomatoes, Calgene, Inc., a Californian company, used rDNA techniques to introduce an antisense polygalacturonase (PG) gene. *Id.* The PG gene is ordinarily present in tomatoes. *Id.* The PG gene encodes the enzyme PG, which is associated with the breakdown of pectin. *Id.* The principle underlying the FLAVR SAVR™ tomato was that the antisense PG gene suppresses the production of the PG enzyme. *Id.*

10. See Katharine Gostek, *Genetically Modified Organisms: How the United States' and the European Union's Regulations Affect the Economy*, 24 MICH. ST. INT'L. L. REV. 761, 761-63 (2016) (explaining that the changes to the EU's regulations will not benefit the EU's economy, but changes in U.S. regulations may benefit the U.S. economy); see also FORTIN, *supra* note 7, at 486 (asserting that genetically modified organisms and food derived from genetically engineered organisms have been a contentious matter in international trade).

11. Jessica Lau, *Same Science, Different Policies: Regulating Genetically Modified Foods in the U.S. and Europe*, HARVARD UNIVERSITY: THE GRADUATE SCHOOL OF ARTS AND SCIENCES: SCIENCE IN THE NEWS (Aug. 9, 2015), <http://sitn.hms.harvard.edu/flash/2015/same-science-different-policies/>.

A. GE Food Regulations and Labeling Requirements in United States

Various federal agencies, such as U.S. Food and Drug Administration (“FDA”), the U.S. Environmental Protection Agency (“EPA”), and the U.S. Department of Agriculture (“USDA”), share regulatory oversight of GE products.¹² While various federal agencies have regulatory oversight over GE foods, the FDA ensures that the nation’s foods, including products that have been genetically modified, are safe for consumption.¹³ FDA asserts that conventional foods and GE foods pose the same risks; they can potentially contain allergens, toxins, or anti-nutrients.¹⁴ Due to this assertion, GE foods are regulated in the same manner as conventional foods based on the doctrine of substantial equivalence.¹⁵ In accordance with this doctrine, any GE crop varieties produced using rDNA techniques are considered to be essentially the same as the conventional varieties produced using traditional breeding methods.¹⁶ GE foods are considered to be the same as the conventional varieties because the substances expected to become components of food—as a result of genetic modification of a plant—will be the same as, or substantially similar to, substances commonly found in foods, such as proteins, fats and

12. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,302-03 (Jun. 26, 1986) (noting the relevant agencies and their functions in the administration of the Coordinated Framework). The Animal and Plant Health Inspection Service determines whether a genetically modified plant has the potential to harm natural habitats or agriculture. *Id.* The EPA regulates specific genetic modifications that protect plants from insects, bacteria, and viruses, including plants that have been genetically modified to contain a pesticide trait. *See id.* The USDA, along with the APHI, oversees the release of certain categories of plants and the field testing of Genetically Engineered crops. *Id.*

13. *See Statement of FDA Mission*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/downloads/aboutfda/reportsmanualsforms/reports/budgetreports/ucm298331.pdf> (last visited Sept. 6, 2017). (“FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation’s food supply cosmetics, and products that emit radiation.”).

14. *See FORTIN, supra* note 7, at 279. Anti-nutrients are natural or synthetic compounds that interfere with the absorption of nutrients. *Statement of Policy - Foods Derived from New Plant Varieties*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096095.htm> (last updated May 2, 2016) [hereinafter *Statement of Policy*].

15. Maria R. Lee-Muramoto, *Reforming the “Uncoordinated” Framework for Regulation of Biotechnology*, 17 DRAKE J. AGRIC. L. 311, 338 (2012).

16. *Id.*

oils, and carbohydrates.¹⁷ Thus, if the conventional food's traits are considered safe, then a GE food's traits—that are substantially equivalent—would also be considered safe. For example, the FDA stated that the genetic modifications for the FLAVR SAVR™ tomato resulted in nutritional characteristics that were within the range of existing tomatoes; therefore, the FLAVR SAVR™ tomatoes were substantially equivalent to existing tomatoes.¹⁸ Based on federal regulations, conventional foods do not ordinarily require premarket approval.¹⁹ Therefore, the FDA is not required to conduct any independent safety, allergen, or other tests, to differentiate GE foods from their conventional counterparts.²⁰

While GE food products are ordinarily exempt from premarket review and approval, there are instances in which food manufacturers are subject to premarket requirements. If a GE food is not substantially equivalent to the conventional food, then the FDA would require premarket review and approval.²¹ When GE foods require premarket review and approval, the products are treated as a food additive and must go through a food additive review.²² Additionally, the FDA recommends that

17. *Statement of Policy*, *supra* note 14.

18. See Jennifer A. Thelen, *FDA Regulation of Food and Drug Biotechnology*, LEDA AT HARVARD LAW SCHOOL, <https://dash.harvard.edu/bitstream/handle/1/8846761/jthelen.html?sequence=1> (last visited Sept. 6, 2017) (stating that the FDA concluded that FLAVR SAVR™ tomatoes had not been significantly altered when compared to varieties of tomatoes with a history of safe use).

19. *Cf.* 21 U.S.C. 348 (inferring that premarket approval is required for food additives, unless an exemption from the regulations concerning food additives applies).

20. Lee-Muramoto, *supra* note 15, at 338 (2012) (declaring that the FDA does not conduct independent safety or allergen testing, unless the GE food product contains an allergen that people would not generally expect in that particular food).

21. See FORTIN, *supra* note 7, at 283 (stating that if a GE-derived food is significantly different in function or structure, then it is treated as a food additive). To be different from conventional foods, a food must be different from conventional foods in a meaningful way or present any different or greater safety concerns than conventional foods. *Statement of Policy*, *supra* note 14. For example, if a food was genetically engineered to include allergens that the conventional food did not have, then the FDA would not find that the GE food was substantially equivalent to the conventional food. See Lee-Muramoto, *supra* note 15, at 338.

22. FORTIN, *supra* note 7, at 283. Any food additives intended to have a technical effect in food is deemed unsafe unless it either conforms to the terms of a regulation prescribing its use or to an exemption for investigational use. *Guidance for Industry: Questions and Answers About the Petition Process*, U.S. FOOD AND DRUG ADMIN., <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm253328.htm#answerA> (last updated July 1, 2016). A petition for a food additive is

food manufacturers communicate with the FDA even if the differences between the GE food and the conventional food are not significant.²³

In the United States, labeling of GE products is shared between various federal agencies.²⁴ Under the Food, Drug, and Cosmetic Act there is no labeling mandate for foods that are genetically modified.²⁵ The FDA stated that “labels would erroneously imply that genetically modified foods differ from conventional foods and that conventional foods are in some way superior.”²⁶ However, if the composition of a GE food differs significantly from its conventional counterpart, that information would require labeling.²⁷ This stems from the misbranding

submitted to request issuance of a regulation allowing new uses of the additive and must contain the necessary supporting data and information. *Id.*

23. *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/RegulatoryInformation/Guidances/ucm059098.htm> (last updated July 1, 2016) [hereinafter *Guidance for Industry: Voluntary Labeling*].

24. See FORTIN, *supra* note 7, at 293 (stating that the three primary agencies that are involved with regulating GMO safety, are also involved the labeling).

25. The Food, Drug and Cosmetic Act (“Act”) requires labeling because (1) the labeling is expressly required by the Act, or (2) the information is “material”, as used in the Act, and the absence of the information is considered misleading under section 201(n) of the Act. *Id.* On July 29, 2016, President Obama signed the National Bioengineered Food Disclosure Standard into law which, in part, directs USDA to establish a national standard to disclose certain food products or ingredients that are bioengineered. See generally 7 U.S.C.A. § 1639b (West). As a result of the National Bioengineered Food Disclosure Standard, the regulations issued by the USDA will establish labeling of human food derived from biotechnology. See *id.*

26. MARION NESTLE, *SAFE FOOD: THE POLITICS OF FOOD SAFETY* 145-50, 222 (Darra Goldstein ed., 2010) (discussing the alleged benefits of genetically engineered foods).

27. 21 U.S.C. 321(n) (proving that labeling is misleading if, among other things, it fails to reveal facts that are material in light of representations made or suggested in the labeling, or material with respect to consequences that may result from the use of the food to which the labeling relates under the conditions of use prescribed in the labeling, or under such conditions of use as are customary or usual). The term “material” is actually not defined in the Food, Drug, and Cosmetic Act. Historically, the agency has interpreted the term, within the context of food, to mean information about the attributes of the food itself. *Guidance for Industry: Voluntary Labeling*, *supra* note 23. For example, FDA has required special labeling in cases where the absence of such “material” information may: (1) pose special health risks; (2) mislead the consumer in light of other statements made on the labeling; or (3) in cases where a consumer may assume that a food, because of its similarity to another food, has nutritional, organoleptic, or functional characteristics of the food it resembles when in fact it does not. *Id.* The FDA does not consider the methods to create GE food to be “material” within the meaning of “misleading” in section 201(n) as used in the Food, Drug, and Cosmetic Act. *Id.*

provision of the Food, Drug, and Cosmetic Act.²⁸ While labeling is generally not required by the Food, Drug, and Cosmetic Act, manufacturers may voluntarily label their GE food products, provided that such labeling is truthful and not misleading.²⁹

In conclusion, the United States determines the safety of a GE food product based on its composition, not the method or process by which it was produced.³⁰ Based on this determination, most GE foods are not subject to premarket review or approval.³¹ In addition, the Food, Drug, and Cosmetic Act does not require a specific labeling scheme if a food has been genetically engineered.³²

B. EU's Regulatory Requirements Concerning GE Foods and Labeling Requirements

Since 2003, the precautionary principle has governed the EU's approach to GE foods.³³ The precautionary principle is risk-adverse; because potential risks of GE foods are not completely known, regulatory decisions require a high burden of proof for product safety.³⁴ Therefore, in the EU, all GE food products go through a premarket approval process.³⁵ Companies of GE food products submit applications for approval to an EU member state; the centralized European Food Safety Authority

28. 21 U.S.C. § 343(a)(1) (stating that a food is misbranded if its labeling is false or misleading in any particular).

29. *Labeling of Foods Derived from Genetically Engineered Plants*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/food/ingredientspackaginglabeling/geplants/ucm346858.htm> (Jan. 1, 2017). In general, an accurate statement about whether a food was not produced using bioengineering is one that provides information in a context that clearly refers to bioengineering technology. Examples of such statements include: "not bioengineered" or "not genetically modified through the use of modern biotechnology." *Id.*

30. *See* Lee-Muramoto, *supra* note 15, at 338.

31. *Id.* at 334.

32. *Id.*

33. *See* Gostek, *supra* note 10, at 773.

34. Lau, *supra* note 11. Precautionary principle refers to preventing not only known environmental harms and health risks but also to prevent conduct that may be harmful although scientific evidence is unavailable to prove actual harm. *See* FORTIN, *supra* note 7, at 489 (arguing that precautionary principle creates confusion because there is no standard definition, and any uncertainty on safety requires prohibition of a potentially harmful or risky activity until it is proven to be safe).

35. *See* Lau, *supra* note 11 (asserting that all GE foods are regulated because they are made with processes different from those used to produce conventional foods).

(“EFSA”) then conducts scientific risk assessments.³⁶ After the EFSA’s acceptance of safety, the recommendation is forwarded to the European Commission.³⁷ The European Commission Directorate General for Health and Consumer Protection drafts proposals based on the EFSA’s risk assessment; however, it can reject or base its proposal on other considerations beyond the risk assessment.³⁸ A regulatory committee comprised of representatives of member states’ authorities then decides whether to accept the proposal through a weighted voting system.³⁹ If there is disagreement amongst the member states committee failing to reach a majority decision, then the European Commission makes the final decision for approval.⁴⁰

Following the approval, EU regulations mandate that manufacturers inform consumers that products are genetically modified through labeling.⁴¹ Specifically, a product containing more than 0.9% GE material must be labeled as being GE foods.⁴² Under EU regulation, if a food consists of more than one ingredient, the phrases “genetically modified” or “produced from genetically modified (name of the ingredient)” must appear

36. See Sci. Commun. of the Eur. Comm’n, *Risk Assessment*, HEALTH AND FOOD SAFETY: SCIENTIFIC COMMITTEES, available at http://ec.europa.eu/assets/sante/health/scientific_committees/risk_assessment/index_en.htm (last visited Sept. 6, 2017) (stating that the Scientific Committees assess the potential risks before making a legislative proposal, namely the probability and the severity of an adverse effect, in relation to the hazards and to the exposure) [hereinafter *European Risk Assessment*]. Margaret Rosso Grossman, *Traceability and Labeling of Genetically Modified Crops, Food, and Feed in the European Union*, 1 J. FOOD L. & POL’Y 43, 85 (2005) (inferring that even though the EFSA conducts risks assessment for GE food products, EFSA has no authority to approve a product even if the product has been found completely safe). EFSA is an independent European agency funded by the European Union set up in 2002 following a series of food crises in the late 1990s which is responsible for risk assessment for food safety. See *About EFSA*, EFSA: EUROPEAN FOOD SAFETY AUTHORITY, <https://www.efsa.europa.eu/en/aboutefsa> (last visited September 4, 2017).

37. See Lau, *supra* note 11.

38. See *European Risk Assessment*, *supra* note 36 (stating that the European Commission makes a legislative proposal based on the risk assessment, and all other relevant aspects). For example, the European Commission may authorize a substance, prohibit a substance, or define exposure limits for a substance. *Id.*

39. See Lau, *supra* note 11.

40. See *id.*

41. Commission Regulation 1829/2003, 2003 O.J. (L 268) 13 (EC).

42. *Id.* (“This Section shall not apply to foods containing material which contains, consists of or is produced from GMOs in a proportion no higher than 0,9 per cent of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable.”).

in the list of ingredients in parentheses immediately following the applicable ingredient.⁴³ If the ingredients are designated categorically, the phrase “contains genetically modified (name of organism)” or “contains (name of ingredient) produced from genetically modified (name of organism)” must appear in the list of ingredients.⁴⁴ Lastly, if no ingredient list is present, then the phrase “genetically modified” or “produced from genetically modified (name of organism)” must be conspicuously on the labeling.⁴⁵

In conclusion, the EU’s regulations concerning genetically modified foods are among the strictest in the world.⁴⁶ The EU focuses on the method or process of creation when determining the safety of a GE food, and not on the final composition. Due to this determination, all GE foods are subject to premarket review or approval.⁴⁷ In addition, all GE foods that meet a specific threshold are required to meet a specific labeling scheme, disclosing that a food has been genetically engineered.⁴⁸

II. The Institutional Structures of the United States Differs From Europe’s, Which Affects the Role That NGOs Have in Shaping Food Regulations and Corporate Responsibility

The regulations of GE foods are different in the United States and the EU, however, both sides claim that their regulations were created to address public health and environmental safety issues.⁴⁹ Because the purpose behind the

43. *Id.* (indicating that this information may appear in a footnote to the list of ingredients, but must be printed in a font of at least the same size as the list of ingredients). If there is no list of ingredients, then the information shall appear clearly on the labeling. *Id.*

44. *Id.* (indicating that this information may appear in a footnote to the list of ingredients, but must be printed in a font of at least the same size as the list of ingredients). If there is no list of ingredients, then the information shall appear clearly on the labeling. *Id.*

45. *Id.*

46. See *Restrictions on Genetically Modified Organisms: European Union*, LIBR. OF CONG., <https://www.loc.gov/law/help/restrictions-on-gmos/eu.php> (last visited September 4, 2017).

47. *Fact Sheet: Questions and Answers on EU’s Policies on GMOs*, EUROPEAN COMM’N PRESS RELEASE DATABASE (Apr. 22, 2015), http://europa.eu/rapid/press-release_MEMO-15-4778_en.htm.

48. *Id.*

49. See Doh & Guay, *supra* note 4, at 59.

regulations is the same, assessing the institutional processes of the United States and Europe that led to the varying regulations is imperative. This section explains how scientific uncertainties and ethical concerns played out differently in the EU and the United States due to institutional and ideational reasons.⁵⁰ Additionally, this section demonstrates that the United States institutional structure is too different from Europe's to allow NGOs to have a role in shaping food law and corporate responsibility.

A. The Influences Leading to GE Regulations

The original EU regulations concerning GE products were very similar to the rules in the United States.⁵¹ However, food safety scares and the rise of anti-genetically engineered food protests in Europe sent the EU regulations concerning GE foods in a different direction.⁵² NGOs reinforced that the EU regulations should take a different direction.⁵³ Industry tried to counter the NGOs viewpoint and dissipate the food safety fears, but industry actions only strengthened the NGOs' position.⁵⁴ Europe adopted the precautionary principle based on input from various NGOs, which assumed the new genetic foods must be proven safe before introduction into the marketplace.⁵⁵ The

50. M.J. PETERSON, THE EU-US DISPUTE OVER REGULATION OF GENETICALLY MODIFIED ORGANISMS, PLANTS, FEEDS, AND FOODS – CASE SUMMARY, INTERNATIONAL DIMENSIONS OF ETHICS EDUCATION IN SCIENCE AND ENGINEERING CASE STUDY 4 (2010).

51. *Id.* at 6.

52. *Id.* (stating that the food safety scares included: (1) a fear that humans would contract "mad cow disease" from English beef, and (2) the discoveries of toxic materials in Belgian and French animal feedstocks).

53. *See, e.g., Restrictions on Genetically Modified Organisms: European Union, supra* note 46 (asserting that NGOs expressed the need to clarify even further that the 0.9% labeling threshold is not a tolerance level but applies only to the adventitious and technically unavoidable presence of GMOs).

54. *See* PAULETTE KURZER & ALICE COOPER, WHAT'S FOR DINNER? VARIATIONS IN EUROPEAN SUPPORT FOR GENETICALLY MODIFIED FOOD 3 (2005), <http://aei.pitt.edu/3092/1/EUSAKurzerCooper05.pdf> ("In countries with intensely hostile publics, the biotech industry, scientific experts, and government officials are outmaneuvered by anti-GMO voices, who reclaim the debate by introducing new concepts concerning the risks inherent in experimenting with technological innovations to the country's food production regime.").

55. *See* Lesley K. McAllister, *Judging Gmos: Judicial Application of the Precautionary Principle in Brazil*, 32 *ECOLOGICAL L.Q.* 149, 150 (2005) (stating that the precautionary principle embraces the idea that full scientific certainty should not be

EU's resistance regarding GE foods related to three environmental risks associated with biotechnology: (1) genetically engineered traits could harm non-target species; (2) cross-pollination could cause relatives of the cultivated crop to inherit the genetically modified trait; and (3) pests targeted by the genetic modification will evolve resistant.⁵⁶

While the EU's regulations were largely influenced by NGOs, the regulations in the United States were largely influenced by the food industry.⁵⁷ US firms developing agricultural applications of GE technologies formed an effective nationwide industry lobby.⁵⁸ The industry based lobbying group successfully influenced how GE products would be regulated.

In 1986, the Reagan administration set the basic parameters of the United States' policy in the Coordinated Framework for the Regulation of Biotechnology,⁵⁹ which ensured the development of biotechnology without burdensome regulations.⁶⁰ Then in 1989, the National Research Council ("NRC") published an influential report regarding the safety of GMOs,⁶¹ concluding that "the product of genetic modification

required before governments take preventative action against potentially serious environmental harms).

56. See, e.g., WORLD HEALTH ORGANIZATION (WHO), MODERN FOOD BIOTECHNOLOGY, HUMAN HEALTH AND DEVELOPMENT AN EVIDENCE-BASED STUDY iii (2005); see generally Rebecca Bratspies, *The Illusion of Care: Regulation, Uncertainty, and Genetically Modified Food Crops*, 10 N.Y.U. ENV'T'L. L.J. 297 (2002) (linking Bt corn to pest resistance).

57. PETERSON, *supra* note 50, at 5 (asserting that due to pressures from conservatives and business interests, the United States' regulatory approaches for genetically modified products rely heavily quantifiable estimates of potential harms and benefits used to make cost-benefit analyses).

58. *Id.* at 11 (comparing the United States industry lobbying techniques with European firms; Europe failed to form industry lobbies, particularly at the EU-wide level).

59. See Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302-03 (Jun. 26, 1986) (explaining that the Coordinated Framework for the Regulation of Biotechnology encouraged the approach under which the federal agencies in the United States treated genetic modification the same as other forms of breeding).

60. See Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C.L. REV. 733, 738 (2003) (reviewing the development and implementation of the regulatory framework of GE products through FDA, USDA, and EPA).

61. See Gostek, *supra* note 10, at 767. The purpose of the National Research Council is to help improve public policy, understanding, and education in matters of science, technology, and health. See THE NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, MEDICINE, ARTICLES OF ORGANIZATION OF THE NATIONAL RESEARCH COUNCIL, https://web.archive.org/web/20160519172226/http://www.nationalacademies.org/nrc/na_0

and selection should be the primary focus for making decisions . . . not the process by which the products were obtained.”⁶² In addition, NRC concluded that although information concerning “the process used to produce a genetically modified organism is important in understanding the characteristics of the product . . . the nature of the process is not a useful criterion for determining whether the product requires less or more oversight.”⁶³ Lastly, the NRC report concluded that “[t]he same physical and biological laws govern the response of organisms modified by modern molecular and cellular methods and those produced by classical methods.”⁶⁴ The NRC Report was a large step towards the acceptance of GE products.⁶⁵

In conclusion, regulations concerning GE foods, as well as GE food labeling, differ in the United States as compared to the EU.⁶⁶ The United States focuses on the end product, while the EU focuses on the process.⁶⁷ The varying regulations resulted from scientific uncertainties and ethical concerns playing out differently in the EU and the United States. In addition, the EU’s regulations were influenced by NGOs, and the regulations in the United States were influenced by industry interest groups.

B. Institutional Structures of the United States and Europe

EU NGOs’ influence on GE product regulations was successful; however, NGOs in the United States failed to influence GE regulations.⁶⁸ Due to the varying institutional

70358.html (last visited Sept. 7, 2017) (“The Council of the National Academy of Sciences, under the authority conferred upon the Academy by its charter enacted by Congress and approved by President Lincoln on March 3, 1863.”).

62. See NAT’L RESEARCH COUNCIL, FIELD TESTING GENETICALLY MODIFIED ORGANISMS: FRAMEWORK FOR DECISIONS 14 (1989), <http://www.nap.edu/catalog/1431/field-testing-genetically-modified-organisms-framework-for-decisions>.

63. See *id.* at 14-15.

64. See *id.* at 15.

65. Strauss, *supra* note 8, at 779 (presenting that the US does not segregate from non-GE crops because, in stark contrast to the EU, U.S. law does not require labeling, segregating, or monitoring of these crops).

66. *Id.* at 779-81.

67. Lau, *supra* note 11.

68. See Doh & Guay, *supra* note 4, at 60-61 (asserting that NGOs in the United States had not succeeded in extending these adversarial relationships to biotechnology policy-making). The NGOs in the United States stated their failure to influence GE regulations stemmed from “a lack of news-grabbing biotechnology”, and failure to use the

structures, NGOs play a different role in shaping food law and corporate responsibility in the United States than in Europe.⁶⁹ Institutional variation between the United States and Europe emanates from differences in social, political, economic, historical, and geographic experiences.⁷⁰

The United States focuses on federal and sub-federal institutions.⁷¹ The focus on federalism and the separation of national powers stems from a historical experience, emphasizing a decentralized political structure.⁷² The resulting decentralized political system creates numerous access points for NGOs to influence the government.⁷³ However, NGOs have no formal standing in the public policy process.⁷⁴ Therefore, NGOs fail to successfully lobby in the United States.

While the United States is focused on federal and sub-federal institutions, Europe is focused on EU-wide and national institutions.⁷⁵ This institutional structure affords NGOs success when influencing regulation. In addition, interest groups have a formal place in the policy-making process.⁷⁶ For NGOs, the main access points to influence policy-making are the Commission and Parliament.⁷⁷ The Commission is the initial drafter of legislation and welcomes the opportunity to receive information from lobbyists.⁷⁸ Lastly, multiparty political systems exist in most EU member states, making it easier for

judicial system. *Id.* Note, that NGOs have gained some success in influencing GE labeling regulations. *See generally* 7 U.S.C.A. § 1639b (West).

69. *See id.* at 49 (explaining that the main institutions in Europe and the United States include political, legal, and social).

70. *See generally*, NEW DIMENSIONS IN THE HUMANITIES AND SOCIAL SCIENCES (Harry R. Garvin ed., Bucknell University Press 1977).

71. *See* Cristina Rodriguez, *Negotiating Conflict Through Federalism: Institutional and Popular Perspectives*, 123 YALE L.J., 2094, 2096 (2014) (emphasizing that having many institutions with lawmaking power enables overlapping political communities to work toward national integration, while preserving governing spaces for meaningful disagreement when consensus fractures or proves elusive).

72. *See id.* at 2099-3000.

73. *See* Doh & Guay, *supra* note 4, at 52 (2006) (stating that the access points that were created include the executive, legislative, and judicial branches at the national level, as well as comparable entities at the state and local levels).

74. GLOBALIZATION AND NGOS: TRANSFORMING BUSINESS, GOVERNMENT, AND SOCIETY 25 (Jonathan P. Doh & Hildy Teegan eds., 2003).

75. *See* Doh & Guay, *supra* note 4, at 49.

76. GLOBALIZATION AND NGOS, *supra* note 74, at 25.

77. *See* Doh & Guay, *supra* note 4, at 53.

78. *Id.*

NGOs to form political parties and win seats in the national legislature than do two-party systems, which exist in the USA and the UK.⁷⁹

Institutional variation between the United States and Europe stem from social, political, economic, historical, and geographic experiences.⁸⁰ EU NGOs' influence on food law was successful; however, NGOs' in the United States failed to influence food law. Due to the varying institutional structures, public universities and private colleges, rather than NGOs, should play a role in shaping food law and corporate responsibility in the United States.

III. The United States Should Allow Public Universities and Private Colleges to Shape Food Law and Corporate Responsibility

The United States' institutional structure is too different from Europe's; NGOs cannot successfully shape food law and corporate responsibility. However, some type of institution or organization must serve as the counterweight to capitalism and globalization in the United States. Without that counterweight, the food industry will lobby the governmental systems, producing monetary or other private benefits for industry, or influencing government legislation in ways that undercut any attempts to serve the broader public interests.⁸¹ In addition,

79. PETERSON, *supra* note 50, at 11 (stating that the multiparty political system contributes to higher level of environmental consciousness among European voters than the average US voters).

80. *See generally*, NEW DIMENSIONS IN THE HUMANITIES AND SOCIAL SCIENCES, *supra* note 70.

81. Craig Holmana & William Luneburg, *Lobbying and Transparency: A Comparative Analysis of Regulatory Reform*, 1 INTEREST GROUPS & ADVOCACY, 75, 78 (2012). The food industry lobbying for its own interests, and influencing consumers, is best demonstrated through the Dietary Supplement Health and Education Act (DSHEA). Dietary Supplement Health and Education Act of 1994 (DSHEA), Pub. L. No. 103-417, 108 Stat. 4325, (codified as amended in scattered sections of 21 U.S.C. §§ 301-399 (2000)). DSHEA worked to prevent the federal government's interference with the supplement industry in four ways. *See generally* Melissa Card & John Abela, *Self-Prescribing a Legal Overdose or Duped into Deficiency? – Should Dietary Supplement Regulations Be Changed to Avoid Health Adversities?* IFIS: FOOD AND HEALTH INFORMATION, (forthcoming fall 2017). The first means was the expansion of the definition of a dietary supplement. Prior to DSHEA, dietary supplements were defined as vitamins and minerals. *Id.* DSHEA expanded the statutory definition to include herbal, botanical, and diet products. *Id.* The second means in which DSHEA prevented federal

NGOs create and institutionalize new norms in society promoting what they perceive to be more ethical and socially responsible business practices.⁸² The issue becomes which institution should serve as a counterweight to capitalism and globalization, and promote ethical and socially responsible business practices in food law? This section concludes that, in the United States, public universities and private colleges should shape food law and corporate responsibilities, rather than NGOs. This section argues that institutional structures in the United States include public universities and private colleges, therefore, public universities and private colleges should have a seat at the table when it comes to policy-making. Additionally, this section emphasizes that public universities and private colleges are the best places for collaboration amongst diverse perspectives to create solutions addressing industry needs, while also counteracting capitalism and globalization.

In part, NGOs are ineffective at influencing United States' law and corporate responsibility because there are too many access points, and NGOs have no formal standing in the public policy process.⁸³ However, universities and colleges have a direct access point to influence food law and corporate responsibility. University and college members comprise the Advisory Committees of the FDA.⁸⁴ The Advisory Committees provide advice to the FDA Commissioner on specific complex

intervention was that manufacturers did not need to prove that their product was safe prior to manufacturing them. *Id.* The third means in which DSHEA prevented federal intervention was that DSHEA grandfathered in the safety of supplements that were marketed in the United States prior to October 15, 1994. *Id.* The last means in which DSHEA prevented federal intervention was that DSHEA allowed supplement manufacturers to label their products with statements of nutritional support. *See also* MARION NESTLE, *FOOD POLITICS: HOW THE FOOD INFLUENCES NUTRITION AND HEALTH* (3rd ed. 2013).

82. *See Jay Aronson, Non-governmental Organizations Lecture*, CARNEGIE MELLON, (Sept. 28, 2017), <https://www.cs.cmu.edu/~iliano/courses/07F-CMU-CS502/lectures/TGD07-L16-NGO.pdf> (stating that the counterweight to the impersonal forces of governmental bureaucracy and globalization is non-governmental organizations).

83. *See Doh & Guay, supra* note 4, at 52.

84. *Roster of the Science Board to the Food and Drug Administration*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/ScienceBoardtotheFoodandDrugAdministration/ucm115370.htm> (last updated June 29, 2017).

scientific and technical issues that are important to the FDA.⁸⁵ The Advisory Committees' advice influences the FDA's decisions on various regulations, and provides functions that support the FDA's mission of protecting and promoting public health.⁸⁶

In addition to having access to the FDA, universities and colleges are better suited to influence food law and corporate responsibility because universities and colleges afford collaboration from a diverse group of individuals who are well-educated, and have both industry's and consumers' perspectives in mind. In fact, universities and colleges can serve the FDA even better than current advisory committees because universities and colleges can assess the science, as well as the economic impact, policy considerations, social injustice concerns, and legal issues.⁸⁷ For example, genetic engineering would have benefitted from diverse viewpoints because GE foods require people to reimagine the relationship between science, politics, health, and society.⁸⁸ Therefore, universities contain the various disciplines that are necessary to reach a conclusion regarding science, politics, and society.

IV. Conclusion

Disputes between Europe and the United States over real and perceived concerns about food safety will continue due to different perspectives on corporate responsibility and different institutional processes for settling those differences. While NGOs are the counterweight to capitalism and globalization, the United States' institutional process does not allow for NGOs to have an influence on food law and corporate responsibility. In

85. *Science Board to the Food and Drug Administration*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/ScienceBoardtotheFoodandDrugAdministration/default.htm> (last updated May 2017). Additionally, the Science Board will provide advice that supports the FDA in keeping pace with technical and scientific developments, and it will provide expert review of Agency sponsored intramural and extramural scientific research programs. *Id.*

86. *Committees & Meeting Materials*, U.S. FOOD & DRUG ADMIN. <https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/default.htm> (last updated May 2017).

87. *E.g., Food Law & Policy*, CENTER FOR HEALTH LAW & POLICY INNOVATION, <http://www.chlpi.org/food-law-and-policy/> (last visited Sept. 8, 2017).

88. KELLY CLANCY, *THE POLITICS OF GENETICALLY MODIFIED ORGANISMS IN THE UNITED STATES AND EUROPE* 4 (2016).

the United States, public universities and private colleges should shape food law and corporate responsibilities, rather than NGOs. The institutional structures in the United States include public universities and private colleges, therefore, public universities and private colleges have a seat at the table when it comes to policy-making. Additionally, public universities and private colleges are the best places for collaboration amongst diverse perspectives to create solutions addressing industry's needs, while also acting as a counterweight to capitalism and globalization.

Muddying the Waters: Catfish Inspection Authority Transitions to the Food Safety and Inspection Service

Michelle Johnson-Weider*

SUMMARY

Over the last 20 years, steadily increasing imports into the United States of Vietnamese fish similar to domestically raised catfish have put tremendous strain on an American industry already struggling from natural disasters and rising food and fuel costs.¹ American catfish producers have fought declining market share through trade remedies and intensive lobbying efforts that resulted in federal laws to prohibit Vietnamese fish from being marketed as catfish, an effort bitterly opposed by free trade advocates and which has done little to stem the declining sales of domestic catfish.² The small yet regionally important industry has managed outsized legislative victories thanks to a few well-placed allies in Congress.³ On September 1, 2017, responsibility for the inspection of catfish shifted completely from the Food and Drug Administration, which has jurisdiction over most food and all other seafood, to the Food Safety and Inspection Service of the United States Department of Agriculture, marking the end of an 18-month transitional period.⁴ Because it is generally more difficult legislatively to eliminate existing programs than it is to

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1. *See infra* pp. 3-5.

2. *See infra* p. 10.

3. *See infra* pp. 8-10.

4. Mandatory Inspection of Fish of the Order Siluriformes and Products Derived From Such Fish, Final Rule, 80 Fed. Reg. 75590 (Dec. 2, 2015) (codified at 9 C.F.R. pts. 300).

establish new ones, this shift should insulate domestic catfish producers from further legislative changes, though it remains to be seen whether the new inspection regime is sufficient to save the American catfish industry.

I. Background: Decline of an American Industry

Aquaculture, the “cultivation of aquatic organisms in controlled aquatic environments,” is the source of almost half of all seafood consumed by humans worldwide.⁵ In 2009, the United States was the second largest consumer of seafood and the largest importer, importing between 91 and possibly as much as 94 percent of all seafood eaten in the United States.⁶ In 2016, the seafood trade deficit exceeded \$14 billion.⁷

Domestic aquaculture production is a relatively small business in the United States, accounting for only 0.4 percent of the total market value of agricultural products sold in the United States in 2012.⁸ However, farm-raised catfish is very important to the economy of several southern states, particularly Mississippi, Alabama, and Arkansas.⁹ While total domestic aquaculture farm sales in the United States have grown slowly, the percentage represented by catfish (as reported to the Census of Aquaculture) shrunk from 46 percent in 1998 to 27 percent in 2013.¹⁰

5. Michael Rubino, *What is Aquaculture?* NAT'L OCEANIC AND ATMOSPHERIC ADMIN. (June 2011), <http://www.noaa.gov/stories/what-aquaculture>.

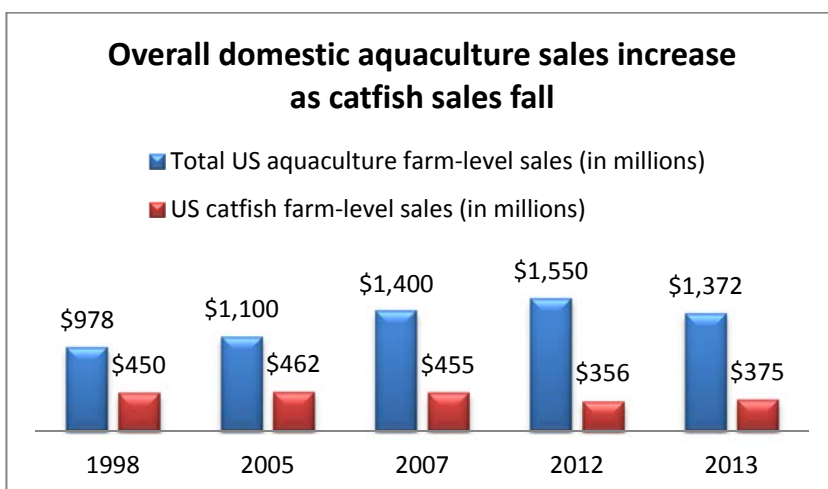
6. *Aquaculture in the United States*, NAT'L OCEANIC AND ATMOSPHERIC ADMIN. FISHERIES, http://www.nmfs.noaa.gov/aquaculture/aquaculture_in_us.html (last visited on Sept. 23, 2017) [hereinafter NOAA FISHERIES]; U.S. GOV'T ACCOUNTABILITY OFF., IMPORTED FOOD SAFETY: FDA'S TARGETING TOOL HAS ENHANCED SCREENING, BUT FURTHER IMPROVEMENTS ARE POSSIBLE 1 (2016), <https://www.gao.gov/assets/680/677538.pdf> [hereinafter FDA'S TARGETING TOOL].

7. NOAA FISHERIES, *supra* note 6.

8. U.S. DEP'T OF AGRIC., NAT'L AGRIC. STATISTICS SERV., 2012 CENSUS OF AGRICULTURE: UNITED STATES SUMMARY AND STATE DATA 9 (Vol. 1, Part 51 2014), https://agcensus.usda.gov/Publications/2012/Full_Report/Volume_1,_Chapter_1_US/usv1.pdf [hereinafter 2012 CENSUS OF AGRICULTURE].

9. *Catfish*, MISSISSIPPI STATE UNIVERSITY EXTENSION SERVICE (Aug. 21, 2014), <http://extension.msstate.edu/agriculture/catfish>.

10. U.S. DEP'T. OF AGRIC., NAT'L AGRIC. STATISTICS SERV., 2005 CENSUS OF AQUACULTURE, 2002 CENSUS OF AGRICULTURE 5 (Vol. 3, Special Studies Part 2 2006) [hereinafter 2005 CENSUS OF AQUACULTURE]; 2012 CENSUS OF AGRICULTURE, *supra* note 8 at 9, 25; U.S. DEP'T. OF AGRIC., NAT'L AGRIC. STATISTICS SERV., 2013 CENSUS OF AQUACULTURE, 2012 CENSUS OF AGRICULTURE 14, 28-29 (Vol. 3, Special Studies Part 2 2014) [hereinafter 2013 CENSUS OF AQUACULTURE].



Beginning in the late 1990s, with the end of the US trade embargo on Vietnam,¹¹ catfish producers in the United States faced increasing competition from foreign imports, primarily frozen fillets of “Vietnamese catfish,” about 14.8 million pounds of which were imported during the first seven months of 2006, a 780-percent increase over the same period in 2004.¹² These imports are a direct result of the normalizing of trade relations between the United States and Vietnam, a process that led to the signing of the U.S.-Vietnam Bilateral Trade Agreement in December 2001 and continued into Obama Administration negotiations over the Trans-Pacific Partnership.¹³

The Vietnamese imports are enormously controversial.¹⁴ American producers argue that the imported fish, raised on small farms in the Mekong River Delta,¹⁵ are not catfish at all, but are

11. See, e.g., Douglas Jehl, *Opening to Vietnam; Clinton Drops 19-Year Ban on U.S. Trade with Vietnam; Cites Hanoi's Help on M.I.A.'s*, NEW YORK TIMES (Feb. 4, 1994), <http://www.nytimes.com/1994/02/04/world/opening-vietnam-clinton-drops-19-year-ban-us-trade-with-vietnam-cites-hanoi-s.html>.

12. DAVID J. HARVEY, U.S. DEP'T. OF AGRIC., *AQUACULTURE OUTLOOK: DOMESTIC AQUACULTURE COMPETING WORLDWIDE 5* (2006), <http://usda.mannlib.cornell.edu/usda/ers/LDP-AQS/2000s/2006/LDP-AQS-10-05-2006.pdf>.

13. MICHAEL F. MARTIN, CONGRESSIONAL RESEARCH SERVICE, *U.S.-VIETNAM ECONOMIC AND TRADE RELATIONS: ISSUES FOR THE 114TH CONGRESS 1, 3* (2016), <https://fas.org/sgp/crs/row/R41550.pdf>.

14. *Id.* at 12-13.

15. See, e.g., David Bennett, *U.S., Vietnam in word battle over catfish*, DELTA FARM PRESS (June 14, 2002), <http://deltafarmpress.com/us-vietnam-word-battle-over-catfish>.

intentionally marketed using a false name to take advantage of American consumers' appreciation of the familiar domestic fish, an appreciation developed, in part, through an expensive advertising campaign paid for by American producers.¹⁶

According to the scientific classification of species, the order *Siluriformes* consists of what are commonly called catfish in English: scaleless, whiskered, naturally bottom-feeding fish with defensive fin spines.¹⁷ These fish are fished, farmed, and eaten throughout the world under a variety of common names.¹⁸ Catfish native to North America are members of the family *Ictaluridae*, found primarily in the southern United States, where they are farmed in open freshwater ponds¹⁹ Vietnamese "catfish" are primarily of the family *Pangasiidae* and known by the common names basa, swai, and tra.²⁰ Airbreathing "catfish" belong to the family *Clariidae* and are found in Africa, Syria, and southern and western Asia.²¹ Throughout this article, the term "catfish" refers to all members of the order *Siluriformes*, unless otherwise specified.

Just as in modern livestock production, competitive advantage in catfish production often depends on reducing both the cost of inputs (feed) and the time required to achieve harvest weight, while increasing the quantity of meat produced from a single animal.²² American channel catfish, native to the Mississippi River Delta, typically take 18 months to 2 years to

16. *Id.*

17. *See id.*

18. John G. Lundberg & John P. Friel, *Siluriformes: Catfishes*, TREE OF LIFE WEB PROJECT, <http://tolweb.org/Siluriformes/15065/2003.01.20> (last updated Jan. 20, 2003).

19. Larry Page & John G. Lundberg, *Ictaluridae: North American Freshwater Catfish, Bullhead Catfishes*, TREE OF LIFE WEB PROJECT, <http://www.tolweb.org/Ictaluridae/15230> (last updated May 23, 2007); *See Background*, U.S. DEP'T OF AGRIC. ECON. RES. SERV., <http://www.ers.usda.gov/topics/animal-products/aquaculture/background.aspx> (last updated Oct. 19, 2016).

20. Bennett, *supra* note 15.

21. *Family Clariidae: Airbreathing Catfishes*, FISHBASE, <http://www.fishbase.org/summary/FamilySummary.php?ID=139> (last visited Oct. 31, 2017).

22. *See, e.g.,* Terrill R. Hanson et al., *Comparative Advantages of the U.S. Farm-Raised Catfish Industry: A Cross-Regional Analysis*, 17 AQUACULTURE ECON. & MGMT. 87 (2013).

reach a harvest weight of 1 to 2 pounds;²³ Vietnamese catfish, native to the Mekong River Delta, are generally harvested after 8 to 10 months, at a weight of 2 to 3 1/2 pounds.²⁴ Vietnam is the world's largest producer of *Pangasius hypophthalmus* and exports frozen fish throughout the world.²⁵

American catfish producers blame the large increase in US imports of Vietnamese fish for declining domestic prices and market share.²⁶ As shown on the following chart (derived from data in the catfish processing reports of the National Agricultural Statistics Service), the quantity of farm-raised catfish processed in the United States has declined steeply as imports of fish belonging to the order *Siluriformes* have increased.²⁷

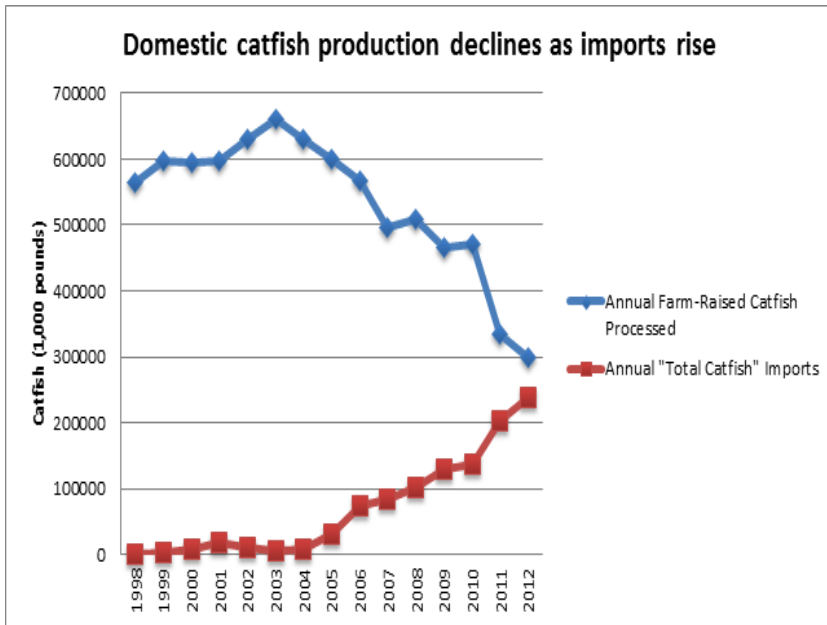
23. *Frequently Asked Questions*, THE CATFISH INSTITUTE, <http://uscatfish.com/faqs/> (last visited Oct. 31, 2017).

24. *Pangasius Farming: An Overview*, THE FISH SITE (Aug. 17, 2015, 1:00 AM), <https://thefishsite.com/articles/pangasius-farming-an-overview>.

25. *Cultured Aquatic Species Information Programme: Pangasius hypophthalmus*, U.S. FOOD AND AGRIC. ORG., http://www.fao.org/fishery/culturedspecies/Pangasius_hypophthalmus/en (last visited Dec. 14, 2017).

26. *E.g.*, Bennett, *supra* note 15.

27. U.S. DEP'T. OF AGRIC. STATISTICS SERV., AGRICULTURAL STATISTICS BOARD, CATFISH PROCESSING 1, 8 (2013), <http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1015> (surveying reports from Dec. 23, 1999, through Mar. 20, 2013).



During the period represented above,²⁸ the average price paid to catfish producers increased from 0.69 cents per pound (January 1998) to 0.82 cents per pound (January 2013), failing to keep pace with soaring commodity costs that made catfish feed almost prohibitively expensive.²⁹

As the total catfish market share has declined, the effects on states has varied. In the following chart (derived from data reported to the 2005 Census of Aquaculture³⁰ and 2012 Census of Agriculture³¹), note in particular the overall decline in Mississippi's total catfish sales and the near total failure of the Louisiana catfish industry (blamed on the devastation of the

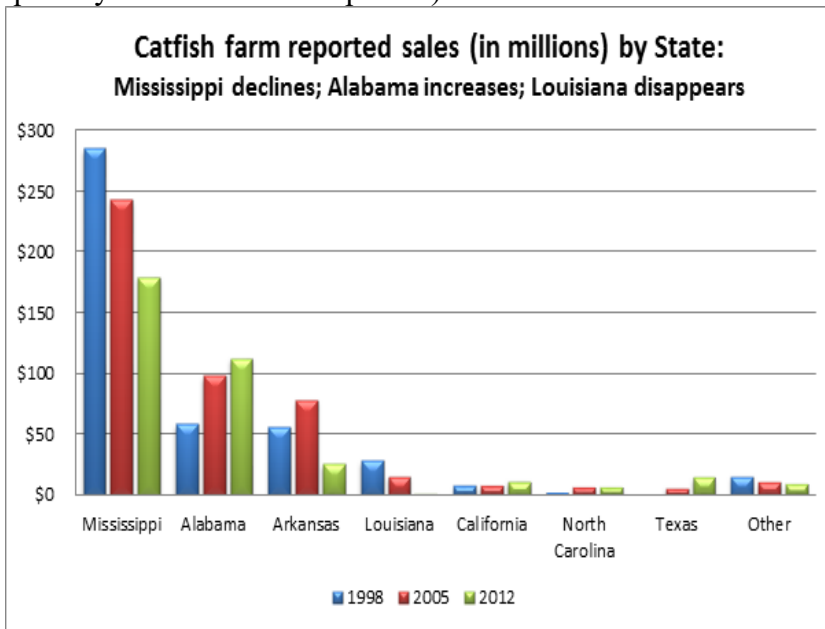
28. See *supra* Figure, domestic catfish production declines as imports rise.

29. E.g., John H. Cushman, Jr., *Catfish Farmers Fight Fish Glut and High Feed Prices*, NEW YORK TIMES (Aug. 31, 2012), <http://www.nytimes.com/2012/09/01/business/markets-and-drought-hurting-us-catfish-producers.html>; David Bennett, *Catfish industry swamped by rising costs*, DELTA FARM PRESS (Aug. 8, 2008), <http://deltafarmpress.com/catfish-industry-swamped-rising-costs>.

30. 2005 CENSUS OF AQUACULTURE, *supra* note 10, at 22.

31. 2012 CENSUS OF AGRICULTURE, *supra* note 8, at 395.

2005 hurricanes, rising fuel and feed costs, and the surging quantity of Vietnamese imports³²):



II. A Complicated Regulatory Framework

Three federal agencies are directly involved in regulating the catfish industry.³³ Catfish producers can choose to voluntarily contract with the Seafood Inspection Program of the National Oceanic and Atmospheric Administration (“Department of Commerce”) to inspect processing facilities on a fee-for-service basis and certify the facilities as Sanitarily Inspected Fish Establishments.³⁴ The Food and Drug Administration (“FDA”) of the Department of Health and

32. E.g., Johnny Morgan, *Economic downturn, imports hurt catfish industry*, DELTA FARM PRESS (Mar. 25, 2011), <http://deltafarmpress.com/markets/economic-downturnimports-hurt-catfish-industry>.

33. Veronique de Rugy, *How Government Cronies Redefined the Catfish*, REASON (Jun. 30, 2016), <https://reason.com/archives/2016/06/30/how-government-cronies-redefine-the-cat/print>.

34. *Program Services*, NAT’L OCEANIC AND ATMOSPHERIC ADMIN. FISHERIES, http://www.seafood.nmfs.noaa.gov/program_services/program_services.html (last visited Sept. 24, 2017); *Long History of Quality*, THE CATFISH INSTITUTE, <http://uscatfish.com/about/> (last visited Sept. 24, 2017).

Human Services regulates the safety of almost all domestic or imported food in the United States and ensures that the food is properly processed, packaged, and labeled;³⁵ until recently the FDA's authority extended to all seafood, including catfish.³⁶ The Food Safety and Inspection Service ("FSIS") of the U.S. Department of Agriculture ("USDA") has similar responsibility over commercial meat, poultry, and egg products and, since September 1, 2017, catfish.³⁷

FDA and FSIS take different approaches to food safety due to the vastly different scopes of their mandates. FDA focuses on establishing guidance and regulations, including a model Food Code for use by state, tribal, and local agencies with a primary responsibility of ensuring retail food safety,³⁸ and Hazard Analysis & Critical Control Points ("HACCP") for specific industries.³⁹ The Seafood HACCP program requires each seafood processor to analyze and address their particular food safety hazards through development and implementation of a plan.⁴⁰ FDA may then verify compliance with the plan through on-site and records inspections or, in the case of foreign processing facilities, examination of records demonstrating processor compliance with equivalent foreign requirements.⁴¹

35. *Ingredients, Packaging and Labeling*, U.S. FOOD AND DRUG ADMIN., <https://www.fda.gov/food/ingredientspackaginglabeling/> (last Updated Dec. 21, 2016).

36. *See generally* Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. §§ 301-399g (West 2017).

37. *See generally* Federal Meat Inspection Act, 21 U.S.C. §§ 601-683 (2015); Egg Products Inspection Act, 21 U.S.C. §§ 1031-1056 (2015); Poultry Products Inspection Act, 21 U.S.C. §§ 451-471 (2015); Agricultural Marketing Act of 1946, 21 U.S.C. §§ 1621-1639j (2016).

38. *FDA Food Code*, U.S. FOOD AND DRUG ADMIN., <https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/default.htm> (last updated Nov. 19, 2017).

39. *Id.*; U.S. FOOD AND DRUG ADMIN., OFFICE OF FOOD SAFETY, SEAFOOD HACCP AND THE FDA FOOD SAFETY MODERNIZATION ACT: GUIDANCE FOR INDUSTRY 3 (2017), <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM569798.pdf>.

40. FDA'S TARGETING TOOL, *supra* note 6, at 7.

41. *Id.*

FDA's approach to seafood safety, particularly in regards to imported seafood, has been widely criticized as ineffective.⁴² FDA does not conduct annual site inspections of all domestic seafood processors and directly inspects only a small percentage of domestic or imported seafood (around 1 percent in the case of imported seafood).⁴³ In 2006, FDA conducted 2,456 inspections out of an estimated total 13,400 domestic seafood processors.⁴⁴

In the case of foreign-processed seafood, FDA targets high-risk imports for inspection at ports of entry and carries out other compliance activities through sampling.⁴⁵ FDA sends only a few inspection teams each year to inspect foreign processors directly.⁴⁶ FDA estimates that about 159 countries export the majority of seafood to the United States, with approximately 14,900 registered foreign firms that export seafood into the United States and a much greater number involved in processing.⁴⁷ However, in each of fiscal years 2004 and 2005, FDA sent inspection teams to only ten countries.⁴⁸ Of the approximately 2,660 importers of seafood into the United States, in 2006, FDA inspected 529.⁴⁹ For many years, domestic catfish producers pointed to the fact that, because FDA inspected such a small percentage of imported fish and foreign processors, and failed to follow through on more criminal prosecutions of importers who mislabeled Vietnamese fish as "catfish," American consumers were unknowingly being exposed to unsafe and mislabeled fish.⁵⁰

42. *E.g.*, U.S. GOV'T ACCOUNTABILITY OFFICE, FOOD SAFETY: FEDERAL OVERSIGHT OF SEAFOOD DOES NOT SUFFICIENTLY PROTECT CONSUMERS 5-6 (2001), <http://www.gao.gov/new.items/d01204.pdf>.

43. ANDREW C. VON ESCHENBACH, U.S. FOOD AND DRUG ADMIN., REPORT TO CONGRESS: FOOD AND DRUG ADMINISTRATION AMENDMENTS ACT OF 2007 (PUBLIC LAW 110-85) SECTION 1006 — ENHANCED AQUACULTURE AND SEAFOOD INSPECTION (2008), <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Seafood/ucm150954.htm>.

44. *Id.*

45. FDA'S TARGETING TOOL, *supra* note 6, at 21-22.

46. *Id.* at 22.

47. VON ESCHENBACH, *supra* note 43.

48. *Id.*

49. *Id.*

50. *E.g.*, Bennett, *supra* note 15.

USDA's FSIS has long had a similar HACCP system in place for meat, poultry, and egg products, but the agency's inspection process is far more robust than FDA's. Approximately 8,000 FSIS inspection personnel conduct on-site inspections of more than 6,000 domestic slaughterhouses and food processors.⁵¹ FSIS inspects all meat, poultry, and processed egg products imported into the United States—more than 3 billion pounds each year—and certifies foreign countries and establishments as being eligible to export food to the United States.⁵² The thoroughness of the FSIS inspection approach, particularly in regards to imported food, makes the agency attractive to anyone who, like most domestic catfish producers, is concerned about FDA's inspection and enforcement record.

III. Initial Congressional Response: Politics, Power, and Labels

Federal legislative action on regional issues like catfish production or ethanol is heavily influenced by the geographic distribution of power in Congress. Interest groups can do well even with the support of only a few well-placed members. Because almost all legislation originates from, or is referred to a congressional committee, members of Congress who serve on the committee with jurisdiction over a particular issue have outsized influence over how that issue is addressed throughout the legislative process.⁵³ A chair, ranking member, or even a senior member of a committee has a much better chance than other members of Congress of ensuring that the member's priorities are considered in development of the legislation.⁵⁴ Members who serve in leadership positions in the House and Senate also have more opportunities to see that their legislative agenda is taken into account.⁵⁵

51. U.S. DEP'T. OF AGRIC., FOOD AND SAFETY INSPECTION SERVICE: PROTECTING PUBLIC HEALTH AND PREVENTING FOODBORNE ILLNESS 7 (2014), <http://www.fsis.usda.gov/wps/wcm/connect/7a35776b-4717-43b5-b0ce-aeec64489fbd/mission-book.pdf>.

52. *Id.*

53. See *About the Senate Committee System*, U. S. SENATE, https://www.senate.gov/general/common/generic/about_committees.htm (last visited 31 Oct. 2017).

54. *Id.*

55. *Id.*

Domestic catfish producers have one well-placed friend in particular to thank for many of the legislative changes ultimately made on their behalf. Senator Thad Cochran, a Republican from Mississippi, is serving his seventh term in the Senate, where he is the third-most senior Senator⁵⁶ and Chairman of the powerful Senate Appropriations Committee (2005-2006, 2015-present⁵⁷). He is also a senior member, former chair (2003-2005), and ranking member (2013-2014) of the Committee on Agriculture, Nutrition, and Forestry (“Senate Ag Committee”), a committee on which he has served continuously since first becoming a Senator in 1979.⁵⁸ Senator Cochran is widely credited with decades of advocacy for domestic catfish producers and using his position to pressure other Senators, who might be otherwise inclined to vote against such measures because of free trade concerns.⁵⁹

In the Senate, jurisdiction over catfish would historically and logically seem to rest in the Committee on Health, Education, Labor, and Pensions, which has oversight responsibilities for the Food and Drug Administration.⁶⁰ The Senate Ag Committee, which has jurisdiction over FSIS, agricultural production, and a myriad of other issues covered by the massive Farm Bill, would be another obvious choice.⁶¹ However, Congress initially addressed the concerns of domestic catfish producers through the appropriations process, by enacting restrictions on fiscal year 2002 funding for FDA, which at the time had regulatory authority over enforcing the correct labeling, for marketing purposes, of all fish, whether domestic or

56. *Id.*

57. *Biography*, OFFICIAL WEBSITE OF SENATOR THAD COCHRAN, <http://www.cochran.senate.gov/public/index.cfm/biography> (last visited Dec. 14, 2017).

58. *Id.*

59. *Id.*

60. See David Rogers, *Catfish swimming into trade debate*, POLITICO (May 18, 2015), <http://www.politico.com/story/2015/05/catfish-trade-debate-118070>; Eric Bradner, *Cochran's last stand in catfish war*, POLITICO (Aug. 16, 2013), <http://www.politico.com/story/2013/08/thad-cochran-catfish-095620>.

61. *Health*, U.S. SENATE COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS, <http://www.help.senate.gov/about/issues/health> (last visited Sept. 24, 2017).

imported.⁶² The funding restriction prohibited FDA from allowing any fish or fish products labeled as “catfish” to enter the United States unless the fish was classified within the family *Ictaluridae*.⁶³ In other words, only catfish native to North America could be legally imported into or sold in the United States under the name “catfish.”

Language in an appropriations bill is generally effective for only one fiscal year.⁶⁴ Congress extended and formalized the labeling requirements in the 2002 Farm Bill, by requiring FDA to consider as “misbranded” any non-*Ictaluridae* fish marketed as catfish.⁶⁵ The use of the term “misbranded” allowed FDA to pursue enforcement actions against violators of the new catfish labeling requirements, although Congress did not provide any additional funding for FDA to carry out these responsibilities.⁶⁶ The joint explanatory statement of the committee of conference stated that the provision “clarifies that the term catfish may not be considered a common or usual name for the fish *Pangasius bocourti*, or any other fish not classified within the family *Ictalariidae* [*sic*],” demonstrating that the legislative intent was to target Vietnamese catfish.⁶⁷ The 2002 Farm Bill also included country-of-origin labeling provisions that required farm-raised fish at retail sale to be labeled with its country of origin.⁶⁸ A United States label for farm-raised fish is only permitted for fish “hatched, raised, harvested, and processed in the United States.”⁶⁹ While domestic catfish producers hailed these

62. *Jurisdiction*, U.S. SENATE COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY, <http://www.agriculture.senate.gov/about/jurisdiction> (last visited Sept. 24, 2017).

63. Guidance for Industry; Implementation of Section 755 of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 2002, Pub. L. No. 107-76, § 755 (2001) Regarding Common or Usual Names for Catfish; Availability, 67 Fed. Reg. 5604 (Feb. 6, 2002).

64. *Id.*

65. *Id.*

66. Farm Security and Rural Investment Act of 2002, § 10806(a), 21 U.S.C. § 321d(a) (2015).

67. See H.R. Rep. No. 107-424, at 657 (2002) (Conf. Rep.).

68. *Id.*

69. Farm Security and Rural Investment Act of 2002, Publ. L. No. 107-171, § 10816, 116 Stat. 533.

changes, they proved unpopular with free trade advocates, especially those trying to normalize trade with Vietnam.⁷⁰

IV. Antidumping Order: American Catfish Producers Versus Vietnam

The major domestic catfish industry trade association, which had lobbied Congress for the labeling changes,⁷¹ soon expressed disappointment that FDA was not doing more to inspect imported catfish and prosecute violators of the new requirements.⁷² The Catfish Farmers of America continued the fight on its own, hiring investigators to discover and report violations to FDA and lawyers to file an antidumping petition with the United States International Trade Commission.⁷³ The petition, filed in July 2002, alleged that Vietnam was responsible for falling domestic catfish prices due to the imports of frozen fish fillets at less than fair value.⁷⁴ The Commission and the Department of Commerce sided with the producers, issuing an antidumping duty order,⁷⁵ which required U.S. Customs and Border Protection to assess antidumping duties on the relevant Vietnamese frozen fish imports.⁷⁶ After both the five-year review in 2009 and the second review in 2014, the Commission upheld the initial antidumping duty order, determining that revocation of the order “would be likely to lead to continuation or recurrence of material injury” to the domestic catfish industry.⁷⁷

70. Bruce A. Babcock & Chad E. Hard, *Judging the Performance of the 2002 Farm Bill*, 11 IOWA AG. REV. 1, 1 (2005).

71. See Bennett, *supra* note 15.

72. *Id.*

73. *E.g., id.*; David Bennett, *Catfish Farmers of America: Anti-dumping petition filed against Vietnam*, DELTA FARM PRESS (Aug. 9, 2002), <http://deltafarmpress.com/catfish-farmers-america-anti-dumping-petition-filed-against-vietnam>.

74. *Id.*

75. Notice of Antidumping Duty Order: Certain Frozen Fish Fillets from the Socialist Republic of Vietnam, 68 Fed. Reg. 47909 (Aug. 12, 2003).

76. *Id.*

77. U.S. INT'L TRADE COMM'N, CERTAIN FROZEN FISH FILLETS FROM VIETNAM, INVESTIGATION NO. 731-TA-1012 (REVIEW) 1 (2009), https://www.usitc.gov/publications/701_731/pub4083.pdf; U.S. INT'L TRADE COMM'N, CERTAIN FROZEN FISH FILLETS FROM VIETNAM, INVESTIGATION NO. 731-TA-1012 (SECOND REVIEW) 1 (2014), https://www.usitc.gov/publications/701_731/pub4498.pdf.

As demonstrated earlier in the charts showing domestic production and catfish market share, the situation for domestic catfish producers temporarily improved during this period. Ultimately, however, the initial congressional action and the antidumping order failed to stop the rise in Vietnamese imports.⁷⁸ Domestic catfish producers pressured state legislatures to enact state catfish labeling laws.⁷⁹ As Congress began consideration of the 2008 Farm Bill, producers lobbied for a new federal legislative fix, one that would represent a fundamental change in how imported catfish is inspected.

V. Congressional Response: Shifting Inspection Responsibility to FSIS

In the 2008 Farm Bill, Congress began shifting responsibility for catfish from FDA to FSIS.⁸⁰ The first change required the Secretary of Agriculture to establish “a voluntary fee based grading program for all fish of the order Siluriformes.”⁸¹ Congress then amended the Federal Meat Inspection Act to include “catfish, as defined by the Secretary,” thus requiring FSIS to conduct catfish inspections and ensure the proper labeling of catfish.⁸² This new responsibility would not take effect until the Secretary of Agriculture issued final regulations, which Congress directed the Secretary to do, in consultation with FDA, not later than 18 months after the date of

78. *US Gets Hooked on Vietnamese Catfish*, GRO INTELLIGENCE (Oct. 14, 2016), <https://gro-intelligence.com/insights/us-vietnam-catfish-production>.

79. *E.g., Summary of State Catfish Country of Origin Laws*, CATFISH FARMERS OF AMERICA, <http://www.catfishfarmersofamerica.com/countryoforiginlabelinglaws/> (last visited Dec. 15, 2017) (noting state catfish labeling laws enacted by Louisiana (effective 2009), Tennessee (2010), Mississippi (2013), Alabama (2015), and Arkansas (2016)); Hanna Raskin, *Catfish Industry Fighting for New Labeling Law in Texas*, DALL. OBSERVER (Mar. 2, 2011), <http://www.dallasobserver.com/restaurants/catfish-industry-fighting-for-new-labeling-laws-in-texas-7043293>.

80. Dan Flynn, *Agencies Reach Catfish Inspection Agreement Required by Farm Bill*, FOOD SAFETY NEWS (May 14, 2014), <http://www.foodsafetynews.com/2014/05/catfish-agreement-called-for-in-farm-bill-reached-by-agencies/#.WjNHt9-nHIU>.

81. Agricultural Marketing Act of 1946, § 203(n), 7 U.S.C. § 1622(n) (2016).

82. Food, Conservation, and Energy Act of 2008, Publ. L. No. 110-234, § 11016(b), 122 Stat. 2130, amending 21 U.S.C. § 601(w)(2) (2013) (amended by Act Feb. 7, 2014).

enactment of the 2008 Farm Bill (June 18, 2008).⁸³ The joint explanatory statement of the committee of conference stated, “It is the intent of Congress that catfish be subject to continuous inspection and that imported catfish inspection programs be found to be equivalent under USDA regulations before foreign catfish may be imported into the United States.”⁸⁴

While the legislative text anticipated that FSIS would start catfish inspection sometime in 2010,⁸⁵ reality proved much different. Congress frequently imposes deadlines in legislation that agencies are unable or unwilling to meet and in the case of catfish inspection, it seemed that the Obama Administration’s trade goals and fiscal priorities did not align with the new congressional mandate.⁸⁶ The Secretary of Agriculture did not even issue a proposed regulation until early 2011.⁸⁷ In the proposed rule, the Secretary requested public comments on two options for defining “catfish:” the first, that the term include only fish of the family *Ictaluridae* and the second, that the term include all fish of the order *Siluriformes*.⁸⁸ As it turned out, Congress would intervene again long before the Secretary finalized the regulation.

During the debate over the 2014 Farm Bill, which began in 2012, members who wanted to return catfish inspection to FDA, so as to prevent further trade disruptions, scored an initial victory against those who wanted FSIS responsibility.⁸⁹ Senators John Kerry (D-MA) and John McCain (R-AZ) sponsored an

83. *USDA Releases Final Rule Establishing Inspection Program for Siluriformes Fish, Including Catfish*, U.S. DEP’T. OF AGRIC. (Nov. 25, 2015), <https://www.fsis.usda.gov/wps/portal/fsis/newsroom/news-releases-statements-transcripts/news-release-archives-by-year/archive/2015/nr-112515-01>.

84. H.R. REP. NO. 110-627, at 938 (2008) (Conf. Rep.).

85. *Update to CFP on FSIS Activities*, FOODPROTECT, <http://www.foodprotect.org/media/reportdate/8-08%20USDA-FSIS%20Report.pdf> (last visited Dec. 14, 2017).

86. David Bennett, *Obama budget would shutter USDA catfish inspection program*, DELTA FARM PRESS (Apr. 11, 2013), <http://deltafarmpress.com/government/obama-budget-would-shutter-usda-catfish-inspection-program>.

87. *Mandatory Inspection of Catfish and Catfish Products*, 76 Fed. Reg. 10434 (proposed Feb. 24, 2011) (to be codified at 9 C.F.R. pt. 300).

88. *Id.*

89. Dan Flynn, *U.S. Catfish Farmers Emerge As Big Winners in 2014 Farm Bill*, FOOD SAFETY NEWS (Jan. 31, 2014), <http://www.foodsafetynews.com/2014/01/u-s-catfish-farmers-emerge-as-big-winners-in-2014-farm-bill/#.WfYooTteDUo>.

amendment to repeal the FSIS catfish inspection program, returning sole authority to FDA.⁹⁰ The amendment was approved by Senate floor vote, undoubtedly assisted by a recent report of the Government Accountability Office (“GAO”) bluntly entitled “Seafood Safety: Responsibility for Inspecting Catfish Should Not Be Assigned to USDA.”⁹¹

Debate over the Farm Bill continued for nearly two years, however, and in the end, the interests of domestic catfish producers prevailed through the efforts of well-placed allies. Senator Blanche Lincoln (D-AR), chair of the Senate Ag Committee from September 2009 to January 2011, and her successor as chair, Senator Debbie Stabenow (D-MI), both supported Senator Cochran’s catfish position during consideration of the 2014 Farm Bill.⁹² Senator John Boozman (R-Ark), one of the few remaining Southerners on the Senate Ag Committee, also supported the interests of his state’s catfish producers.⁹³ Over in the Committee on Agriculture of the House of Representatives, Chairman Frank Lucas (R-OK3) joined Representatives Collin Peterson (D-MN7, ranking member), Rick Crawford (R-AR1), and Martha Roby (R-AL2) in citing food safety to beat back an effort to repeal the FSIS inspection program.⁹⁴

The final 2014 Farm Bill included several provisions affecting catfish producers. Congress directed the Federal Crop

90. *Senators McCain and Kerry on GAO Report Supporting Elimination of USDA Catfish Office*, MORRIS ANDERSON (June 8, 2012), <http://www.morrisanderson.com/resource-center/entry/SENATORS-McCAIN-AND-KERRY-ON-GAO-REPORT-SUPPORTING-ELIMINATION-OF-USDA-CATF/>.

91. *See generally* U.S. GOV’T ACCOUNTABILITY OFF., SEAFOOD SAFETY: RESPONSIBILITY FOR INSPECTING CATFISH SHOULD NOT BE ASSIGNED TO USDA (2012), <http://www.gao.gov/products/GAO-12-411>.

92. Helena Bottemiller, *Lincoln Pushes for USDA Catfish Inspections*, FOOD SAFETY NEWS (May 28, 2010), <http://www.foodsafetynews.com/2010/05/lincoln-again-pushes-for-usda-catfish-inspections/>; *See also* 161 CON. REC. S3015, S3022-24, S3052-53 (daily ed. May 19, 2015) (statement of Sen. Stabenow).

93. *Boozman, Crawford Say Farm Bill Good For Arkansas*, TIMES REC. (Jan. 28, 2014, 5:27 AM, updated 10:33 AM), <http://swtimes.com/news/politics/boozman-crawford-say-farm-bill-good-arkansas>.

94. David Bennett, *House Agriculture Committee debates USDA catfish inspection program*, DELTA FARM PRESS (July 12, 2012), <http://deltafarmpress.com/government/house-agriculture-committee-debates-usda-catfish-inspection-program>.

Insurance Corporation to consider providing margin coverage to catfish producers and authorized emergency disaster assistance for certain producers of farm-raised fish.⁹⁵ Most significantly, however, Congress removed the discretion of the Secretary of Agriculture to define the meaning of “catfish,” stating that the term would mean “all fish of the order Siluriformes.”⁹⁶ When considered in conjunction with the labeling laws already in effect, this meant that a legal double-standard now existed: the broadest possible definition of “catfish” applied in determining which fish were subject to inspection, but the narrowest possible definition applied in determining which fish could be labeled and sold as “catfish.”⁹⁷ Congress directed the Secretary to issue final regulations within 60 days of enactment and to begin carrying out catfish inspection within 1 year, and required the Secretary to execute a memorandum of understanding with FDA to improve interagency communication and ensure that FSIS inspections would not be duplicative with FDA activities.⁹⁸

The joint explanatory statement of the committee of conference explained that the Farm Bill addressed the definition of catfish to speed implementation of FSIS’ inspection program and avoid “arbitrary or unjustifiable distinctions in the level of inspection.”⁹⁹ The conference committee countered points raised in the GAO report and by other opponents, stating that FSIS inspection was necessary to “ensure the safety of the American food supply from food containing dangerous contaminants and banned substances” such as the “inappropriate and unregulated use of chemicals and veterinary drugs in aquaculture in some countries.”¹⁰⁰ The statement even went so far as to say that FSIS inspection was in compliance with the World Trade Organization (“WTO”) and “consistent with the principles of most-favored-nation and national treatment, in that U.S. and

95. See Agricultural Act of 2014, Pub. L. No. 113-79, 128 Stat. 649, 702 (2014) [hereinafter Agricultural Act of 2014].

96. *Id.* at 981.

97. *Id.*; see also *Accurate Labeling of Catfish Is the Law*, U.S. CATFISH (May 29, 2014), <http://uscatfish.com/accurate-labeling-catfish-law/>.

98. Agricultural Act of 2014, *supra* note 95, at 981.

99. H.R. Rep. No. 113-333, at 556-557 (2014) (Conf. Rep.).

100. *Id.*

foreign producers, processors, and products would be treated equally.”¹⁰¹ The provision ended with a particularly blunt conclusion: “The Managers are dissatisfied that the implementation process has already exceeded 5 years and see no barrier to FSIS completing this [memorandum of understanding] and fully implementing the underlying inspection mandate within 60 days from the date of enactment of this Act.”¹⁰²

The 2014 Farm Bill became law on February 7, 2014.¹⁰³ On April 30, 2014, FSIS and FDA entered into a memorandum of understanding to “plan for the orderly transition, in phases, from FDA to FSIS of primary regulatory oversight of domestically produced and imported *Siluriformes* fish and fish products.”¹⁰⁴

VI. Trade Advocates’ Unsuccessful Attempts to Block FSIS Inspection

While domestic catfish producers hoped that the 2014 Farm Bill would put to rest any remaining arguments over catfish labeling and FSIS inspection, free trade advocates in Congress made another impassioned attempt to stop the new program in May 2015. The impetus was Senate consideration of a trade promotion authority bill providing authority to negotiate trade agreements, including the Trans-Pacific Partnership (“TPP”) Agreement. Senator John McCain (R-AZ), who has bitterly opposed for years what he calls the “catfish sham”,¹⁰⁵ led the charge, aided by the two senators from New Hampshire.¹⁰⁶

Senator Jeanne Shaheen (D-N.H.) explained her opposition to the USDA Catfish Inspection Program based on

101. *Id.* at 557.

102. *Id.*

103. Agricultural Act of 2014, *supra* note 95, at 649.

104. Memorandum of Understanding between the Food Safety and Inspection Service, U.S. Dep’t of Agric., and the Food and Drug Admin., U.S. Dep’t of Health and Human Services (Apr. 30, 2014) (on file with Food Safety and Inspection Service) <http://www.fsis.usda.gov/wps/wcm/connect/8675a5cb-7bca-4a8f-a563-7788adceb583/MOU-FSIS-FDA-Fish-Products.pdf/MOU-FSIS-FDA-Fish-Products.pdf>.

105. *E.g.*, Senator John McCain, *The fishy deal on catfish*, POLITICO (June 7, 2013, 2:04 PM EDT), <http://www.politico.com/story/2013/06/the-fishy-deal-on-catfish-092415>.

106. *See* 161 CONG. REC. S3009, 3017 (daily ed. May 19, 2015).

the possibility of the WTO-sanctioned trade retaliation against US agricultural exports and the concerns of constituent seafood processors who depend on imported fish and worry that Congress will subject other seafood products to FSIS scrutiny.¹⁰⁷ Senator McCain lambasted the “wasteful, pork barrel, outrageous program” of catfish inspection, which he claimed could jeopardize the TPP and potentially cost American agricultural producers “billions of dollars in lost market access to Asian nations.”¹⁰⁸

According to Senator McCain, the TPP was necessary not only to “promote hundreds of billions of dollars of American exports” but also to strengthen American security interests in the Pacific, whereas the catfish inspection program was intended “to create a trade barrier to protect a small handful of catfish farmers in two or three Southern States” and had already cost USDA \$20 million dollars without a single catfish inspected.¹⁰⁹ He warned that some countries might need as long as 5 to 7 years before being able to satisfy the new FSIS requirements and resume regular catfish exports, which he said highlighted the strong protectionist streak underlying program implementation.¹¹⁰ Senator McCain cited nine separate GAO reports that recommended Congress repeal the FSIS inspection program, as well as editorials in the *Wall Street Journal* and *New York Times* and letters from the Council for Citizens Against Government Waste and the National Restaurant Alliance, among others, condemning the program.¹¹¹ Senator Kelly Ayotte (R-NH) joined the strident floor speeches, stating that the TPP could create more than 8,000 new jobs in New Hampshire, all of which were imperiled if the FSIS catfish inspection program continued as that might result in a trade war and lawsuits against the United States.¹¹²

107. 161 CONG. REC, S3017 (May 19, 2015) (statement of Sen. Shaheen).

108. 161 CONG. REC, S3017 (May 19, 2015) (statement of Sen. McCain).

109. 161 CONG. REC, S3018 (May 19, 2015) (statement of Sen. McCain).

110. *Id.*

111. 161 CONG. REC, S3018-20 (May 19, 2015) (statement of Sen. McCain).

112. 161 CONG. REC, S3021 (May 19, 2015) (statement of Sen. Ayotte).

Senator Roger Wicker (R-MS) defended the program on the basis of food safety, claiming that FDA was inspecting only about 2 percent of all imported catfish, of which “an alarming volume . . . failed to meet consumer safety standards” due to unsanitary foreign aquaculture production.¹¹³ Senator Thad Cochran (R-MS) followed, reiterating that “American consumers could be exposed to dangerous chemicals and unapproved drugs in the imported catfish they eat.”¹¹⁴ Ultimately, Senator McCain’s amendment, which was cosponsored by 12 Democrats and 6 Republicans, was ruled non-germane and denied a vote.¹¹⁵

Throughout the rest of 2015 and into early 2016, Senators McCain, Shaheen, and Ayotte offered repeated amendments to repeal the FSIS inspection program to bills that came before the Senate and each time the amendments failed without receiving votes.¹¹⁶ Congress made its position on the issue even more clear in the omnibus appropriations act that funded the government for fiscal year 2016, which required FSIS to continue implementation of the new inspection program and FDA to continue to enforce the existing labeling requirements.¹¹⁷

Eventually, the Obama Administration eased Vietnamese concerns over the FSIS inspection program by agreeing to provide technical assistance and a transitional period to allow Vietnam to continue exporting fish to the United States while working to meet new FSIS requirements.¹¹⁸ On December 2, 2015, FSIS issued a final rule for carrying out catfish

113. 161 CONG. REC. S3021-22 (May 19, 2015) (statement of Sen. Wicker).

114. 161 CONG. REC. S3022 (May 19, 2015) (statement of Sen. Cochran).

115. *S. Amdt. 1226 to S. Admt. 1221 to H.R. 1314 — 114th Congress (2015-2016)*. CONGRESS.GOV, <https://www.congress.gov/amendment/114th-congress/senate-amendment/1226/cosponsors> (last visited Dec. 15, 2017); 161 CONG. REC. S3253,33294 (daily ed. May 22, 2015).

116. 161 CONG. REC. S3021 (daily ed. May 19, 2015) (statement of Sen. Ayotte).

117. RENÉE JOHNSON, CONG. RESEARCH SERV., FY2016 APPROPRIATIONS: SAFETY AGENCIES 1-2 (2016), <http://nationalaglawcenter.org/wp-content/uploads/assets/crs/R44309.pdf>.

118. Helena Bottemiller Evich, *USTR Offer ‘Catfish’ Aid to Vietnam*, POLITICO MORNING AGRICULTURE (Nov. 6, 2015, 10:00 AM EST), <http://www.politico.com/tipsheets/morning-agriculture/2015/11/ustr-offers-catfish-aid-to-vietnam-211136>.

inspections.¹¹⁹ Under the final rule, FSIS inspections of catfish began March 1, 2016.¹²⁰

An 18-month transitional period was included to allow foreign countries to continue exporting catfish to the United States while preparing the documentation necessary to demonstrate to FSIS that their inspection systems were functionally equivalent to that of the United States in regards to program administration, enforcement of water quality and processing standards, inspection regularity, and other factors.¹²¹ FSIS implemented transitional inspection procedures akin to those used for meat slaughter operations, with inspectors present every day during all hours of operation at domestic catfish slaughter and slaughter-processing facilities, and more limited inspection of processing-only plants and reinspection of imported catfish.¹²² FSIS noted that it might later adjust inspection frequency at catfish slaughter and slaughter-processing facilities based on its experiences during the transitional period.

VII. Early FSIS Successes, Legislative Last Gasp, and Congressional Recognition

Less than a month into the new FSIS inspection regime, news media reported that the agency refused entry to two shipments of Vietnamese catfish after the fish tested positive for illegal dyes and antibiotics.¹²³ The US catfish industry and Senator Cochran's office heralded the effectiveness of the new

119. Mandatory Inspection of Fish of the Order Siluriformes and Products Derived From Such Fish, 80 Fed. Reg. 75590 (December 2, 2015).

120. *Id.*

121. *Id.* at 75598.

122. *Id.* at 75606; *FY 2017 Budget Request for Food Safety: Before the Subcomm. on Agriculture, Rural Development, Food and Drug Administration, & Related Agencies of the H. Comm. on Appropriations*, 114 Cong. (Feb. 24, 2016) (statement of Al Almanza, Deputy Under Secretary for Food Safety), <http://docs.house.gov/meetings/AP/AP01/20160224/104499/HHRG-114-AP01-Wstate-AlmanzaA-20160224.pdf>.

123. *E.g.*, Ian Kullgren & Catherine Boudreau, *U.S. inspectors stop contaminated catfish imports from Vietnam*, POLITICO (May 23, 2016), <https://www.cochran.senate.gov/public/index.cfm/2016/5/u-s-inspectors-stop-contaminated-catfish-imports-from-vietnam>; *USDA-FSIS Inspection Halts Dangerous Vietnamese Pangasius Shipment*, THE CATFISH INSTITUTE (May 24, 2016), <http://uscatfish.com/usda-fsis-inspection-halts-dangerous-vietnamese-pangasius-shipment/>).

program.¹²⁴ Not everyone was impressed, however. With President Obama on a state visit to Vietnam, a country that remained deeply concerned by the new inspection procedures, the Senate considered a joint resolution of disapproval to nullify the rule establishing FSIS catfish inspection.¹²⁵ Both Senators from Mississippi spoke passionately against the resolution, with Senator Wicker arguing that the \$1.1 million annual cost of the FSIS inspection program was small considering it protected “Americans against 175,000 cases of cancer . . . [and] 91 million exposures to antimicrobials.”¹²⁶

Senator Shaheen countered that “you are more likely to get hit by lightning than to get sick from imported or domestic catfish” and argued that, since FDA was entrusted with all other forms of seafood, it made little sense to establish a separate inspection program just for catfish, especially one that might cost USDA \$15 million a year to run.¹²⁷ She warned that the FSIS inspection program, a “thinly disguised illegal trade barrier against foreign catfish”, could allow catfish-exporting countries to obtain WTO sanctions against other US agricultural exports.¹²⁸ Senators McCain and Ayotte also rose in support, noting that ten GAO reports had now called the FSIS inspection program wasteful and duplicative.¹²⁹ While the debate seemed like a carbon copy of the one the Senate engaged in almost exactly a year before, this time the result was decidedly different. The Senate passed the joint resolution of disapproval 55-43, a result that Vietnam’s Foreign Ministry said was “highly appreciated.”¹³⁰

In the end, however, the domestic catfish industry was successful in beating back this latest threat to the new inspection regime. Despite support in the House of Representatives for

124. Kullgern & Boudreau, *supra* note 123.

125. See Bill Tomson, *Vietnam takes gripes on USDA catfish inspection to WTO*, AGRIPULSE (Mar. 30, 2016, 1:45 PM), <https://www.agri-pulse.com/articles/6767-vietnam-takes-gripes-on-usda-catfish-inspection-to-wto>; S.J. Res. 28, 114th Cong. (2016).

126. 162 CONG. REC. S3132 (May 25, 2016) (statement of Sen. Wicker).

127. 162 CONG. REC. S3133 (May 25, 2016) (statement of Sen. Shaheen).

128. *Id.*

129. 162 CONG. REC. S3134 (May 25, 2016) (statements of Sen. McCain & Sen. Ayotte).

130. Anh Kiet, *Vietnam highly appreciated the US Senate’s vote to end catfish inspection*, HANOITIMES (June 3, 2016, 16:03), <http://hanoitimes.com.vn/news/vietnam/2016/06/81E0A41B/vietnam-highly-appreciated-the-us-senate-s-vote-to-end-catfish-inspection/>.

disapproving the final rule, a vote was never called and the resolution died with the end of the 114th Congress.¹³¹

Throughout the 2016 congressional drama, FSIS continued to move forward with inspections. In August, the environmental advocacy group Food & Water Watch reported that FSIS had rejected another shipment containing more than 40,000 pounds of Vietnamese catfish testing positive for illegal veterinary drugs.¹³² FSIS scrutinized domestic producers as well, with a Louisiana producer choosing to recall over 21,000 pounds of catfish after routine FSIS sampling revealed levels of dye that potentially rose to the legal standard of adulteration.¹³³

Congress rewarded FSIS in the Consolidated Appropriations Act, 2017, providing a \$17 million increase in funding for the agency over 2016 appropriations.¹³⁴ In the Joint Explanatory Statement, Congress recognized “FSIS’ diligent work in preventing from entering or removing 547,928 pounds (or more than 273 tons) of adulterated or ineligible imported Siluriformes product from U.S. commerce since April 15, 2016” and directed the agency to “reinspect all imported Siluriformes fish and fish product shipments” in the same manner as FSIS does for imported meat and poultry products.¹³⁵ It seemed that the FSIS inspection program had finally passed its last legislative hurdle.

VIII. FSIS Reduces Slaughter Inspection Frequency as New Regime Begins

131. Bill Tomson, *USDA catfish inspection takes a beating in House hearing*, AGRIPULSE (Dec. 7, 2016, 6:54 PM), <https://www.agri-pulse.com/articles/8092-usda-catfish-inspection-takes-a-beating-in-house-hearing>.

132. Statement of Food & Water Watch Executive Director Wenonah Hauter, *FSIS Catfish Inspection Program Stops Another Unsafe Shipment from Vietnam*, FOOD & WATER WATCH (Aug. 9, 2016), <https://www.foodandwaterwatch.org/news/fsis-catfish-inspection-program-stops-another-unsafe-shipment-vietnam%C2%A0>.

133. *Haring Catfish, Inc. Recalls Siluriformes Fish Products Due To Possible Adulteration*, FOOD AND SAFETY INSPECTION SERV. (July 14, 2016), <https://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts/recall-case-archive/archive/2016/recall-060-2016-release>.

134. Consolidated Appropriations Act, 2017, Publ. L. No. 115-31, 12, 115th Cong.; Consolidated Appropriations Act, 2016, Publ. L. No. 114-113, 13, 114th Cong.

135. 163 CONG. REC. H3331 (May 3, 2017); see Dan Flynn, *Congress hails FSIS for blocking 272 tons of bad foreign catfish*, FOOD SAFETY NEWS (July 5, 2017), <http://www.foodsafetynews.com/2017/07/congress-hails-fsis-for-blocking-272-tons-of-bad-foreign-catfish/>.

Although in the 2008 Farm Bill, Congress stated that its intent was for catfish to be subject to continuous inspection¹³⁶ and, while Congress had praised FSIS' thorough import inspection regime just days before, on May 17, 2017, FSIS issued a notification and request for comments announcing its intent to reduce certain types of inspection coverage.¹³⁷ Under the new plan, FSIS would inspect catfish slaughter and slaughter-processing establishments once per production shift, rather than all hours of operation each day, which had been its standard during the transitional period.¹³⁸ FSIS explained its belief that Congress intended FSIS to inspect catfish establishments under the same standard used for meat and poultry processing establishments, and noted its recent experience inspecting highly automated and streamlined domestic catfish slaughter-processing operations, which resemble meat processing-only operations more than meat slaughter establishments.¹³⁹ FSIS also stated that it would amend its regulatory definition of fish processing to align with FDA's definition, which combines slaughter and processing activities, so as to formally recognize the differences from meat processing.¹⁴⁰

FSIS received and considered eight comments on its proposal to reduce inspection coverage to once per production shift.¹⁴¹ One from the Consumers Union (described as "the policy and mobilization arm of Consumer Reports"), disagreed with the proposal due to its singular focus on FSIS' domestic experience with the 16 official catfish slaughter establishments.¹⁴² The commenter argued that since foreign

136. H.R. Rep. No. 110-627, at 938 (2008) (Conf. Rep.).

137. Changes to the Inspection Coverage in Official Establishments That Slaughter Fish of the Order Siluriformes, 82 Fed. Reg. 22609 (May 17, 2017) (to be codified at 9 C.F.R. 300).

138. *Id.*

139. *Id.* at 22610.

140. *Id.* at 22611.

141. Changes to the Inspection Coverage in Official Establishments That Slaughter Fish of the Order Siluriformes, 82 Fed. Reg. 41501 (Sept. 1, 2017) (to be codified at 9 C.F.R. 300).

142. Letter from Michael Hansen, Ph.D., Senior Scientist of Consumers Union, to U.S. Dep't. of Agric., Food Safety and Inspection Serv. (July 17, 2017) (on file with

countries importing catfish into the United States are required to have inspection regimes equivalent to FSIS' domestic procedures, any reduction in FSIS standards will necessarily reduce overseas inspections, potentially exposing US consumers to Vietnamese imports contaminated with illegal antibiotics or chemicals.¹⁴³ Conversely, a comment from the Ministry of Agriculture and Rural Development of Vietnam said that even the reduced inspection coverage was excessive, given the low risk of human health impacts from fish as compared to meat and the "super-intensive" cultivation of Vietnamese fish.¹⁴⁴

FSIS rejected all expressed concerns, defending its proposed approach as providing "a high level of assurance that the fish products are safe, wholesome, and properly packaged and labeled" and detailing the extensive activities taken to prevent and detect adulteration in imported fish.¹⁴⁵ To require each unit of catfish to be individually inspected would, FSIS asserted, "create enormous costs without significantly increasing the effectiveness of inspection."¹⁴⁶ FSIS' new inspection plan took effect with full implementation of the FSIS catfish inspection regime on September 1, 2017.¹⁴⁷

IX. Future Outlook for FSIS Inspection

The domestic catfish industry, while the source of less than a quarter of the sales of the total US aquaculture industry—

Regulations.Gov), <http://consumersunion.org/wp-content/uploads/2017/07/CU-comments-on-FSIS-catfish-inspection-7-17-17-final.pdf>.

143. *Id.*

144. Letter from Ngo Hong Phong, Deputy Director of National Agro-Forestry and Fisheries Quality Assurance Department of Vietnam, to Jane H. Doherty, International Coordination Executive of the Food Safety and Inspection Serv. of the U.S. Dep't. of Agric. (July 17, 2017) (on file with Ministry of Agriculture and Rural Development of Vietnam), <https://www.regulations.gov/contentStreamer?documentId=FSIS-2017-0003-0012&attachmentNumber=1&contentType=pdf>.

Changes to the Inspection Coverage in Official Establishments That Slaughter Fish of the Order Siluriformes, 82 Fed. Reg. 41502 (Sept. 1, 2017) (to be codified at 9 C.F.R. 300).

146. *Id.*

147. *Id.* at 41501; see *Inspection Program For Siluriformes Fish, Including Catfish*, FOOD SAFETY AND INSPECTION SERV. (Sept. 7, 2017), <https://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/siluriformes>; Dan Flynn, *FSIS adjusts catfish inspection process; transition period ends*, FOOD SAFETY NEWS (Sep. 5, 2017), <http://www.foodsafetynews.com/2017/09/fsis-adjusts-catfish-inspection-process-transition-period-ends/>.

which itself makes up less than one percent of the total market value of agricultural products sold in the United States—has proven remarkably adept at achieving legislative victories against free trade interests that represent a much larger economic impact. These successes are largely due to the longstanding support of a few well-placed members of Congress, who have used their seniority and power to protect this small regional interest. With FSIS finally implementing its catfish inspection program and further Senate action on trade authorities unlikely in the near future, the domestic catfish industry should now be able to celebrate its legislative achievements and focus on meeting the new FSIS requirements. Indeed, early reports suggest that the industry is already seeing increases in the quantity of catfish produced in Alabama, Arkansas, and Mississippi.¹⁴⁸

Whether the new inspection regime will be sufficient in the long term to overcome the other market forces pressuring American catfish production remains to be seen as does whether Vietnam follows through with its WTO complaints over the program. Another challenge may be the Trump Administration, which proposed in its fiscal year 2018 budget to transfer catfish inspection back to FDA “to avoid potentially duplicative efforts and costs.”¹⁴⁹ Of course, the Obama Administration had similar concerns and was unsuccessful in overriding the determined efforts of the domestic catfish industry and its staunch congressional allies.

Perhaps the biggest question is whether other domestic agricultural producers will try to follow the example of the catfish industry and garner congressional support for shifting other inspection regimes from FDA to FSIS. Given the much greater cost of FSIS’ more thorough inspection process, which even under the recently implemented reduced frequency provides far more frequent and comprehensive inspection than

148. Dan Flynn, *USDA offers cramming sessions on ‘wild caught’ catfish regs*, FOOD SAFETY NEWS (Aug. 22, 2017), <http://www.foodsafetynews.com/2017/08/usda-offers-cramming-sessions-on-wild-caught-catfish-regs/>.

149. U.S. DEP’T OF AGRICULTURE, FY 2018 BUDGET SUMMARY 5 (2017), <https://www.usda.gov/sites/default/files/documents/USDA-Budget-Summary-2018.pdf>.

FDA can, such a move could have considerable economic as well as trade implications and would even further muddy the federal regulatory waters around food safety. To overcome those considerations, other agricultural industries would need strong and committed congressional allies willing to leverage their seniority and influence to achieve another improbable success.

The Blight of the Bumblebee: How Federal Conservation Efforts and Pesticide Regulations Inadequately Protect Invertebrate Pollinators From Pesticide Toxicity*

INTRODUCTION

Over three-quarters of global crop production depends upon insect pollination; in other words, one in three bites of food relies on bugs to reach your dining room table.¹ Bee pollination helps produce crops such as apples, citrus, onions, blueberries, cucumbers, avocados, coffee, and pumpkins, to name a few.² Cross-pollination from wild bees, such as the bumblebee, contribute to ninety percent (90%) of wild plant growth.³ In addition to being essential to food production, bees also significantly contribute to the economy, adding more than \$15 billion to the United States' agricultural industry alone.⁴ Valuable cash crops reliant on pollination, such as coffee and cocoa, are important sources of income in developing countries, not to mention daily indulgences throughout the world.⁵ Were bees to vanish completely, that morning cup of coffee or slice of

* Dedicated to my parents, David and Kelli Helmick, who instilled in me the values of prioritizing an education.

1. Damian Carrington, *Loss of Wild Pollinators Serious Threat to Crop Yields, Study Finds*, THE GUARDIAN (Feb. 28, 2013), https://www.theguardian.com/environment/2013/feb/28/wild-bees-pollinators-crop-yields;_Why_We_Need_Bees:_Nature's_Tiny_Workers_Put_Food_on_Our_Tables, NAT'L RES. DEF. COUNCIL (Mar. 2011), <https://www.nrdc.org/sites/default/files/bees.pdf>.

2. Christina Sarich, *List of Foods We Will Lose if We Don't Save the Bees*, HONEY LOVE (Aug. 15, 2013) <http://honeylove.org/list-of-food/>; *Why We Need Bees*, *supra* note 1.

3. *Why We Need Bees*, *supra* note 1.

4. *Presidential Memorandum— Creating a Federal Strategy to Promote the Health of Honey Bees and Other Pollinators*, THE WHITE HOUSE, OFFICE OF THE PRESS SECRETARY (June 20, 2014), <https://www.whitehouse.gov/the-press-office/2014/06/20/presidential-memorandum-creating-federal-strategy-promote-health-honey-b> [hereinafter *Presidential Memo*].

5. *Pollinators Supply Under Threat*, FOOD AND AGRIC. ORG. OF THE U.N. (Feb. 26, 2016), <http://www.fao.org/news/story/en/item/384726/icode/>.

chocolate birthday cake might become quite scarce. Absent a targeted, collaborative intervention by local governments, agriculturalists, and conservationists, the buzzing pollinator may soon become extinct and, consequently, global economies and food supplies would suffer.

Extinction threatens over forty percent (40%) of bee species across the globe.⁶ Over a decade ago, beekeepers all over the world began reporting significant hive disappearances and deaths, with some reporting losses as high as ninety percent (90%); many attribute this massive extinction to Colony Collapse Disorder (“CCD”).⁷ CCD does not have a single cause, but is the result of multiple factors.⁸ Perhaps the most controversial factor contributing to bee extinction is pesticide toxicity.⁹ Pesticides can poison untargeted insects if the application instructions are not followed; however, some of these chemicals are so inherently toxic that even limited exposure results in debilitating illness and death to bees.¹⁰ One of the most widely used class of pesticides—neonicotinoids or neonics—has been linked to severe side effects, such as diminished colony growth and increased mortality rates in various bee species.¹¹ Yet, the easy application and effectiveness of neonicotinoids have made this type of pesticide popular among farmers and gardeners.¹²

6. SIMON G. POTTS ET AL., INTERGOVERNMENTAL SCI-POL’Y PLATFORM ON BIODIVERSITY AND ECOSYSTEM SERV., THE ASSESSMENT REPORT ON POLLINATORS, POLLINATION AND FOOD PRODUCTION: SUMMARY FOR POLICY MAKERS 9 (2016), https://www.ipbes.net/sites/default/files/downloads/pdf/spm_deliverable_3a_pollination_20170222.pdf.

7. *Pollinator Protection: Colony Collapse Disorder*, EPA <https://www.epa.gov/pollinator-protection/colony-collapse-disorder> (last updated Apr. 18, 2017).

8. *Id.*

9. Seth Borenstein, *Bees Hurt by Some Crop Pesticides, But Not All*, US NEWS (Jan. 6, 2016), <http://www.usnews.com/news/politics/articles/2016-01-06/apnewsbreak-epa-says-pesticide-harms-bees-in-some-cases>.

10. L. Hooven et al., *How to Reduce Bee Poisoning from Pesticides*, 591 PACIFIC NORTHWEST EXTENSION 1, 3-9 (2013), <https://catalog.extension.oregonstate.edu/sites/catalog/files/project/pdf/pnw591.pdf>.

11. L.W. Pisa et al., *Effects of Neonicotinoids and Fipronil on Non-Target Invertebrates*, 22 ENVIRON. SCI. POLLUT. RES. 68, 72 (2015).

12. Allison Aubrey, *Buzz Over Bee Health: New Pesticide Studies Rev Up Controversy*, NPR (Apr. 22, 2015, 6:36 PM), <http://www.npr.org/sections/thesalt/2015/04/22/401536105/buzz-over-bee-health-new-pesticide-studies-rev-up-controversy>.

This vital pollinator's population has been so severely diminished in recent years that the U.S. Fish and Wildlife Service ("FWS") recently intervened. In September 2016, the FWS granted endangered species status to seven species of bee native to Hawaii.¹³ This was the first time the FWS granted this type of protection to any bee species.¹⁴ The FWS continued to grant invertebrate pollinators protection when it added the Rusty-Patched Bumblebee ("Bumblebee") to the Endangered Species Act ("ESA") on January 11, 2017.¹⁵

Once commonly spotted on clover fields and wild flowers throughout the continental U.S., the Rusty-Patched Bumblebee is rapidly disappearing. This particular bumblebee is vital to the survival of crops such as tomatoes, blueberries, apples, and others.¹⁶ The fuzzy pollinator's habitat, long life cycle, and underground nesting preferences make it especially vulnerable to pesticide contamination.¹⁷

The Endangered Species Act protects plant and animal species vulnerable to extinction from a myriad of threats, including those posed to Bumblebees by pesticides.¹⁸ The ESA's objectives and protections, as they apply to bees, directly conflict with farmers' use of pesticides to protect crops. ESA protections extend to the trading, sale, taking, and degradation of critical habitats.¹⁹ More specifically, the ESA protects against endangered species being killed or harmed.²⁰

When farmers use pesticides toxic to pollinators or improperly apply pesticides to fields, exposed bees die in

13. Merrit Kennedy, *Bees Added to U.S. Endangered Species List for 1st Time*, NPR (Oct. 3, 2016), <http://www.npr.org/sections/thetwo-way/2016/10/03/496402620/bee-species-added-to-u-s-endangered-species-list-for-1st-time>.

14. *Id.*

15. *In a Race Against Extinction, Rusty Patched Bumble Bee is Listed as Endangered: First Bumble Bee Protected Under the Endangered Species Act*, U.S. FISH AND WILDLIFE SERV. (Jan. 10, 2017), <https://www.fws.gov/midwest/news/861.html>.

16. *Bumble Bees: Rusty Patched Bumble Bee (Bombus Affinis)*, XERCES SOC'Y, <http://www.xerces.org/rusty-patched-bumble-bee/> (last visited Jan. 11, 2017).

17. *Fact Sheet Rusty Patched Bumble Bee (Bombus Affinis)*, U.S. FISH AND WILDLIFE SERV. (Jan. 10, 2017), <https://www.fws.gov/midwest/endangered/insects/rpbb/pdf/RPBBFactSheet10Jan2017.pdf> [hereinafter *Fact Sheet*].

18. 16 U.S.C.S. § 1531 et seq.

19. 16 U.S.C.S. § 1532; *Endangered Species Act*, NATIONAL WILDLIFE FEDERATION, <http://www.nwf.org/Wildlife/Wildlife-Conservation/Endangered-Species-Act.aspx> (last visited Aug. 28, 2017).

20. 16 U.S.C.S. § 1532(19).

droves. Pesticides are vital to protect crops from unwanted pests; in the same turn, bees are equally necessary to pollinate these crops, facilitating growth and harvest. These agricultural practices raise a novel question: how will the ESA protect endangered bee species from harmful, but necessary pesticides?

An examination of the ESA's conservation efforts towards the Rusty-Patched Bumblebee serves as a case study for the gaps in protections afforded by the law as it concerns invertebrate pollinators and pesticides. Specifically, this Comment will focus on how the ESA, as it exists, cannot adequately protect endangered invertebrate pollinators from inadvertent pesticide poisoning. For purposes of brevity, this Comment will focus on the neonicotinoid category of pesticides as they pose the most recognized and severe threat per recent scientific research. It is important to note additional classifications of pesticides may threaten invertebrate pollinators not discussed in this article.

Part I provides an overview of the Rusty-Patched Bumblebee, why it is important to conserve, and the threats pesticides pose to it. Part II summarizes the Endangered Species Act, how it protects endangered or threatened species, and the current plan of action for the endangered bumblebee. Part III of this Article examines pesticide regulations at the Federal, State, and International levels and their shortfalls and benefits. Part IV concludes by arguing in favor of relegating financial resources and increased regulatory authority to the states to reduce Bumblebee exposure to pesticides and improve conservation efforts.

I. Rusty-Patched Bumblebees and the Threats They Face

Bees are integral to the ecosystem, economy, and agriculture; absent their pollination, gardens, and crops would cease to thrive and other forms of life that depend on vegetation would suffer. The survival and vitality of bee populations now hinge upon human intervention.

A. The Bumblebee's Role in the North American Economy, Ecosystem, and Agriculture

The buzzing bumblebee often goes unnoticed as it flits from flower to flower, but this tiny winged invertebrate is an

essential component in the global economy. Native bee pollination adds an annual \$3 billion to America's economy.²¹ Conversely, declines in bee populations have cost the global economy an estimated \$5.7 billion annually.²² In an effort to curb diminishing wild bee numbers, the FWS granted endangered status to the Rusty-Patched Bumblebee on January 10, 2017.²³ This is the first species of bumblebee native to the continental U.S. to be granted such protection.²⁴ The Bumblebee officially received endangered species status on March 21, 2017.²⁵

A large, fuzzy bee marked with a distinct rust colored patch, the Rusty-Patched Bumblebee's population has declined by eighty-seven percent (87%) since the late 1990's.²⁶ The bumblebee's native habitat once spanned twenty-eight states, from the northern shores of Maine to the peach orchards of Georgia and as far west as North Dakota.²⁷ Now, the fuzzy pollinator can only be found scattered across thirteen states and

21. *In a Race Against Extinction*, *supra* note 15.

22. *Presidential Memo*, *supra* note 4.

23. *Rusty Patched Bumblebee*, *supra* note 16.

24. *Rusty Patched Bumble Bee, Archives*, U.S. FISH & WILDLIFE SERV., <https://www.fws.gov/midwest/endangered/insects/rpbb/archives.html> (last updated June 5, 2017).

25. *Endangered Species: Rusty Patched Bumble Bee (Bombus Affinis)*, U.S. FISH & WILDLIFE SERV., <https://www.fws.gov/midwest/endangered/insects/rpbb/> (last updated June 6, 2017); See Juliet Eilperin, *The Trump Administration Puts off Listing Bumble Bee as Endangered*, THE WASHINGTON POST (Feb. 9, 2017), https://www.washingtonpost.com/news/energy-environment/wp/2017/02/09/trump-administration-puts-off-listing-bumblebee-as-endangered/?utm_term=.47ddb5c52ee0. The Trump Administration enacted a regulatory freeze on listing the Rusty-Patched Bumblebee as an endangered species on February 10, 2017. *Id.* The administrative freeze delayed the endangered species protections from taking effect until March 21, 2017, more than one month after they were set to begin. *Id.* The delay was not expected to impact the FWS's conservation efforts. *Id.* A reversal of the FWS designation requires the Administration to prove through scientific evidence that the species has recovered. *Id.*

26. *Rusty Patched Bumblebee*, *supra* note 16.

27. *Id.*; The twenty-eights states that once made up the Rusty Patched Bumblebee's natural habitat include Connecticut, Delaware, Georgia, Indiana, Maine, Maryland, Massachusetts, lower Michigan, Minnesota, , New Hampshire, New Jersey, New York, North Carolina, Ohio, Pennsylvania, South Carolina, Vermont, Virginia, West Virginia, Wisconsin, and portions of North Dakota, South Dakota, Iowa, Illinois, Kentucky, and Tennessee. *Id.*; Tatiana Schlossberg & John Schwartz, *A Bumblebee Gets New Protection on Obama's Way Out*, THE NEW YORK TIMES (Jan. 10, 2017), https://www.nytimes.com/2017/01/10/science/endangered-bee.html?_r=0.

one Canadian province.²⁸ A field survey from 2007-2009 found just over 16,000 Rusty-Patched Bumblebees throughout the continental United States, compared to historical numbers of 73,000 in the same regions.²⁹

Not dependent upon any one type of flower to survive, Bumblebees are incredibly efficient pollinators, second only to honeybees in crop pollination importance.³⁰ Rusty-Patched Bumblebees can pollinate in cooler temperatures and lower light levels than other bee species.³¹ These characteristics enable the Bumblebee to pollinate longer throughout the day and on overcast days. This effective pollinator also has a longer pollination period, emerging in April to begin pollinating and hibernating in October.³²

Coupled with these unique characteristics, the Rusty-Patched Bumblebee also performs a special type of pollination function called “buzz pollination.”³³ Bumblebees perform buzz pollination by grabbing the pollen-producing structure of the flower with its jaws and vibrating its wings, freeing pollen that otherwise would have remained in the flower.³⁴ Tomatoes, peppers, and cranberries require buzz pollination to produce fruit and thrive.³⁵ Along with these flavorful crops, Bumblebees are integral to pollinating wildflowers, blueberries, plums, apples, alfalfa, and onion seeds.³⁶ Alfalfa pollination is crucial to nourish dairy cows whose produce creates dietary staples for American consumers.³⁷ The disappearance of the Rusty-Patched

28. *Fact Sheet*, *supra* note 17; The thirteen states where the Rusty Patched Bumblebee can now be found are Illinois, Indiana, Iowa, Maine, Maryland, Massachusetts, Minnesota, North Carolina, Ohio, Pennsylvania, Tennessee, Virginia, and Wisconsin. *Id.*

29. *Bombus Affinis (Rusty Patched Bumble Bee)*, THE IUCN RED LIST OF THREATENED SPECIES (2015), <http://www.iucnredlist.org/details/44937399/0>.

30. Sydney A. Cameron et al., *Patterns of Widespread Decline in North American Bumble Bees*, 108 PROC. OF THE NAT'L ACAD. OF SCI. OF THE U.S 662, 663-65 (2011), <http://www.pnas.org/content/108/2/662.full>; *see also Rusty Patched Bumble Bee*, *supra* note 16.

31. *Rusty Patched Bumblebee*, *supra* note 16.

32. Cameron et al., *supra* note 30.

33. *Fact Sheet*, *supra* note 17.

34. *Id.*

35. *Id.*

36. *Fact Sheet*, *supra* note 17; *Rusty Patched Bumble Bee*, *supra* at note 16.

37. *Pollinate Your Plate Part 2: A Filling Lunch*, DIADASIA BLOG (May 26, 2015), <https://diadasia.wordpress.com/2015/05/26/pollinate-your-plate-part-2-a-filling-lunch/>.

Bumblebee would create a domino effect, negatively impacting derivative crops and the species who consume them.

B. Toxic Threats: Neonicotinoids and Why the Rusty-Patched Bumblebee is Susceptible to Contamination

The massive bee disappearances and deaths in recent decades are often attributed to CCD. CCD is the phenomenon when a majority of worker bees disappear from a colony, leaving a queen and immature bees behind.³⁸ Researchers have been unable to narrow CCD down to one cause.³⁹ Numerous factors are believed to contribute to CCD: invasive pests, parasites, changes in habitat, inadequate sources of nutrition, and pesticides.⁴⁰ All of these factors pose significant threats to bee populations, but pesticides are solely the result of human action. Because pesticides are only introduced to wild bee populations through human intervention, this is arguably the easiest threat to remedy.

Bumblebees may be exposed to pesticides in a variety of ways and not solely because of improper pesticide application. The FWS attributes the Rusty-Patched Bumblebee's decline, in part, to intensive farming, increased application of pesticides to crops, and pesticide toxicity.⁴¹ All of these practices increase pesticide levels present in the air, soil, and ground water thereby increasing the Bumblebee's chances of exposure.

A particularly popular and hazardous class of pesticides are neonicotinoids.⁴² Introduced in the 1990's, neonicotinoids, also known as neonics, are some of the most widely used pesticides, having over \$1 billion in global market value.⁴³ Neonicotinoids, literally meaning "new nicotine-like insecticide," are chemically related to nicotine.⁴⁴ They bind to certain types of receptors

38. *Colony Collapse Disorder*, *supra* note 7.

39. *Id.*

40. *Id.*

41. *Fact Sheet*, *supra* note 17.

42. *What is neonicotinoid?*, TEXAS A&M AGRILIFE EXTENSION, <http://citybugs.tamu.edu/factsheets/ipm/what-is-a-neonicotinoid/> (last visited Oct. 30, 2016).

43. Tjeerd Blacquiere et al., *Neonicotinoids in Bees: A Review on Concentrations, Side-Effects and Risk Assessment*, 21 *ECOTOXICOLOGY* 973, 974-98 (2012).

44. *What is neonicotinoid?*, *supra* note 42.

within the nerve synapse introducing toxins directly to the nervous system to eliminate unwanted pests.⁴⁵

These pesticides are popular among farmers because they are simple to use and effectively protect crops from unwanted pests.⁴⁶ Farmers plant seeds in the spring and apply the water-soluble neonicotinoids directly to the soil.⁴⁷ As the crop draws the neonic-laced ground water through its structure, the pesticide is distributed throughout the plants' pollen and nectar.⁴⁸ Insects that feed on the plant's structure, nectar, or pollen ingest the pesticide, effectively delivering the toxin into the pests' system.⁴⁹ Unfortunately, unwanted insects are not the only invertebrates susceptible to the neonicotinoid's toxins. The lingering pesticide also poisons bees that feed on contaminated nectar and pollen, which can remain for months in the crop's structure after initial treatments.⁵⁰

Not only are neonicotinoids popular among farmers, but they have become household staples for gardeners as well.⁵¹ The various applications of neonicotinoids make them practical and easy to use: neonic-treated seeds,⁵² foliar spray, trunk injections for trees, and granules applied to the soil are user-friendly options for the amateur gardener.⁵³ Name brand products like Miracle Gro Plant Food, Knockout Ready-To-Use Grub Killer, Aloft, Green Light, 12 Month Tree & Shrub Protect Feed, and

45. *Id.*

46. Aubrey, *supra* note 12.

47. *What is neonicotinoid?*, *supra* note 42.

48. *What are Neonicotinoids?*, PESTICIDE ACTION NETWORK UK, http://www.pan-uk.org/about_neonicotinoids/ (last visited Oct. 30, 2016).

49. *See id.*

50. *Preliminary Pollinator Assessment to Support the Registration Review of Imidacloprid*, EPA, OFF. OF CHEM. SAFETY AND POLLUTION PROT. 2, 16 (Jan. 4, 2016), <https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPP-2008-0844-0140&contentType=pdf>.

51. Jennifer Hopwood & Matthew Shepherd, *Neonicotinoids in Your Garden*, WINGS: ESSAYS ON INVERTEBRATE CONSERVATION 22, 23 (2012) http://www.xerces.org/wp-content/uploads/2016/05/HopwoodShepherd_NeonicsInYourGarden_WingsFall2012.pdf.

52. Tom Oder, *Neonicotinoids: What Home Gardeners Need to Know*, MOTHER NATURE NETWORK (Aug. 15, 2017), <https://www.mnn.com/your-home/organic-farming-gardening/stories/neonicotinoids-what-home-gardeners-need-to-know>.

53. *Neonicotinoids in Your Garden*, XERXES SOC'Y, <http://www.xerces.org/wings-magazine/neonicotinoids-in-your-garden/> (last visited Mar. 12, 2017).

Marathon are but a few products that contain neonics.⁵⁴ Many of these products may be applied by gardeners to flowers and vegetables that Bumblebees pollinate.⁵⁵

Initially touted as harmless to non-target insects, a wave of research over the past decade contradicts the neonic industry's innocuous claims. A study released in the spring of 2016, implicated two of the three most widely-used neonicotinoids—imidacloprid and thiamethoxam—as negatively affecting bees.⁵⁶

Research demonstrates neonicotinoids have numerous negative side-effects on bumblebees: decreased larvae production and growth, diminished colony growth rate, and fewer queens surviving to maturation.⁵⁷ One study noted pesticide-exposed-bumblebees exhibited reduced nest growth and an eighty-five percent (85%) decrease in queen production, compared with their non-exposed counterparts.⁵⁸ Neonicotinoid residues in pollen present high risks to bumblebees; a linear relationship exists between daily doses of neonics and a fifty percent (50%) increase in bee mortality rates.⁵⁹ Studies found one particular strain of neonicotinoid, imidacloprid, poses the highest risk to bumblebees, with a 31.8 – 49% probability that exposed bumblebees would ingest a lethal dose after two days of feeding on contaminated pollen.⁶⁰

An English study indicated that neonicotinoid application to oilseed rape⁶¹ increased exposure to foraging pollinators, which were negatively affected three times more than non-foraging pollinators.⁶² The results of this research suggests that neonicotinoids' sub-lethal effects could increase losses to bee

54. *Id.*; *Help the Honey Bees!*, CTR. FOR FOOD SAFETY (Apr. 2013), http://www.centrforfoodsafety.org/files/pesticide_list_final_59620.pdf.

55. *Neonicotinoids in Your Garden*, *supra* note 53.

56. Damian Carrington, *Two of the World's Top Three Insecticides Harm Bumblebees*, THE GUARDIAN (Apr. 28, 2016), <https://www.theguardian.com/environment/2016/apr/28/two-worlds-top-three-leading-insecticides-harm-bees-study-shows>.

57. Pisa et al., *supra* note 11, at 74.

58. *Id.* at 76.

59. *Id.* at 71.

60. *Id.*

61. BBC, *Who what why: Why is There More Oilseed Rape Being Grown?*, BBC NEWS (May 29, 2012), <http://www.bbc.com/news/magazine-18249840>; Oilseed rape is flowering plant grown for its oil; it is also known as rapeseed. *Id.*

62. Ben Woodcock et al., *Impacts of neonicotinoid use on long-term population changes in wild bees in England*, NATURE COMMUNICATIONS (Aug. 16, 2016), <https://www.nature.com/articles/ncomms12459.pdf>.

populations and restrictions on neonicotinoids may decrease population decline.⁶³

Even low dose exposure to neonicotinoids significantly interferes with a bee's ability to pollinate.⁶⁴ Bees exposed to these pesticides collected less pollen, ventured outside the hive less often, and visited flowering plants less frequently.⁶⁵ Bees exposed to neonicotinoids are able to gather food within the hive, yet bees attempting to gather pollen and nectar from adjacent fields struggled to detect sources of nectar and pollen.⁶⁶ Further, the research reveals that fruit trees pollinated by exposed bees produced fruit with fewer seeds.⁶⁷ Neonicotinoids—commonly used on wheat, corn, soy, and cotton—even in sub-lethal doses, also make bees more susceptible to *Nosema*, a gut parasite.⁶⁸

Other studies suggest neonicotinoid exposed bees failed to supply enough food to their hives to support queen production.⁶⁹ Queen bees are crucial to the colony's survival; queen failure is a significant contributing factor to bee extinction.⁷⁰ Additionally, exposed queens showed significant changes in their reproductive anatomy and physiology.⁷¹ The changes seen in the queen bees' anatomy and physiology are linked to fewer

63. *Id.*

64. Steve Connor, *Neonics: Controversial Pesticide 'affects ability of bumblebees to pollinate fruit trees'*, THE INDEPENDENT (Aug. 16, 2016), <http://www.independent.co.uk/news/science/neonics-controversial-pesticide-affects-ability-of-bumblebees-to-pollinate-fruit-trees-a6739571.html>.

65. Pisa et al., *supra* at note 11 at 74.

66. *Id.* at 76-77.

67. Connor, *supra* note 64.

68. Jennifer S. Holland, *The Plight of the Honeybee*, NATIONAL GEOGRAPHIC NEWS (May 10, 2013), <http://news.nationalgeographic.com/news/2013/13/130510-honeybee-bee-science-european-union-pesticides-colony-collapse-epa-science.html>; Eric C. Mussen, *Diagnosing and Treating Nosema Disease*, UC DAVIS (Mar. 11, 2011), <http://entomology.ucdavis.edu/files/147621.pdf>. *Nosema* disease is caused by two fungi named *Nosema Apis* and *Nosema Ceranae*. *Id.* *Nosema* is a fungus-like, intra-cellular parasite that penetrates the gut and absorbs nutrients from the cells within the gut. *Id.* The parasite makes its way through the bumblebee's body cavity, infecting other tissues. *Id.* Heavily infected bees may contain millions of the parasitic spores. Parasite-infected intestinal tissues become riddled with secondary infections. *Id.* Infected bees cannot ingest food and their life span can be reduced up to 78%. *Id.*

69. Hopwood & Shepherd, *supra* note 53, at 25.

70. Geoffrey R Williams et al., *Neonicotinoid Pesticides Severely Affect Honey Bee Queens*, 5 SCIENTIFIC REPORTS 1, 1-5 (2015), <http://www.nature.com/articles/srep14621.pdf>.

71. *Id.* at 1, 4.

healthy queen bees able to produce worker bees.⁷² Scientists at the Royal Holloway University of London released new research, which examined the specific effects neonicotinoids have upon bumblebee queens.⁷³ Bumblebee queens fed neonic laced syrup were twenty-six percent (26%) less likely to lay eggs than queens not exposed to the pesticide.⁷⁴ The results of this research are incredibly significant: without a queen who can lay eggs, the bumblebee colony dies.⁷⁵

Physical features and habit preferences increase the Rusty-Patched Bumblebee's risk of exposure. Due to their preference for nesting underground, pesticide-contaminated soil poses an additional threat to Bumblebees that other bees do not face.⁷⁶ Bumblebees nesting near farms and other agricultural operations have limited habitat alternatives because they generally have a smaller foraging range.⁷⁷ Additionally, Bumblebees nesting near agricultural areas applying neonicotinoids face exposure through neonic-laced water, nectar, and pollen.⁷⁸ Bumblebees gathering contaminated pollen and nectar expose larvae to the toxic pesticide when they return to the hive, thereby furthering the destructive cycle.⁷⁹ Neonicotinoids are also absorbed through the Bumblebee's exoskeleton;⁸⁰ the Rusty-Patched Bumblebee's larger size and weight further increases its exposure.⁸¹

Assessing the impacts of insecticides on bee species is a challenge because of the numerous bee species and the variety of neonicotinoid mixtures.⁸² The majority of the research

72. *Id.* at 1, 5.

73. Dan Charles, *Popular Pesticides Keep Bumblebees from Laying Eggs*, NPR (Aug. 14, 2017), <http://www.npr.org/sections/thesalt/2017/08/14/542895824/popular-pesticides-keep-bumblebees-from-laying-eggs>.

74. *Id.*

75. *Id.*

76. Pisa et al., *supra* note 11, at 75.

77. *Id.*

78. COMM. ON THE STATUS OF ENDANGERED WILDLIFE IN CAN., ENV'T & CLIMATE CHANGE CAN., RECOVERY STRATEGY FOR THE RUSTY-PATCHED BUMBLE BEE (*BOMBUS AFFINIS*) IN CANADA 10 (2016), https://www.registrelep-sararegistry.gc.ca/virtual_sara/file/s/plans/rs_rusty_patched_bumble_bee_e_proposed.pdf.

79. *Id.*

80. *Id.*

81. Pisa et al., *supra* note 11, at 75. In comparison with the smaller honeybee, the Rusty-Patched Bumblebee is a significantly larger and heavier invertebrate pollinator. *Id.*

82. See Pisa et al., *supra* note 11 at 69-72, 75.

available examines the effects neonicotinoids have upon commercial bees, such as the honeybee.

II. Endangered Species Act

The Endangered Species Act was described by the United States Supreme Court as “the most comprehensive legislation for the preservation of endangered species enacted by any nation.”⁸³ Congress ratified the Endangered Species Act (“ESA”) in 1973 and it remains one of the most far-reaching wildlife conservation laws ever created.⁸⁴ As of 2009, 1,361 plant and animal species native to the United States have been granted endangered or threatened status.⁸⁵ But before each of these listed species received federal protection, their populations were radically reduced and indigenous habitats severely encroached.⁸⁶ This section will address the ESA’s purposes, including its takings provision and conservation endeavors.

A. Purpose, Policies, and Procedures

The Endangered Species Act’s purpose is to preserve the ecosystems of endangered or threatened species, to conserve endangered or threatened plants and animals, and to help recover the populations of at risk animals, plants, and insects.⁸⁷ The ESA requires federal agencies to use their authority to protect endangered and threatened species and prohibits them from “authorizing, funding, or carrying out any action that would jeopardize, destroy, or modify” a listed species’ “critical habitat.”⁸⁸ Enforcement of the ESA falls upon the FWS⁸⁹

83. *Tenn. Valley Auth. v. Hill*, 437 U.S. 153, 180 (1978).

84. *Endangered Species Act: A History of the Endangered Species Act of 1973*, U.S. FISH AND WILDLIFE SERV., <https://www.fws.gov/endangered/laws-policies/esa-history.html> (last updated Aug. 23, 2016); *Listing a Species as a Threatened or Endangered Species: Section 4 of the Endangered Species Act*, U.S. FISH AND WILDLIFE SERV. (Aug. 2016), <https://www.fws.gov/endangered/esa-library/pdf/listing.pdf>.

85. 16 U.S.C.S. § 1532(9) (2012).

86. *Listing and Critical Habitat: Overview*, U.S. FISH & WILDLIFE SERV. (Aug. 3, 2017) <https://www.fws.gov/endangered/what-we-do/listing-overview.html>.

87. 16 U.S.C.S. § 1531(b).

88. *A History of the Endangered Species Act*, *supra* note 84.

89. *About the U.S. Fish and Wildlife Service*, U.S. FISH AND WILDLIFE SERV. (Mar 24, 2016), https://www.fws.gov/help/about_us.html. The U.S. Fish and Wildlife Service is a bureau of the Department of the Interior. It enforces federal wildlife laws, such as the

working in conjunction with the National Marine Fisheries Service (“NMFS”),⁹⁰ state, and local agencies, tribes, non-governmental organizations, and private citizens.⁹¹

The FWS and the NMFS have the ultimate decision making authority on which species will be classified as “threatened” or “endangered” under the ESA.⁹² An “endangered species” is any animal or plant “in danger of extinction throughout all or a significant portion of its range.”⁹³ A “threatened species” is “likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.”⁹⁴ A species may be endangered or threatened if there is an on-going or imminent threat of “destruction, modification, or curtailment of its habitat or range,” overuse for “commercial, recreational, scientific, or educational purposes,” disease, predators, or other natural or manmade factors impacting survival.⁹⁵

Proceedings to classify a species as endangered or threatened begin with a petition, followed by a ninety (90) day review of any threats posed to the species.⁹⁶ Once the FWS determines a species is under significant threat of extinction, it begins the regulatory procedures to grant protections under the ESA.⁹⁷ First, the FWS assesses the species’ status by publishing notices of review which identify candidate species and by collecting biological information about the candidates.⁹⁸ During the listing process, the FWS prioritizes species by evaluating the threat’s magnitude and immediacy and the species’

ESA, conserves and restores wildlife and fish habitats, and excises taxes on fishing and hunting to equipment to State agencies. *Id.*

90. *National Oceanic and Atmospheric Administration: Our Mission*, NOAA FISHERIES, http://www.nmfs.noaa.gov/aboutus/our_mission.html (last visited Aug. 5, 2017). Also known as NOAA Fisheries, the NMFS oversees the nation’s ocean resources and their habitats. *Id.* As it relates to the ESA and FWS, the NMFS oversees the nation’s ocean resources and their habitat. *Id.* As it relates to the ESA and FWS, the NMFS recovers and conserves protected species and their habitats. *Id.* NMFS is an office of the National Ocean and Atmospheric Administration within the Department of Commerce. *Id.*

91. *Listing a Species*, *supra* note 84.

92. *Implementation of the ESA and Related Litigation*, U.S. DEPT. OF JUSTICE (May 15, 2015), <https://www.justice.gov/enrd/endangered-species-act>.

93. 16 U.S.C.S. § 1532(6) (2012).

94. 16 U.S.C.S. § 1532(20).

95. 16 U.S.C.S. § 1533 (a)(1).

96. *Listing a Species*, *supra* note 84.

97. *Id.*

98. *Id.*

distinctiveness.⁹⁹ After a substantial threat is established, the FWS then publishes a proposed rule and holds a sixty (60) day comment period.¹⁰⁰ Comment periods are open to the public, allowing individuals to comment and offer additional information on the proposed rule.¹⁰¹ The final ruling on whether to list the candidate species as endangered or threatened may be issued up to a year after the proposed rule's initial publication.¹⁰²

B. Prohibitions Against the Taking of a Species

Candidate species that make it through the FWS classification procedures receive federal protections. These protections include conservation efforts and prohibitions against takings, transportation, and sales of listed species.¹⁰³ Conservation efforts endorsed by the ESA include, but are not limited to, "research, census, law enforcement, habitat acquisition and maintenance, propagation, live trapping, and transplantation."¹⁰⁴ Federal agencies, headed by the FWS, contribute the lion's share of financial resources toward conservation efforts. For Fiscal Year 2014, the FWS spent \$1,437,810,654 to conserve both domestic and foreign species; Federal agencies reported expenditures of \$1,368,502,501 and state governments reported a total of \$69,308,153.¹⁰⁵

The crux of ESA protections is the prohibition against takings. A "taking" of an endangered species is broadly defined and includes harassing, harming, wounding, and killing, or any attempt to engage in such conduct.¹⁰⁶ Harm, under the taking's definition, is any act which "actually kills or injures wildlife," including "significant habitat modification or degradation where it actually kills or injures wildlife by significantly impairing essential behavioral patterns, including breeding, feeding, or

99. *Id.*

100. *Id.*

101. *Listing a Species, supra* note 84.

102. *Id.*

103. *See, e.g.*, 16 U.S.C.S. §§ 1531-1532.

104. 16 U.S.C.S. § 1532(3).

105. *Federal and State Endangered and Threatened Species Expenditures*, U.S. FISH AND WILDLIFE SERV. (2014), https://www.fws.gov/Endangered/esa-library/pdf/20160302_final_FY14_ExpRpt.pdf.

106. 16 U.S.C. § 1531; *see also* 16 U.S.C. § 1538.

sheltering.”¹⁰⁷ Illegal takings of protected species can result in criminal charges, civil penalties, and injunctions.¹⁰⁸ Civil penalties can amount to up to \$25,000 per violation.¹⁰⁹ A knowing violation of any provision under the ESA, aside from violations of permits and certificates, may result in fines up to \$25,000, imprisonment for no longer than six months, or both, upon conviction.¹¹⁰

Pesticide poisoning of the Bumblebee falls squarely within the definition of an ESA taking, therefore, it is within the FWS purview to enforce the ESA when endangered insects die or become ill as a result of pesticide exposure.¹¹¹ However, pesticide applications pose challenges for the FWS to enforce the illegal takings prohibition. For example, foliar-spray applications of neonicotinoids may drift outside the intended application range, contaminating Bumblebee nesting and foraging areas without the pesticide applicator even being aware he or she has violated federal law.¹¹² This example poses two unique questions: first, should a pesticide applicator be held responsible for the neonic drifting outside of the application range when he or she had no control over the drift? If so, how should the taking sanctions be applied to this situation? Neonicotinoid exposure could potentially lead to the collapse of an entire colony, even if only a few bees are initially exposed.¹¹³

So, should the pesticide applicator be held responsible for the Bumblebees that were initially exposed or should he or she be sanctioned for the derivative exposure of the entire hive? Fines for the initial Bumblebee contamination may not sufficiently address the applicator’s culpability, but levying fines

107. 50 C.F.R. § 17.3 (1994); *Babbitt v. Sweet Home Chapter of Cmty. for a Great Or.*, 515 U.S. 687, 696-99 (1995).

108. CHRISTINA LOCKE ET AL, DEPT. OF AGRIC., TRADE & CONSUMER PROT., THE WISCONSIN POLLINATOR PROTECTION PLAN 1 (Apr. 2016), <https://datcp.wi.gov/Documents/PPPComplete.pdf>.

109. 16 U.S.C.S. § 1540(a)(1).

110. 16 U.S.C.S. § 1540(b)(1).

111. 16 U.S.C.S. § 1540; *see also Babbitt* 515 U.S. at 691.

112. Jennifer Hopwood et al., *How Neonicotinoids Can Kill Bees*, XERCES SOC’Y, http://www.xerces.org/wp-content/uploads/2016/10/HowNeonicsCanKillBees_XercesSociety_Nov2016.pdf (last visited Sept. 10, 2017).

113. *Id.*; *see also* Chensheng Lu et al., *Sub-lethal exposure to neonicotinoids impaired honey bees winterization before proceeding to colony collapse disorder*, 67 BULLETIN OF INSECTOLOGY, 125, 126-29 (2014), <http://www.bulletinofinsectology.org/pdfarticles/vol67-2014-125-130lu.pdf>.

for every single bee death resulting from the initial contamination may be too severe and an inequitable application of the law. Further, how will the FWS determine which Bumblebees fell ill or died from inadvertent neonic contact and which pollinators died of natural causes? The time and personnel necessary to make these determinations would be extremely costly and an inefficient use of resources. Yet the FWS cannot neglect its congressionally mandated duties by ignoring the complex array of issues these circumstances present.

Further, the ESA provides “any taking otherwise prohibited by [16 U.S.C.S. § 1538(a)(1)(B)] if such taking is incidental to, and not the purpose of, the carrying out of an otherwise lawful activity” may be excused via permit issued by the Secretary.¹¹⁴ These permits may only be issued after an applicant submits a conservation plan.¹¹⁵ However, certain exemptions may be made based on economic hardship.¹¹⁶ Given the important role pesticides play in producing viable harvests, it is likely farmers will seek economic hardship exemptions under the ESA. Even though less harmful alternatives are available, farmers could still make an argument for undue economic hardship if prohibited from applying neonics, given their effectiveness.¹¹⁷

For example, in the U.S., corn is the most common cash crop; over 90 million acres of land are planted with corn.¹¹⁸ Soybeans are the second most planted crop with 77.5 million acres planted in 2009.¹¹⁹ One third of soybean acreage (23.2 million acres) and at least seventy-nine percent (79%) of corn acreage (71.1 million acres) were planted with neonicotinoid-

114. 16 U.S.C.S. § 1539(a)(1)(B).

115. 16 U.S.C.S. § 1539(2). The conservation plan must specify the impact likely to result from a taking, what steps will be taken to minimize and mitigate such impact, what funding will be available to implement these steps, alternatives to the taking considered by the applicant and why these alternatives are not being implemented, and any other measures the Secretary may require. *See id.*

116. 16 U.S.C.S. § 1539(b)(2).

117. Endangered Species Act of 1973, 16 U.S.C.A. § 1539, 29 (1973).

118. *Corn and Other Food Grains: Background*, U.S. DEPT. OF AGRIC. ECON. RES. SERV., <https://www.ers.usda.gov/topics/crops/corn/background/> (last updated Sept. 14, 2017).

119. *Soybeans & Oil Crops: Background*, U.S. DEPT. OF AGRIC. ECON. RES. SERV., <https://www.ers.usda.gov/topics/crops/soybeans-oil-crops/background/> (last updated May 1, 2017).

coated seeds.¹²⁰ Based on research performed by EPA, neonicotinoid seed treatments provide anywhere between \$0 to \$6 in benefits per acre compared to their alternatives.¹²¹ This means, if farmers switched to an alternative treatment, they could suffer losses up to \$426,600,000 for corn acreage and up to \$139,500,000 for soybean acreage.¹²² Though these losses make up a small percentage of the market value for these cash crops, it is significant enough to detrimentally impact a local farmer's bottom line. It is feasible that a farmer could receive an undue economic hardship exemption and be permitted to continue using neonicotinoid treated seeds, thereby negating the protections provided to the Rusty-Patch Bumblebee under the ESA.

C. Habitat Conservation Efforts

In conjunction with the taking prohibitions, the FWS provides for critical habitat designation as a way to conserve protected species.¹²³ A critical habitat is a geographic area with features essential to propagate a threatened or endangered species.¹²⁴ Once an area is designated as a critical habitat, federal agencies must consult with the FWS to ensure their actions will not destroy or modify the critical habitat.¹²⁵ Critical

120. Sara LaJeunesse, *Rapid Increase in Neonicotinoid Insecticides Driven by Seed Treatments*, PENN STATE NEWS (Apr. 2, 2015), <http://news.psu.edu/story/351027/2015/04/02/research/rapid-increase-neonicotinoid-insecticides-driven-seed-treatments>.

121. Memorandum from Clayton Myers, Ph.D., Entomologist & Elizabeth Bill, Economist, Biological and Economic Analysis Branch, Biological and Economic Analysis Division to Neil Anderson, Chief of Risk Management and Implementation Branch I, Pesticide Re-evaluation Division 2 (Oct. 3, 2014) (on file with the Office of Chemical Safety and Pollution Prevention) https://www.epa.gov/sites/production/files/2014-10/documents/benefits_of_neonicotinoid_seed_treatments_to_soybean_production_2.pdf.

122. KATHLEEN KASSEL ET AL., *SELECTED CHARTS FROM AG AND FOOD STATISTICS: CHARTING THE ESSENTIALS*, 2017 (2017) U.S. DEP'T OF AGRIC. ECON. RES. SERV., 15 <https://www.ers.usda.gov/data-products/ag-and-food-statistics-charting-the-essentials/>. It is important to note corn cash receipts for 2015 totaled \$47.2 billion and soybean cash receipts totaled \$33.2 billion in the same year. *Id.* These calculations demonstrate a fraction of the market value these crops have. Further, these calculations are rough estimates based upon available data to illustrate the economic consequences farmers could potentially suffer if forced to switch to non-neonicotinoid alternatives per the ESA and to demonstrate the viability of a claim for undue economic hardship.

123. U.S. FISH & WILDLIFE SERV., *CRITICAL HABITAT, WHAT IS IT?*, 2 (Sept. 2011), https://www.fws.gov/sacramento/es/Critical-Habitat/Home/Documents/critical_habitat.pdf.

124. *Id.* at 1.

125. *Id.* at 2.

habitats are not refuges or sanctuaries. Any changes or modifications by private landowners to a designated area located on private property, which do not involve Federal funding, is not regulated by the FWS.¹²⁶ The designation only affects activities that require a Federal permit, license, or funding.¹²⁷ Essentially, habitat conservation efforts fall into two categories: collaborative conservation programs and regulated takings.¹²⁸ For the sake of brevity, this Comment will not examine the regulated takings provision of the ESA, given its complex nature and limited relevance to this Comment.

Collaboration is crucial to ensure the survival of at risk species since local governments, agencies, and citizens are more familiar with the specific challenges and threats present in their areas.¹²⁹ More than half of endangered or threatened species live on privately owned lands; this necessitates the cooperation and collaboration between the FWS, communities, tribes, and private landowners.¹³⁰

Congress provided for partnerships between the FWS and non-Federal parties to collaborate on Habitat Conservation Plans (“HCP”).¹³¹ HCPs are documents required to apply for an incidental taking.¹³² The HCP outlines measures which the applicant will take to conserve the species in question.¹³³ Applicants must demonstrate that the impact of the incidental taking will be minimized and that it will not reduce the species chances of survival and recovery.¹³⁴

The Cooperative Endangered Species Conservation Fund (“CESCF”) provides grants to states and territories so they may

126. *Id.* at 1.

127. *Id.*

128. Endangered Species Act of 1973, 16 U.S.C.A. § 1532 (1973). In situations where a given ecosystem essential to an endangered or threatened species survival cannot otherwise be preserved, regulated takings are permissible under the ESA. *Id.*

129. *Endangered Species Grants: Overview*, U.S. FISH AND WILDLIFE SERV., <https://www.fws.gov/endangered/grants/index.html> (last updated June 14, 2017).

130. *Id.*

131. *Habitat Conservation Plans: Overview*, U.S. FISH AND WILDLIFE SERV., <https://www.fws.gov/endangered/what-we-do/hcp-overview.html> (last updated Aug. 3, 2017).

132. *Id.* An incidental taking permit allows the holder to proceed with an activity that would normally be considered an illegal taking. *Id.*; *Habitat Conservation Plans Under the Endangered Species Act*, U.S. FISH AND WILDLIFE SERV. (Apr. 2011), <https://www.fws.gov/endangered/esa-library/pdf/hcp.pdf> [hereinafter *Habitat Conservation Plans*].

133. *Habitat Conservation Plans*, *supra* note 131.

134. *Id.*

participate in voluntary conservation projects.¹³⁵ To participate, states must contribute at least twenty-five percent (25%) of the estimated costs; if two or more states or territories engage in a joint program, each may contribute ten percent (10%).¹³⁶ Federal monies supply the remaining funding. Approximately \$56.3 million was awarded in the fiscal year 2016 under four grant programs: Conservation Grants, Habitat Conservation Planning Assistance Grants, HCP Land Acquisition Grants, and Recovery Land Acquisition Grants.¹³⁷ Conservation Grants financially assist programs for habitat restoration, species status surveys, public education and outreach, and genetic studies, among others.¹³⁸ Habitat Conservation Planning Assistance Grants support HCP development by funding baseline surveys, document preparation, and other planning activities.¹³⁹ HCP Land Acquisition Grants, which received the bulk of Federal funding in 2016, fund land acquisition by State or local governments.¹⁴⁰ Finally, Recovery Land Acquisition Grants finance habitat acquisitions to secure continuing protection for species.¹⁴¹ Federal financing allows local and state governments to tailor conservation efforts to protected species native to the area.¹⁴²

Unfortunately, cuts in the FWS budget impacts the Federal and States' governments ability to collaborate under these programs. The proposed 2018 budget for the FWS would reduce funding for habitat conservation efforts by \$5.8 million.¹⁴³ The Cooperative Endangered Species Conservation Fund proposed budget for Fiscal Year 2018 would be \$19.3 million, a decrease of \$34.1 million.¹⁴⁴ The Conservation Grants to States would receive \$10.5 million, Habitat Conservation Planning Assistance

135. *Cooperative Endangered Species Conservation Fund Grants*, U.S. FISH AND WILDLIFE SERV. (Sept. 2016), <https://www.fws.gov/endangered/esa-library/pdf/section6.pdf> [hereinafter *Conservation Fund Grants*].

136. *Id.*

137. *Id.*

138. *Id.*

139. *Id.*

140. *Conservation Fund Grants*, *supra* note 135.

141. *Id.*

142. *Id.*

143. U.S. FISH AND WILDLIFE SERV., BUREAU HIGHLIGHTS 59-60 (2017), https://www.doi.gov/sites/doi.gov/files/uploads/fy2018_bib_bh059.pdf.

144. *Id.* at 62.

grants would receive \$6.5 million, and the remaining \$2.3 million would be allocated to administrative costs.¹⁴⁵ The proposed FWS 2018 budget would also eliminate funding for land acquisition grants.¹⁴⁶ With federal monies constituting the majority share of funding for these collaborative conservation programs, the efficacy and prevalence of habitat conservation may significantly decrease. Especially with no money being allocated towards land acquisition grants, which typically receives the lion's share of funding,¹⁴⁷ habitat conservation efforts by state and tribal governments are likely to crawl to a halt until either federal funding is reestablished or alternative state conservation initiatives are implemented.

III. Pesticide Regulations

A. Federal Regulations: The Environmental Protection Agency and its Role

The EPA plays a key role in protecting pollinators. Its mission is to protect human health and the environment.¹⁴⁸ One of its key goals is to implement environmental protections which make ecosystems diverse, sustainable, and economically productive.¹⁴⁹ In recent years, the EPA adopted policies and regulations aimed at reducing the impact of pesticides on invertebrate pollinators.

1. FIFRA and Pesticide Labeling Requirements Under the EPA

The EPA's primary means of regulating pesticides falls within the Office of Pesticide Programs ("OPP") enforcement of FIFRA. The OPP regulates the use of pesticides within the United States.¹⁵⁰ OPP executes the Federal Insecticide,

145. *Id.*

146. *Id.*

147. *Id.*

148. *Our Mission and What We Do*, EPA, <https://www.epa.gov/aboutepa/our-mission-and-what-we-do> (last updated Mar. 28, 2017).

149. *Id.*

150. *Summary of the Federal Insecticide, Fungicide, and Rodenticide Act*, EPA (Jan. 10, 2017), <https://www.epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> [hereinafter *Federal Insecticide, Fungicide, and Rodenticide Act*].

Fungicide, and Rodenticide Act (“FIFRA”). Funded by fees from pesticide manufacturers and Congressional monies,¹⁵¹ FIFRA regulates the distribution, sale, and use of pesticides.¹⁵² Under FIFRA, the EPA registers (licenses) any pesticide sold or distributed within the United States.¹⁵³ It ensures pesticides licensed by the EPA will not cause “unreasonable adverse effects on the environment.”¹⁵⁴ An unreasonable adverse effect is “any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.”¹⁵⁵ Given recent research and the Rust Patch Bumblebee’s significance, neonicotinoid toxicity to Bumblebees certainly constitute an “unreasonable adverse effect.”

The FIFRA labeling provision requires pesticide labels to be clearly and prominently displayed.¹⁵⁶ Pesticide labels must display a name, brand, or trademark, the name and address of the producer or registrant, net contents, a product registration number, an ingredient statement, a warning or precautionary statement, the directions for use, and the use classification.¹⁵⁷ Violations of FIFRA may result in steep civil and criminal penalties. Civil penalties may be assessed in a fine up to \$5,000 per violation.¹⁵⁸ Criminal violators may be fined up to \$50,000 or imprisoned for not more than one year, or both.¹⁵⁹ Many companies opt to settle with the EPA, rather than face these statutory penalties.¹⁶⁰

151. *Fiscal Years 2014 and 2013 Financial Statements for the Pesticides Reregistration and Expedited Processing Fund*, EPA OFFICE OF INSPECTOR GEN. (Sept. 22, 2016), https://www.epa.gov/sites/production/files/2016-09/documents/_epa0ig_20160922-16-1-0322_glance.pdf. In Fiscal Year 2014, the EPA collected \$28.6 million in pesticide maintenance fees, \$800,000 over the established target for the fiscal year. *Id.*

152. 7 U.S.C.S. § 136 et seq. (1996).

153. *See id.*; *see also Federal Insecticide, Fungicide, and Rodenticide Act supra*, note 150.

154. 7 U.S.C.S. § 136(bb).

155. *Id.*

156. 40 C.F.R. § 156.10(a)(1)-(a)(4) (2009).

157. 40 C.F.R. § 156.10(b)-(j) (2009). The product registration number is assigned by FIFRA after the pesticide is registered. *See id.*

158. 7 U.S.C.S. § 136l(a)(1) (2012).

159. 7 U.S.C.S. § 136j(a) (2012) (codifying unlawful acts).

160. *Civil Cases and Settlements by Statute*, EPA, <https://cfpub.epa.gov/enforcement/cases/index.cfm?templatePage=12&ID=10> (last updated Oct. 24, 2017).

With increasing concerns over the risks neonics pose to bees, the EPA rolled out additional labeling requirements for this class of pesticides under FIFRA in 2013.¹⁶¹ Neonicotinoid labels must inform users that there are additional prohibitions against application when bees are present, warn that direct contact and ingestion could harm bees, and require the pesticide not be applied until all petals have fallen from flowering plants and trees.¹⁶² Improvements to neonicotinoid labels also include more clear and precise application directions to protect bees from toxic exposure.¹⁶³ These requirements tailor the pesticide regulations to better reduce neonic exposure to bees.¹⁶⁴

Yet, enforcement of FIFRA provisions does little to stay pesticide exposure to the Rusty-Patched Bumblebee, which do not have invested beekeepers to bring claims on their behalf. Unlike commercial honeybees, wild bee hives are not constantly monitored. This means Bumblebee exposure to toxic pesticides could go unnoticed, increasing the probability of hive death from pesticide exposure. Furthermore, FIFRA extends to the labeling, distribution, and application of pesticides. Violations of labeling provisions have negligible impact on the Bumblebee and sanctions for failure to adhere to directions for use of a pesticide are unlikely to recompense the species for its losses. While the neonicotinoid-specific labeling provision proactively combats exposure to bees, even small doses of the pesticide may be harmful to the Rusty-Patched Bumblebee.

2. EPA Actions Targeting Neonicotinoids

Along with new protective policies and more precise labeling requirements, the EPA has accelerated the re-evaluation of neonicotinoid pesticides and issued a temporary suspension on the approval of new outdoor neonicotinoids.¹⁶⁵ The EPA has scheduled reviews of several types of neonicotinoid pesticides,

161. Letter from Steven Bradbury, Director of Office of Pesticide Programs, to Registrants of Nitroguanidine Neonicotinoid Products (Aug. 15, 2013) (on file with Office of Chemical Safety and Pollution Prevention) <https://www.epa.gov/sites/production/files/2013-11/documents/bee-label-info-ltr.pdf>.

162. *Id.*

163. *Id.*

164. *Id.*

165. *EPA Actions to Protect Pollinators*, EPA, <https://www.epa.gov/pollinator-protection/epa-actions-protect-pollinators>, (last updated Jan. 12, 2017).

including imidacloprid and thiamethoxam (two of the most lethal neonics to bee species).¹⁶⁶ The EPA released the first of four preliminary risk assessments of neonicotinoids on January 6, 2016.¹⁶⁷ This risk assessment identified the lowest residue level of imidacloprid likely to negatively affect honeybees; hives exposed to this minimum threshold experienced decreases in populations.¹⁶⁸ Unfortunately, this preliminary risk assessment focused primarily on the effects imidacloprid has on commercial honeybees.¹⁶⁹ None of the scheduled assessments will examine the effects neonicotinoids have on wild bumblebee populations. However, given the Rusty-Patched Bumblebee's susceptibility to neonic poisoning, it is very likely the Bumblebee will experience similar, if not increased, reactions upon exposure to imidacloprid.

In 2017, the EPA implemented a new policy aimed at mitigating risks to commercial bees from agricultural pesticides applied while the bees pollinate crops.¹⁷⁰ Notably, this policy is merely a recommendation for new labeling statements.¹⁷¹ The EPA modified its approach to targeting pesticide compounds that pose acute risks to commercial bees.¹⁷² Essentially, the policy will identify the pesticides which pose the most significant risks to bees using an acute risk assessment methodology.¹⁷³ Once a product is identified as posing a risk, label restrictions will be created to mitigate the risk.¹⁷⁴ Pesticide parent companies may voluntarily comply with the new recommendations; the EPA can only require compliance through FIFRA procedures and this new policy is not a FIFRA provision.¹⁷⁵ None of the new measures are tailored to protect

166. *EPA Releases the First of Four Preliminary Risk Assessments for Insecticides Potentially Harmful to Bees*, EPA (Jan. 6, 2016), <https://www.epa.gov/newsreleases/epa-releases-first-four-preliminary-risk-assessments-insecticides-potentially-harmful>.

167. *Id.*

168. *Id.*

169. *U.S. Environmental Protection Agency's Policy Mitigating the Acute Risk to Bees from Pesticide Products*, EPA OFF. OF PESTICIDE PROGRAMS 1, 10 (Jan. 12, 2017) <https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPP-2014-0818-0477&contentType=pdf> [hereinafter *Policy Mitigating Risk to Bees*].

170. *Id.* at 4.

171. *Id.* at 1.

172. *Id.* at 27.

173. *Id.* at 4.

174. *Policy Mitigating Risk to Bees*, *supra* note 169 at 10.

175. *Id.* at 1.

wild bee populations, but the EPA believes the new actions will impact native species.¹⁷⁶

The EPA has also examined the use of neonic treated soybean seeds.¹⁷⁷ An average of 76 million acres of soybeans were harvested annually from 2009-2013; thirty percent (30%) of soybean acreage was planted with neonicotinoid treated seeds.¹⁷⁸ Imidacloprid, thiamethoxam, and clothianidin (the three most commonly used neonicotinoids) are applied to soybean seeds prior to planting.¹⁷⁹ The Biological and Economic Analysis Division of the EPA (the department which researched the effectiveness of neonicotinoid treated soybean seeds) found negligible differences in soybean yield when soybean seeds were treated with neonics and when soybean seeds were not treated.¹⁸⁰ Farmers who planted neonic-treated soybean seeds gained only an estimated 1.7% in net operating revenue.¹⁸¹ Furthermore, less harmful alternatives provide similar levels of pest-protection to soybeans as neonicotinoid treated seeds at a comparable cost.¹⁸² These findings bolster the growing body of research promulgating the risks of neonics and the efficacy of less harmful alternatives. Unfortunately, research and data without regulation and enforcement does little to combat the threats against the Rusty Patch Bumblebee.

3. EPA Protections at the State Level

The 2017 labeling policy also encourages states and tribes to create local pollinator protection plans.¹⁸³ Due to their flexibility and familiarity with local endangered and threatened species, local governments can better address the issues pollinators face in specific locations.¹⁸⁴ The EPA strongly encourages local governments to undertake locally-based

176. *EPA Finalizes Steps to Better Protect Bees from Pesticides*, EPA (Jan. 12, 2017), <https://www.epa.gov/pesticides/epa-finalizes-steps-better-protect-bees-pesticides> [hereinafter *Steps to Better Protect Bees*].

177. See Memorandum from Clayton Myers & Elizabeth Hill, *supra* note 121.

178. *Id.* at 3.

179. *Id.* at 4.

180. *Id.* at 1.

181. *Id.*

182. Memorandum from Clayton Myers & Elizabeth Hill, *supra* note 121 at 2.

183. *Steps to Better Protect Bees*, *supra* note 176.

184. *Policy Mitigating Risk to Bees*, *supra* note 169.

measures to reduce pesticide exposure,¹⁸⁵ through state Managed Pollinator Protection Plans (“MP³”).¹⁸⁶ The primary purpose of MP³s is to reduce pesticide exposure through communication and coordination between beekeepers, pesticide applicators, and landowners.¹⁸⁷ The EPA believes pesticide risks can be mitigated if beekeepers and pesticide applicators coordinate activities prior to pesticide uses.¹⁸⁸

States may choose how to implement the MP³, whether it be through regulation or voluntary best-management-practice plans.¹⁸⁹ Each state may expand the MP³ scope to include non-pesticide regulations.¹⁹⁰ Though the states are given discretion and flexibility in how they choose to implement their MP³s, the EPA outlined critical elements requisite for the plan to be successful.¹⁹¹ These elements include a participation process for beekeepers, farmers, and pesticide applicators and processes to periodically review and modify the plan.¹⁹² The ultimate goal of a state MP³ is to foster open communication, improve mutual understanding, and safeguard peaceful cooperation to allow parties to successfully operate.¹⁹³

The greatest downfall of the MP³, with respect to the Rusty Patch Bumblebee, is that it fails to incorporate wild bee species in its scope and depends upon voluntary cooperation. If farmers and beekeepers abstain from coordinating their respective activities, then the state’s efforts fall flat. Additionally, the MP³ scope is limited to commercial pollinators under contract to service the pesticide application site; managed and wild bees that are merely nearby a pesticide application site, do not fall under the MP³’s scope.¹⁹⁴

185. Dan Charles, *Cut Down on Bee-Killing Pesticides? Ontario Finds It’s Easier Said than Done*, NPR (Oct. 18, 2016), <http://www.npr.org/sections/thesalt/2016/10/18/496100190/cut-down-on-bee-killing-pesticides-easier-said-than-done>.

186. State FIFRA Issues Research and Evaluation Group, *Final Guidance for State Lead Agencies for the Development and Implementation of Managed Pollinator Protection Plans*, ASS’N AM. PESTICIDE CONTROL OFFICIALS 1 (June 2015), <https://aapco.files.wordpress.com/2015/08/sfireg-mp3-guidance-final.pdf>. [hereinafter *FIFRA Guidance*].

187. *Id.*

188. *Id.*

189. *Id.* at 2.

190. *Id.* at 2-3.

191. See *FIFRA Guidance*, *supra* note 186 at 3-5.

192. *Id.* at 3, 5.

193. *Id.* at 1.

194. *Id.* at 2.

A. State Regulations

States possess wide discretion and authority when it comes to enacting regulations. A variety of avenues may be pursued to achieve a state's goal of pesticide regulation, including legislation, executive orders, and community outreach programs. Recent attention to threatened bee species has spurred some states to undertake new conservation efforts independent of the federal government.

1. *Legislative and Executive Actions*

Recent years have seen an increase in state legislatures restricting neonicotinoid sales and use. In the spring of 2016, Maryland legislatures passed the "Pollinator Protection Act," banning consumer use of neonicotinoid pesticides.¹⁹⁵ The Pollinator Protection Act, one of the first laws ever to prohibit neonicotinoid use in the U.S., is not a complete ban on neonicotinoids, rather it severely restricts their sale and use.¹⁹⁶ This law will restrict sales of neonics only to those who sell restricted-use pesticides.¹⁹⁷ Unless a person is a certified applicator or working under specific circumstances, neonicotinoid use is prohibited.¹⁹⁸ Farmers and veterinarians will also be allowed to use neonicotinoids.¹⁹⁹ Additionally, Maryland's Pollinator Protection Act requires the state Department of Agriculture to integrate habitat expansions into the State's existing MP³.²⁰⁰ The law will go into effect January 1, 2018.²⁰¹

195. H.R. 211, 2016 Gen. Assemb., 436th Sess. (Md. 2016); Pamela Wood, *Bee Advocates Victorious in Maryland General Assembly*, BALTIMORE SUN (Apr. 7, 2016), <http://www.baltimoresun.com/news/maryland/politics/blog/bal-bee-advocates-victorious-in-general-assembly-20160407-story.html>.

196. Wood, *supra* note 195.

197. Md. H.R. 211; *see also* 7 U.S.C. § 136a(c). Pesticides may be classified by the EPA as either general use pesticides or restricted use pesticides upon registration. *Id.* If a pesticide may harm humans or the environment, even if applied according to labeling instructions, it will be classified as restricted use. *See id.* MD. DEP'T OF AGRIC., *Pesticide Applicator Certification and Business Licensing Requirements*, MD. DEP'T AGRIC., <http://www.baltimoresun.com/news/maryland/politics/blog/bal-bee-advocates-victorious-in-general-assembly-20160407-story.html> (last visited Mar. 13, 2017).

198. Md. H.R. 211.

199. Wood, *supra* note 195.

200. Md. H.R. 211.

201. *Id.*

Connecticut took similar measures in late April of 2016 after beekeepers reported losing around sixty percent (60%) of their bees in the past year.²⁰² The Connecticut Senate voted unanimously on the bill and it went into effect January 1, 2017.²⁰³ The new Act requires the Commissioner of Agriculture to draft best practices to minimize airborne neonicotinoid dust, thereby mitigating the effect the dust has on pollinators.²⁰⁴ Application of neonicotinoids to flowering plants is limited to those grown in greenhouses or to anyone conducting academic research.²⁰⁵ Along with neonicotinoid use restrictions, the Act includes plans to improve and to expand domestic and wild pollinator habitats.²⁰⁶ The new legislation also tasked the Connecticut Department of Transportation with planting flowering vegetation along deforested state highways, in an effort to improve wild bee habitats.²⁰⁷ Unlike other pesticide-regulatory legislation, the Connecticut law conserves wild bee habitats, rather than focusing solely on commercial bee concerns.²⁰⁸

California Senators Mark Leno and Ben Allen introduced similar legislation to restrict the use of neonicotinoids.²⁰⁹ The California Pollinator Protection Act would also require labels on all plants and seeds pretreated with neonicotinoids, notifying consumers that the products are toxic to bees.²¹⁰ The California Director of Pesticide Regulation would be required to eliminate pesticides which endanger the environment.²¹¹ Unfortunately,

202. Gregory B. Hladky, *Bee Protection Bill Passes Senate*, Hartford Courant (Apr. 21, 2016), <http://www.courant.com/politics/capitol-watch/hc-bee-protection-bill-passes-senate-20160421-story.html>.

203. S.B. 231, 2016 Gen. Assemb., Feb. Sess. (Conn. 2016).

204. *Id.*

205. *Id.*

206. Hladky, *supra* note 202.

207. *Id.*

208. Annie Lemelin, *Beelieve it! Maryland and Connecticut Pass Landmark Legislation To Protect Pollinators*, CONSERVATION LAW FOUNDATION (June 24, 2016), <https://www.clf.org/blog/beelieve-maryland-connecticut-pass-landmark-legislation-protect-pollinators/>.

209. S.B. 1282, 2016 Leg., Reg. Sess. (Cal. 2016); *see also* *Bill Protects Bees in California from Harmful Pesticides*, SENATOR BILL ALAN (Mar. 9, 2016), <http://sd26.senate.ca.gov/news/2016-03-09-bill-protects-bees-california-harmful-pesticides> [hereinafter *Bees in California*].

210. *Id.*; *see also* *Bees in California*, *supra* note 209.

211. Cal. S.B. 1282.

this Bill died in the California senate due to a failure to meet a deadline.²¹²

Spurred by scientific evidence of neonicotinoid toxicity to commercial and wild bees, Minnesota Governor, Mark Dayton, signed an executive order which restricts the use of neonicotinoids.²¹³ Farmers in Minnesota who want to use neonics must verify the pesticides are necessary.²¹⁴ Minnesota's Department of Agriculture ("MDA") will increase inspections and enforcement efforts to ensure highly toxic pesticides are used in compliance with state regulations.²¹⁵ Additionally, the MDA must develop "pollinator stewardship materials" to distribute, in an effort to minimize exposure to non-target insects, like bumblebees, through education.²¹⁶ Raising awareness is a key provision of this executive order, recognizing that collaborative efforts by farmers, beekeepers, and the public will more swiftly and efficiently conserve threatened bee populations.²¹⁷ A new pest management strategy enacted by the Minnesota Department of Natural Resources will minimize pesticide use on public lands and maximize the restoration, creation, and management of wild pollinator habitats.²¹⁸

2. *Alternative State Programs*

Some states have opted for less formal, legal means of curbing pesticide use and opted for more collaborative, educational methods to meet their ends. One such example is the Wisconsin government's collaboration with the University of Wisconsin.

212. *SB-602 Pesticides: neonicotinoids: labeling*. CAL. LEGIS. INFO. (June 1, 2017), https://leginfo.ca.gov/faces/billHistoryClient.xhtml?bill_id=201720180SB602.

213. Minn. Exec. Order No. 16-07 (Aug. 25, 2016).

214. *Id.*; The executive order did not elaborate what form this additional verification would take, only that farmers must now verify neonicotinoids are necessary. *See id.*; *See also* Dan Charles, *Minnesota Cracks Down on Neonic Pesticides, Promising Aid to Bees*, NPR (Aug. 31, 2016), <http://www.npr.org/sections/thesalt/2016/08/31/491962115/minnesota-cracks-down-on-neonic-pesticides-promising-aid-to-bees>.

215. Minn. Exec. Order No. 16-07 (Aug. 25, 2016); *see also* Dan Charles, *Minnesota Cracks Down on Neonic Pesticides, Promising Aid to Bees*, NPR (Aug. 31, 2016), <http://www.npr.org/sections/thesalt/2016/08/31/491962115/minnesota-cracks-down-on-neonic-pesticides-promising-aid-to-bees>.

216. Minn. Exec. Order No. 16-07 (Aug. 25, 2016).

217. *Id.*

218. *Id.*

In Wisconsin, pollinator-dependent crops contribute over \$55 million in revenue annually.²¹⁹ The state Department of Agriculture, Trade, and Consumer Protection partnered with the University of Wisconsin to develop a plan to protect the state's lucrative pollinators.²²⁰ This plan, dubbed the Wisconsin Pollinator Protection Plan, is an education resource, providing guidance to improve public understanding of pollinator health issues and to minimize risk to pollinators through voluntary actions.²²¹ Many people criticize this plan because it relies on individuals and businesses choosing to self-regulate their behavior to protect bee populations.²²² Scientists and beekeepers doubt that large-scale farming operations for corn and soy will reduce the use of neonicotinoids because these crops do not rely on invertebrate pollinators, despite posing significant risks of toxic exposure by means of contaminated soil and ground water.²²³

C. International Regulations: Canadian and EU Restrictions on Neonicotinoids

The Canadian government and the European Union have been faster to react to the lethal effects neonicotinoids have on invertebrate pollinators than their American counterpart. As a result, neonic restrictions are more pervasive throughout the European continent.

1. *Canadian Neonicotinoid Restrictions*

America's northern neighbor is also concerned with the Rusty-Patched Bumblebee's well-being. Canada added the Rusty-Patched Bumblebee to its "Species at Risk in Ontario List" in 2010, seven years before the United States granted similar status to the Bumblebee.²²⁴ In 2011, the Ontario

219. *Supra* at note 108.

220. *Id.*

221. *Id.*

222. Marion Ceraso, *Critics: State's Plan to Save Bees Provides Little Protection from Pesticides*, WISCONSIN WATCH (Feb. 21, 2016), <http://wisconsinwatch.org/2016/02/critics-states-plan-to-save-bees-provides-little-protection-from-pesticides/>.

223. *Id.*

224. *Rusty-Patched Bumble Bee*, ONTARIO MINISTRY OF NATURAL RESOURCES <https://www.ontario.ca/page/rusty-patched-bumble-bee> (last updated Sept. 25, 2015); *In a Race Against Extinction*, *supra* note 15.

government released a “Recovery Strategy” for the Rusty-Patched Bumblebee.²²⁵ The recovery strategy noted the primary threat to the Rusty-Patched Bumblebee, once common throughout southern Ontario and southwestern Quebec, is the use of pesticides.²²⁶ The main goal for the recovery strategy is to “ensure the species’ long-term survival in Ontario by restoring and maintaining self-sustaining populations.”²²⁷ Canada has already taken steps to protect the Bumblebee through public education programs, collaborative research endeavors developing solutions for the various threats to the Bumblebee, and new laws restricting the use of neonicotinoid insecticides.²²⁸

Ontario recently undertook efforts to reduce the amount of neonicotinoids applied to crops.²²⁹ Widespread neonicotinoid use and severe losses to bee hives prompted a grassroots political movement calling for a ban of this pesticide.²³⁰ Passed in 2015, the new law intends to cut neonicotinoid applications to corn and soybean seeds by eighty percent (80%) (in phases) in 2017.²³¹ The Ontario government targeted corn and soybean seeds because almost one-hundred percent (100%) of corn seeds and sixty percent (60%) of soybean seeds sold within the province are neonic-coated, thus presenting the greatest opportunity to reduce bee exposure.²³² Field research revealed that on average only a 1 to 2% loss of non-pesticide treated seeds; in some cases, though, farmers can lose up to fifteen percent (15%) of their crops.²³³

Before farmers can use neonicotinoid-coated seeds, they must demonstrate a pest problem is present on their land and that the application of neonicotinoids is necessary to save the

225. ONTARIO MINISTRY OF NATURAL RESOURCES, RUSTY-PATCHED BUMBLE BEE, ONTARIO RECOVERY STRATEGY SERIES 1 (Dec. 7, 2011), http://files.ontario.ca/environment-and-energy/species-at-risk/stdprod_086037.pdf.

226. *Id.* at 4.

227. *Id.* at 7.

228. *Bumblebee Recovery*, WILDLIFE PRESERVATION CANADA, <https://wildlifepreservation.ca/bumble-bee-recovery/>, (last visited Sept. 17, 2017); *Bumblebee census takes flight over Ottawa*, CBC NEWS, <http://www.cbc.ca/news/canada/ottawa/bee-census-ottawa-1.3689857>, (last visited Sept. 17, 2017).

229. Charles, *supra* note 185.

230. *Id.*

231. *Neonicotinoid Regulation*, MINISTRY OF THE ENVIRONMENT AND CLIMATE CHANGE ONTARIO (June 6, 2016), <https://www.ontario.ca/page/neonicotinoid-regulations>.

232. *Id.*

233. Charles, *supra* note 185.

crop.²³⁴ The trouble is that the pests neonic-coated seeds target live underground, making it difficult for farmers to know whether the pests are in their fields.²³⁵ Ontario solved this dilemma with a test: farmers wanting to plant neonic-treated corn or soybean seeds must set out bait traps to determine if underground pests are contaminating the field.²³⁶ Farmers go out to their fields, dig holes, and drop insect bait into each hole; if even one pest is found in a hole, they can plant the pesticide treated seed.²³⁷ If no pests are found, the farm cannot plant neonic-treated seeds.²³⁸

Ontario's new restrictions on neonicotinoids balance the farmers' interests in using neonicotinoid treated seeds and the government's interest in reducing toxic exposure to bees. Unfortunately, the new restrictions have hit a few snags. Despite the new prohibitions, many farmers are still using the neonicotinoid coated seeds; one seed dealer in Ontario estimated that between 75 and 85% of corn seed purchased was treated with neonicotinoids during the first year of the new pesticide restrictions.²³⁹ Additionally, a lack of regulation fails to ensure that farmers are accurately reporting the results of their bait-trap-tests.²⁴⁰ Ontario's efforts to restrict neonic-treated seeds serves as a case-study: restrictions with good intentions, but minimal follow-up or regulation are effective only in name. Were similar neonicotinoid prohibitions enacted in the United States, additional reporting requirements for farmers would be necessary to ensure compliance. This could take many forms, but would ultimately be limited to the financial resources available to support additional regulations.

Along with this restriction on neonicotinoid treated seeds, a complete ban on the neonicotinoid, imidacloprid, has been proposed.²⁴¹ An environmental assessment revealed imidacloprid present in Canadian water sources in levels toxic to

234. *Id.*; *Neonicotinoid Regulation*, note 231.

235. Charles, *supra* note 185.

236. *Id.*

237. *Id.*

238. *Id.*

239. *Id.*

240. *Id.*

241. *Health Canada Proposes Ban on Pesticide Linked to Bee Deaths*, BBC NEWS (Nov. 24, 2016), <http://www.bbc.com/news/world-us-canada-38096765>.

insects.²⁴² Bee health is not mentioned in the proposed ban, but apiaries across the country welcome any reduction in neonicotinoids.²⁴³ Absent an out-right ban, Canada's restrictions on neonicotinoids will require further tweaking to better achieve the desired reduction in neonic use while balancing the farmers' interests.

2. *European Union Prohibitions Against Neonicotinoids*

Although the Rusty-Patched Bumblebee is not native to any member state of the European Union, the EU has led the world in banning neonicotinoids. With more than a quarter of Europe's bumblebees and one in ten honeybees at risk, European invertebrate pollinators face crippling population losses.²⁴⁴

The EU has one of the strictest pesticide regulation systems; all pesticides available on the market have been subjected to thorough assessments, ensuring human and animal health is protected.²⁴⁵ In the spring of 2013, the European Union enacted the first continent-wide ban on neonicotinoids.²⁴⁶ The EU Commission proposed the suspension of neonics after the European Food Safety Authority ("EFSA") found three common variations of neonicotinoids—thiamethoxam, clothianidin, and imidacloprid—"posed unacceptable risks to bees."²⁴⁷ Use of these neonics was banned for two years on flowering crops that bees feed upon, like corn, oilseed rape, and sunflowers.²⁴⁸ The ban applies to neonic seed, soil, and foliar treatments, except for treatments inside greenhouses and winter cereal crops.²⁴⁹ In

242. *Id.*

243. *Id.*

244. ANA NIETO ET AL., IUCN GLOBAL SPECIES PROGRAMME, EUROPEAN RED LIST OF BEES iv (2014), http://cmsdata.iucn.org/downloads/erl_of_bees_low_res_for_web.pdf.

245. *Pesticides and Bees*, EUROPEAN COMMISSION, https://ec.europa.eu/food/animals/life_animals/bees/pesticides_en (last updated Sept. 15, 2017).

246. Damian Carrington, *Bee-Harming Pesticides Banned in Europe*, THE GUARDIAN (Apr. 29, 2013), <https://www.theguardian.com/environment/2013/apr/29/bee-harming-pesticides-banned-europe>.

247. *Id.*

248. *Id.*

249. USDA FOREIGN AGRIC. SERV., NEONICOTINOID INSECTICIDES TO BE BANNED IN FRANCE FROM 2018 (Aug. 31, 2016) https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Neonicotinoid%20Insecticides%20to%20Be%20Banned%20in%20France%20from%202018_Paris_France_8-31-2016.pdf.

emergency situations, countries can authorize neonicotinoid use for 120 days.²⁵⁰ The EU crafted the moratorium to focus on commercial pollinators, leaving questions about the efficacy of this ban as it concerns wild bees.²⁵¹

This pioneering ban ended in 2015, but the EFSA has since placed the decision under review.²⁵² In 2015, the EFSA confirmed that neonicotinoid foliar sprays pose risks to bees and submitted its findings to the EU Commission.²⁵³ EU scientists in a letter to the EU Commission stated the review would be completed in January 2017; while the review is conducted, the EU Commission elected to maintain the restrictions on neonicotinoids.²⁵⁴

Independent of the EU Commission, France has restricted neonicotinoid use for nearly twenty years.²⁵⁵ In 1999, France enacted legislation banning the application of the neonic imidacloprid on sunflowers; a similar moratorium on the use of the insecticide on corn followed in 2004.²⁵⁶ Productivity appears unaffected by the neonic restrictions on corn and sunflowers since 2007 brought the best yields of these crops in over a decade.²⁵⁷ 2012 brought additional restrictions on the application of thiamethoxam on rapeseed.²⁵⁸ The French Parliament on July 20, 2016 enacted a bill that bans the use of neonicotinoids in France.²⁵⁹ Any plant protection products and seeds treated with

250. Claire Milne, *Bees, Neonicotinoids and the EU*, FULL FACT (May 20, 2016), <https://fullfact.org/europe/bees-neonicotinoids-and-eu/>.

251. Carrington, *supra* note 246.

252. *Id.*; Arthur Nelson, *EU Scientists Begin Review of Ban on Pesticides Linked to Bee Declines*, THE GUARDIAN (Jan. 7, 2016), <https://www.theguardian.com/environment/2016/jan/07/eu-scientists-begin-review-ban-pesticides-linked-bee-declines>.

253. *Neonicotinoids: foliar spray uses confirmed as a risk to bees*, EUROPEAN FOOD SAFETY AUTH. (Aug. 26, 2015), <http://www.efsa.europa.eu/en/print/press/news/150826>.

254. Neslen, *supra* note 252; *Pesticides and Bees: EFSA to Update Neonicotinoid Assessments*, EUROPEAN FOOD SAFETY AUTHORITY (Jan. 11, 2016), <http://www.efsa.europa.eu/en/press/news/160111>.

255. USDA FOREIGN AGRIC. SERV, *supra* at note 249. At the time this article was written, the review scheduled to be completed in 2017 has yet to be made available to the public.

256. *Id.*

257. EUROPEAN ENV'T. AGENCY, NEONICOTINOID PESTICIDES ARE A HUGE RISK – SO BAN IS WELCOME, SAYS EEA 5 (2013) <https://www.eea.europa.eu/downloads/7fc89e7a25474612ad988c13c2940405/1472813140/neonicotinoid-pesticides-are-a-huge.pdf>.

258. USDA FOREIGN AGRIC. SERV, *supra* at note 249.

259. *Id.*

neonics will be banned.²⁶⁰ The law is set to take effect September 1, 2018.²⁶¹

These extensive prohibitions against neonicotinoid applications address the dangers posed to a narrow, commercial subsection of bees found within the European continent. The primary objective behind these moratoriums is the preservation and viability of profitable honeybees and commercial pollinators. Contributing over €22 billion (approximately \$23.5 billion) to the European economy, the EU stands to lose a significant contributor to its GDP.²⁶² Yet, the overall financial contributions of wild bees has not been quantified and is relatively ignored by European legislatures. A complete ban against neonicotinoids would likely reduce the rate of exposure to wild bees, but until further research is done the impact of these laws remains somewhat speculative and ambiguous.

Though not a member of the EU, Cuba's pesticide-free honey industry serves as a case study that bolsters the latest science linking pesticides to massive bee deaths and supports the ban of neonicotinoids in some capacity.²⁶³ The Soviet Union collapse combined with the U.S. trade embargo made acquiring pesticides unaffordable, resulting in Cuba adopting organic agriculture.²⁶⁴ Pesticide free since 1991, Cuban beekeepers have not suffered extensive hive losses over the past decade.²⁶⁵ They attribute their hives' endurance to the absence of pesticides, all the while their international counterparts continue to suffer losses.²⁶⁶ Cuba's honey market illustrates the virtues of eliminating neonics, as it pertains to the impact of toxic exposure to bees.

IV. Conclusion

260. *Id.*

261. *Id.*

262. David Jolly, *Europe Bans Pesticides Thought Harmful to Bees*, THE NEW YORK TIMES (Apr. 29, 2013), <http://www.nytimes.com/2013/04/30/business/global/30iht-eubees30.html>.

263. Chris Arsenault, *Cuba's Organic Honey Exports Create Buzz as Bees Die Off Elsewhere*, REUTERS (Feb. 9, 2016), <http://www.reuters.com/article/us-cuba-farming-honey-idUSKCN0VI172>.

264. *Id.*

265. *Id.*

266. *Id.*

When it thrived, the Rusty-Patched Bumblebees' indigenous habitat was found in twenty-eight States; since its decline, the Bumblebee is now found in only thirteen States. Because the fuzzy Bumblebee, at its height, was not common throughout the continental U.S.,²⁶⁷ Federal conservation resources and efforts are best targeted at those original twenty-eight States. The FWS and EPA have also noted that local governments and agencies are better equipped to handle threats unique to the area. Federal grants are currently available, upon petition, to preserve critical habitats of listed species.

Unfortunately, additional Federal funding may not be a feasible option in the foreseeable future. The Trump Administration's proposed budget for 2018 undercuts existing funding for Federal agencies key to the preservation of the Rusty-Patched Bumblebee.²⁶⁸ The EPA's proposed budget will be reduced by thirty-one percent (31%) or a \$2.6 billion reduction. While the EPA does not directly regulate conservation efforts, it does enforce FIFRA. The lower budget will likely reduce existing enforcement measures, leading to an increase in pesticide exposure. The Executive Branch's proposed budget also reduces the Department of Interior's funding by twelve percent (12%) or \$1.5 billion.²⁶⁹ Within the Department of Interior is the FWS. Though the proposed budget supports stewardship of land management operations, it is unclear what, if any, impact this will have on endangered species conservation efforts.²⁷⁰ Other tangential budget decreases may impact conservation efforts by way of state's having fewer resources to allocate toward endangered species conservation.

With the proposed budget cuts restricting the Federal government's ability to adjust conservation efforts to address pesticide toxicity to the Rusty-Patched Bumblebee, effective conservation of the Rusty-Patched Bumblebee falls to the states. Some states have already taken it upon themselves to regulate

267. Sclossberg & Schwartz, *supra* note 27.

268. OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, AMERICA FIRST: A BUDGET BLUE PRINT TO MAKE AMERICA GREAT AGAIN (2017), https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/budget/fy2018/2018_blueprint.pdf.

269. *Id.*

270. *Id.*

deadly pesticides in efforts to conserve bee populations. Federal regulations fail to take into account the toxic effects pesticides have on wild bee species, whereas states have recognized the significance of these threats.

New legislation may learn from previous failures and craft more effective conservation measures. Ontario's recent neonicotinoid restriction serves as an example. Reducing the neonicotinoid treated seeds used in the Canadian province offered a solution for beekeepers, but proved difficult to enforce. The law granted significant discretion to pesticide applicators with little to no compliance measures. This could be remedied with compliance measures, such as random bait-trap-tests by government officials or more formal documentation requirements prior to purchase. The downfalls to implementing compliance measures are the costs, personnel, and time it would take for these measures to go into effect.

The most direct and efficient way to reduce toxic pesticide exposure and increase conservation efforts, is to allow state and local governments more latitude when undertaking conservation plans. States could allocate existing resources towards conservation efforts by tailoring existing plans to conserve wild pollinators. For example, Connecticut's pollinator protection legislation includes a provision requiring its Department of Transportation to plant wild flowers along stretches of highway that have already been deforested. This option is cost effective, does not require additional personnel, and may be implemented almost immediately. Another option is to replace ornamental flowers and shrubbery in public space and park landscaping with flowers and plants which draw in Rusty-Patched Bumblebees. State and local governments could also establish neighborhood gardens that grow fruits and vegetables dependent upon the Bumblebee to thrive, such as tomatoes and peppers.

States could also adopt measures similar to those enacted in Minnesota by Governor Dayton. Under the executive order, Minnesota's Department of Natural Resources developed a pest management strategy aimed at reducing pesticide and restoring wild pollinator habitats. Corresponding state agencies could undertake similar measures. Elimination of neonicotinoid pesticide application from state-managed lands could be executed almost immediately. Neonicotinoid pesticides could

easily be replaced with less-harmful alternative insecticides, reducing toxic exposure to the Bumblebee. Also, states could prioritize the restoration and maintenance of Bumblebee habitats by planting wild flowers and restricting or eliminating pesticide application to these designated areas. This narrow restriction would appropriately address the threats posed to the Bumblebee by neonics without severe restrictions on farmers or burdensome costs to taxpayers.

Additionally, educational and outreach programs aimed at informing farmers, pesticide applicators, and community members about the risks neonicotinoids pose to endangered pollinators may prove effective and financially efficient. Collaborative efforts between researchers, scientists, and local governments could spur individuals to undertake conservation efforts on their own. These programs are easily tailored to meet the community's needs and address concerns unique to the area.

Regardless of what measures are enacted, immediate action is necessary to protect the Rusty-Patched Bumblebee from neonicotinoid contamination.

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