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DO RECENT STUDIES PROVE THAT FARMED SALMON ARE TOXIC? A COMMENTARY ON WHETHER THE CURRENT FDA GUIDELINES ADEQUATELY PROTECT CONSUMERS FROM POTENTIAL TOXINS IN FARMED SALMON

I. INTRODUCTION

In our increasingly health conscious society, high quantities of fish are now a staple for most diets. Dieticians recommend salmon, in particular, because it contains high levels of fatty acids, which benefit the heart and brain.¹ Salmon is also recommended because it has relatively low levels of mercury.² There are two types of salmon: wild salmon and farmed salmon.³ In general, salmon sales constitute twenty percent of all retail seafood-dollars.⁴ Farmed salmon, raised for commercial use, represent ninety percent of the salmon consumed in the United States.⁵

Despite the excellent health benefits obtained from salmon, a recent study indicated that there are significantly more cancer-causing chemicals in farm-raised salmon than in wild salmon.⁶ Due to the large quantities of farmed salmon on the market, it is likely that farmed salmon are now the most carcinogenic protein source regularly purchased by consumers.⁷

1. See Erik Stokstad, *Salmon Survey Stokes Debate About Farmed Fish*, SCIENCE, Jan. 9, 2004, at 154 (introducing potential problem of toxic substances in farmed salmon); see also Tom Avril, *Study Finds Farm-raised Salmon Laden With Cancer-causing Chemicals*, PHILADELPHIA INQUIRER (Jan. 9, 2004), available at <http://www.organicconsumers.org/madcow/fish1904.cfm> (last visited Feb. 14, 2004) (noting health benefits of salmon).

2. See Avril, *supra* note 1 (noting lower levels of toxic mercury).

3. See generally Stokstad, *supra* note 1 (pointing out different results between farmed salmon and wild salmon).

4. See Avril, *supra* note 1 (noting frequency of salmon consumption).

5. See *id.* (noting availability of farmed salmon). In the United States, "more than 90 percent of the salmon consumed [are] 'farmed,' raised in floating pens, and available year-round while wild salmon [are] generally available June through October." *Id.* Farmed raised salmon are available all year round and are less expensive, as evidenced by the fact that it sells for 5 dollars a pound compared to wild salmon which are 15 dollars a pound. *Id.* For another price comparison, see Kay, *infra* note 155 and accompanying text.

6. See Avril, *supra* note 1 (discussing recent Global Study, published in journal *Science*, showing farmed salmon are more dangerous and contain more carcinogens than wild salmon).

7. See ENVIRONMENTAL WORKING GROUP, *PCBs in Farmed Salmon: Factory Methods, Unnatural Results*, at <http://www.ewg.org/reports/farmedPCBs/es.php> (last visited Feb. 14, 2004) [hereinafter *EWG Study*] (stating that on average farmed salmon contain sixteen times dioxin-like PCBs found in wild salmon, four times

SCIENCE, an acclaimed journal, recently published a study illustrating the potential health risks associated with farmed salmon.⁸ The study is the most recent comprehensive analysis of toxins found in salmon.⁹ In total, researchers analyzed fifty chemicals, focusing mainly on fourteen pesticides that are banned in the United States.¹⁰ These pesticides, specifically polychlorinated biphenyls (PCBs), can linger in the human body and the environment for decades.¹¹ As a result of these findings, the study recommended that consumers should limit consumption of farm-raised salmon to only once per month.¹²

The United States Food and Drug Administration (FDA) disregarded these results because the quantity of carcinogens falls well below the established minimum level of safety for commercially sold fish.¹³ This level, however, was established in 1984, and the study questions whether FDA's standard for these compounds is now outdated.¹⁴ Accordingly, the study's authors criticized FDA's "outdated" limits because they do not consider the most recent scientific data.¹⁵

The authors' primary argument compared FDA standards with the United States Environmental Protection Agency's (EPA) standards.¹⁶ In particular, EPA sets limits on PCBs found in wild

that in beef and 3.4 times that in other seafood). The EWG is a non-profit organization that performed an extensive study of PCBs in farmed salmon. *See id.*

8. *See* INDIANA UNIVERSITY OFFICE OF COMMUNICATIONS AND MARKETING, *Farmed Salmon More Toxic Than Wild Salmon, Study Finds: Eating Salmon May Pose Health Risks*, at <http://newsinfo.iu.edu/news/page/normal/1225.html> (last updated Jan. 20, 2004) (describing study's origins).

9. *See id.* (noting study's reliance on EPA standards and importance of informing consumer of higher toxin levels found in farmed salmon).

10. *See* Ronald A. Hites et al., *Global Assessment of Organic Contaminants in Farmed Salmon*, SCIENCE, January 9, 2004, at 226 (detailing number of chemicals evaluated by study during testing).

11. *See id.* at 228 (discussing adverse health effects of chemicals, specifically polychlorinated biphenyls (PCBs), found in study result).

12. *See id.* (recommending that consumers eat farmed salmon no more than once per month to keep body levels within healthy ranges). For a further discussion of recommendations made by the study, see *infra* note 107 and accompanying text.

13. *See id.* (explaining FDA's disapproval of study).

14. *See* Avril, *supra* note 1 (FDA standard was enacted twenty years ago in 1984 and has not been updated since).

15. *See id.* (noting Global Study's criticism of FDA regulations of PCBs in farmed salmon).

16. *See id.* (illustrating marked disparity between EPA and FDA standards for regulation of PCBs found in salmon, with EPA regulating wild salmon and FDA addressing farmed salmon).

salmon.¹⁷ FDA, on the other hand, sets forth the PCB limits in farmed salmon, and more generally, for commercially sold fish.¹⁸ If subjected to EPA's standard, which is forty times more protective, FDA regulated farmed salmon would greatly exceed the minimum allowance for PCBs and several other compounds.¹⁹

This Comment will consider whether the current FDA standard for evaluating carcinogen levels in salmon is up to date and whether it adequately protects salmon consumers. Part II of this Comment will set forth the relevant findings from recent studies and the potential dangers associated with these toxic chemicals.²⁰ Part III will analyze the current FDA standard for farmed salmon and compare it with EPA's standard for wild salmon.²¹ Part IV will address whether FDA should modify or update their standard through a comparison with EPA standard, and whether this one particular study warrants FDA to commence action.²² Finally, Part V of this Comment will, from a medical standpoint, evaluate the potential impact the study's results will have on consumers in the United States.²³

II. BACKGROUND

A. Disparity between EPA and FDA Standards

FDA and EPA standards are disparate with respect to the safe amount of PCBs that are permitted in farmed salmon versus wild salmon. This is illustrated in a recent study of farmed salmon, which found over thirty parts per billion of PCBs per salmon farmed in the United States and Canada.²⁴ Though this amount is

17. See *EWG Study*, *supra* note 7 (noting purpose of EPA guidelines, which were most recently updated in 1999 and that such guidelines apply to PCBs in wild salmon and reflect most recent "peer-reviewed science").

18. See *id.* (noting FDA guidelines for PCBs in farmed salmon and lack of FDA updates to current scientific standards).

19. See Stokstad, *supra* note 1, at 155 (noting disparity between EPA and FDA limits for PCBs in wild and farmed salmon respectively).

20. For a discussion on the study's factual findings, see *infra* notes 24-51 and accompanying text.

21. For a discussion of the current FDA and EPA standards, see *infra* notes 52-99 and accompanying text.

22. For a critical analysis of current standards compared with the study's results, see *infra* notes 100-45 and accompanying text.

23. For a discussion of the likely impact on those who regularly consume farmed salmon, see *infra* notes 146-58 and accompanying text.

24. See *Study Finds Higher Level of Toxins in Farmed Salmon* [hereinafter *Seattle*], SEATTLE TIMES (Jan. 12, 2004), available at http://seattletimes.nwsourc.com/html/health/2001833048_salmon09.html (last visited Feb. 15, 2004) (discussing large difference in FDA and EPA standards in PCB regulation).

within FDA's limit, it would greatly exceed EPA's limit, which recommends no more than eight to twelve parts per billion of PCB contaminants per week.²⁵

B. PCB Health Effects

Although there is limited testing on whether PCBs cause cancer in humans, well-designed testing has been performed with laboratory animals.²⁶ Independent studies on animals by General Electric scientists, EPA scientists and the National Cancer Institute have yielded the same results: PCBs cause cancer.²⁷ In humans, most carcinogenicity data comes from PCB levels in people with certain types of cancer and from workers previously exposed to PCBs.²⁸ After examining the *human* data, EPA believes that "PCBs are probable human carcinogens."²⁹ Thus, EPA studies have conclusively proved that PCBs cause cancer in animals, and human studies support the conclusion that PCBs are carcinogens.³⁰ EPA has also determined that PCBs may cause a multitude of other health problems, including weakening of the immune system, adverse reproductive effects and adverse neurological and endocrine effects.³¹

C. Relevant Studies

1. Global Study

The Global Study examined seven hundred farmed and wild salmon for more than fifty chemicals, focusing on PCBs, dioxins

25. *See id.* (noting that study results, while acceptable from FDA standpoint, would not be within EPA limits).

26. *See EWG Study, supra* note 7 (discussing data available to determine what actual health risks PCBs pose to humans).

27. *See id.* (citing several studies that determined carcinogenic effect of PCBs including: liver tumors, rare stomach tumors and thyroid tumors).

28. *See id.* (asserting that data exists indicating that PCBs cause liver, skin, intestinal cancer and potentially lymphoma).

29. *Polychlorinated Biphenyls*, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, available at <http://www.epa.gov/opptintr/pcb/effects.html> (last modified Jun. 24, 2002) (noting results and EPA conclusions related to PCBs) (emphasis added).

30. *See id.* (citing multiple health affects resulting from exposure to PCBs based from laboratory studies). EPA uses a "weight-of-evidence" approach to evaluate the potential carcinogenicity of environmental contaminants; and in the case of PCBs, EPA performed a peer reviewed assessment that concluded PCBs are probable carcinogens. *See id.*

31. *See id.* (asserting various adverse effects from PCB exposure along with supporting laboratory results in animals).

and banned pesticides.³² The Global Study analyzed farmed Atlantic salmon fillets from eight regions and from sixteen large cities in Europe and North America.³³ Researchers also tested salmon feed from two companies that serve eighty percent of the global market.³⁴ They then compared the concentrations of contaminants in farmed salmon versus wild salmon by variance analysis.³⁵ The results showed thirty-seven parts per billion (ppb) of PCBs in farmed salmon compared with nearly five ppb in wild salmon.³⁶

When the chemical concentrations were combined overall, the farmed salmon measured ten times higher in ppb than in wild salmon.³⁷ Moreover, the disparity in dioxin-like PCBs was even greater.³⁸ In addition to higher PCB levels, the Global Study data also highlighted that farmed salmon contains higher levels of many other pollutants, including: brominated flame retardants, pesticides such as DDT and dieldrin, and carcinogenic combustion by-prod-

32. See Hites, *supra* note 10, at 226 (setting forth method in study). Four universities and one analytical lab worked in conjunction to conduct a global, large scale, \$2.4 million study. See *id.*; see also Jane Kay, *Toxic Risks in Farmed Salmon — Consumers Told to be Wary Study Finds PCBs, Dioxins, Pesticides, Probably from Diet*, SAN FRANCISCO CHRONICLE (Jan. 9, 2004), available at <http://www.sfgate.com/cgi-bin/article.cgi?file=/c/a/2004/01/09/MNG6C46KRV1.DTL> (last visited Feb. 14, 2004) (providing statistics involved with study, which cost \$2.4 million dollars and conducted research at four universities, including Cornell and Indiana, and analytical lab).

33. See Kay, *supra* note 32 (stating order of contaminated farmed salmon). The following represents most to least in terms of PCB concentration: Northern Europe, Canada, Maine, Chile and the State of Washington; while most-contaminated “fillets” of farmed salmon came from supermarkets in San Francisco; Boston; Frankfurt, Germany; Edinburgh, Scotland; Paris, France; London, England; and Oslo, Norway. See *id.* It should be noted that researchers used five wild species of Pacific salmon, and not wild Atlantic salmon because few are available commercially. See *id.* Researchers did not use farmed Pacific salmon because they are not raised in significant numbers. See *id.*

34. See *id.* (noting study also considered salmon feed, but it did not encompass mercury because mercury is not largely present in salmon).

35. See Hites, *supra* note 10, at 226 (explaining method used to compare contaminant results in farmed salmon and wild salmon). In the comparison, researchers considered farmed salmon a single geographical group while still testing for variances in different locations. See *id.*

36. See Kay, *supra* note 32 (stating study’s results).

37. See *id.* (noting study’s commentary on disparity between farmed and wild salmon chemical levels).

38. See Hites, *supra* note 10, at 226 (stating study’s results of dioxin-like PCB contaminants).

ucts.³⁹ The study also stated that farmed salmon may contain up to forty times more PCBs than any other major protein source.⁴⁰

As a result of the PCB contamination, the researchers estimated that 800,000 people face an excess lifetime cancer risk of more than one in ten thousand while 10.4 million people face a risk of one in one hundred thousand.⁴¹ The study concluded that to be on par with wild salmon, PCB levels would need to drop by ninety percent to protect those who regularly consume salmon.⁴²

2. *Environmental Working Group Farmed Salmon Study*

The Global Study closely followed another study of farmed salmon that yielded similar results.⁴³ In that study, researchers described PCBs as “persistent, cancer-causing chemicals that were banned in the United States. . .and are. . . slated for global phase-out.”⁴⁴

The study, which was performed by the Environmental Working Group (EWG), also illustrated that there are significantly more PCBs in farmed salmon than in wild salmon.⁴⁵ In May 2003, EWG researchers purchased salmon from supermarkets in three U.S. cities with samples spanning five countries of origin and ten separate farming companies.⁴⁶ The EWG study was not published in a peer reviewed journal, but the results were consistent with two previously performed studies and with the subsequent Global Study.⁴⁷ Like

39. *See id.* (noting previously published study found higher toxins in farmed salmon).

40. *See id.* (noting that more dioxin-like PCBs exist in farmed salmon than in commercial seafood, beef, pork, milk and poultry); *see also* Kay, *supra* note 32 (noting high presence of PCBs in farmed salmon).

41. *See* Hites, *supra* note 10, at 226 (conducting exposure and risk assessment of PCB contamination in farmed salmon); *see also* EWG Study, *supra* note 7 (gathering figures on cancer risks).

42. *See* EWG Study, *supra* note 7 (noting level of safe PCB levels for those consuming high amounts of salmon).

43. *See id.* (noting that non-profit Environmental Working Group studied both farmed and wild salmon).

44. *See id.* (stating health effects of PCBs, PCB regulatory status in United States, and noting global phase-out plan under United Nations Convention on Persistent Organic Pollutants).

45. *See id.* (noting that results indicated high PCB levels in farmed salmon).

46. *See id.* (reciting method used in study).

47. *See* Robina Suwol, *Farmed Salmon is Said to Contain High PCB Levels*, Jul. 30 2003, available at http://www.calisafe.org/_disc1/00000058.htm (last updated Aug. 05, 2003) (noting that study was not published by peer reviewed journal, but was consistent with previous studies).

the Global Study, the EWG study indicated that farmed salmon contain five to ten times the PCB level found in wild salmon.⁴⁸

Both the EWG and Global Study proposed that farmed salmon accumulate more PCBs because of salmon fishmeal feed.⁴⁹ The fishmeal feed is highly concentrated in fats and oils containing PCBs, which results in higher concentrations of PCBs that are stored in salmon's fatty tissue.⁵⁰ Even though fishing industry groups using the fish feed condemned these studies, the Global Study and the earlier EWG study provide support for this theory.⁵¹

III. THE LEGAL STANDARD

A. Issue Presented From the Salmon Study: EPA and FDA Have Different Standards for PCB Regulation in Salmon

The legal issue presented is whether FDA's limit for PCBs in farmed salmon adequately protects consumers from carcinogens.⁵² The Global Study criticized FDA's comparatively loose PCB standards in light of EPA's standards.⁵³ In the study, farmed salmon PCB levels measured approximately fifty ppb.⁵⁴ FDA's standard is 2,000 ppb, while EPA's standard is significantly more protective.⁵⁵ EPA recommends no more than four to six ppb of PCB contaminants per meal in wild salmon, leaving a large disparity between the two agencies.⁵⁶

48. See *EWG study*, *supra* note 7 (stating PCB results); see Hites, *supra* note 10, at 227-28 (stating study's results concerning PCBs contaminants and variances in graphical form, yielding average level 5.2 times higher in farmed salmon); see also Kay, *supra* note 32 (noting PCB's former use in transformers and that dioxins are products of combustion); See also Avril, *supra* note 1 (showing industrial fishermen disapproved of study).

49. See *EWG Study*, *supra* note 7 (proposing that feed provided to farmed salmon caused high PCB levels because of feed's high quantities of fat and oils that harbor such toxic chemicals); see also Hites, *supra* note 10, at 226 (noting potential source of contaminants).

50. See Hites, *supra* note 10, at 226 (proposing that feed provided to farmed salmon are cause of high PCB levels and that PCBs are stored in salmon's fatty tissues). Salmon are carnivorous fish, high in the food chain, and consequently, they "bioaccumulate contaminants." See Stokstad, *supra* note 1.

51. See Hites, *supra* note 10, at 227-28 (noting PCB ratio in farmed salmon versus wild salmon).

52. See *id.* at 228 (noting that FDA standards may be outdated).

53. See *id.* (recommending that FDA alter its standards).

54. See *id.* (citing figures from study and comparing to FDA standards). Some chemicals, though suspected carcinogens, do not have established standards for safe consumption. See *id.*

55. See *id.* (discussing EPA standards for PCBs in wild salmon).

56. See *id.* (noting disparity between FDA and EPA standards with EPA using two meals per week as standard); see also Seattle, *supra* note 24.

1. *Scientific Basis for Environmental Limits*

In determining the proper scientific limits for environmental law, science is described as “the thorn in the side of environmental policy.”⁵⁷ To set environmental policy, scientific studies and theories are necessary.⁵⁸ However, these studies are not always performed due to a variety of factors.⁵⁹ Technological or economical feasibility often dictates the regulation of toxins.⁶⁰ Recently, Congress has indicated the need for a “more finely calibrated, science-based approach” to regulating toxins.⁶¹

When evaluating the validity of agency decisions, courts state that there must be substantial evidence to support an agency’s regulatory decision which would apply to setting limits for PCB levels.⁶² Yet, courts often defer to the agency because of their expertise even when that deference is not warranted. This would be the case when the agency standards are outdated, such as the 1984 FDA limits for PCBs in farmed salmon.⁶³

2. *EPA Standards for Regulating PCBs*

EPA derives its authority to regulate PCBs in wild salmon from the Clean Water Act (CWA).⁶⁴ Accordingly, EPA designated PCBs

57. Wendy E. Wagner, *The Science Charade in Toxic Regulation*, 95 COLUM. L. REV. 1613, 1614 (1995) (noting factors considered when implementing environmental law).

58. *See id.* (discussing requirements for setting environmental policy).

59. *See id.* (discussing tension between need for sound scientific basis and reality faced by regulatory agencies who succumb to reduced public participation, excessive regulatory delays and inaccurate use of science). This concept was further demonstrated by comments made by Representative Charles Rangel (D-NY) and the Honorable Bella S. Abzug, describing Congress’ failure to utilize a science-based approach to water pollution control. *See id.* (citations omitted).

60. *See id.* (claiming that Congress noted need for better scientific methods).

61. *See id.* (acknowledging need for more accurate, scientific methods when regulating toxic substances).

62. *See id.* at 1661 (noting court’s standard of review for agency decisions and need for toxic standards to be supported by detailed technical explanation). The Supreme Court dismissed OSHA claims that a certain cancer risk could not be precisely determined by holding that the agency must show, based on substantial evidence, that the standard set for Benzene did not present a significant risk of health impairment. *See Indust. Union Dep’t v. Am. Petroleum Inst.*, 448 U.S. 607, 653 (1980). This decision forced OSHA into an extensive scientific investigation. *See Wagner, supra* note 57 at 1662.

63. *See Wagner, supra* note 57, at 1664-65 (stating that courts tend to defer to agencies as experts; and if agency can convince court that toxic standard lies on “frontiers of scientific inquiry,” courts will only perform cursory review).

64. *See generally* Clean Water Act, 33 U.S.C. §§ 1251-1378 (2000) (asserting goal of “restoration and maintenance of chemical, physical and biological integrity of Nation’s waters”).

as “hazardous substances.”⁶⁵ The 1992 revision set new PCB tolerance levels to reflect the following goals: (1) revising the cancer potency factors estimated by the agency, and (2) translating animal evidence of carcinogenicity into human risk values.⁶⁶ The CWA noted that there are no “safe” levels of carcinogens because even small doses will cause a small incidence of illness.⁶⁷ Consequently, EPA promulgated stringent guidelines for regulating the quantity of PCBs that may be present in American waters.⁶⁸ This translates into extremely low PCB tolerance levels in food obtained from these waters.⁶⁹

EPA employs a scientific method for determining the risks associated with harmful compounds.⁷⁰ When determining PCB tolerance levels, EPA employed a scientific, “weight-of-evidence” approach to evaluate potential carcinogenicity of a contaminant followed by the viewing of results from individual studies in context with a complete carcinogenicity database.⁷¹ In conjunction with this method, EPA relied on animal studies that conclusively proved that PCBs cause cancer.⁷² Taking all of this data into account, EPA determined there was strong evidence to suggest that PCBs are “probable human carcinogens.”⁷³

65. 40 C.F.R. pt. 116.4 (2004) (listing PCBs as hazardous substance); *see* Clean Water Act, Section 303(c)(2)(B), 33 U.S.C. § 1313 (2004) (setting forth legal elements of section 303(c)). EPA delineated CWA elements: defining water quality standard as designated beneficial uses of water; requiring that State standards protect public health or welfare; enhance the quality of water to serve the CWA; and requiring States to review their standards at least once during each three year period. *See* Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants; States’ Compliance, 57 Fed. Reg. 60,848 (Dec. 22, 1992) (to be codified as 40 C.F.R. pt. 131).

66. *See* Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants; States’ Compliance, 57 Fed. Reg. 60,862 (Dec. 22, 1992) (noting Act’s goals regarding carcinogenicity).

67. *See id.* (stating that “EPA’s human health guidelines assume that carcinogenicity is a ‘non-threshold phenomenon,’ that is, there are no ‘safe’ or ‘no-effect levels’ because even extremely small doses are assumed to cause a finite increase in the incidence of the response (i.e., cancer)”).

68. *See* 40 C.F.R. pt. 131.36 (2004) (stating maximum PCB quantity to comply with Clean Water Act). For reportable quantities, *see* 40 C.F.R. pt. 117.3 (2004).

69. *See generally* 40 C.F.R. pt. 131.36; *see also* Avril, *supra* note 1 (citing EPA’s tight regulation on PCB with regards to wild salmon).

70. *See generally* UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *supra* note 29 (discussing method EPA used to determine PCB’s carcinogenic effect).

71. *See id.* (describing EPA’s general method for determining whether compound or contaminant is carcinogenic).

72. *See id.* (noting that animal studies conclusively showed that PCB caused cancer and that human studies, performed by various groups, are also consistent with this result).

73. *Id.* (stating level of carcinogenicity associated with PCBs).

In determining adverse health effects, as demonstrated by the carcinogen guidelines, EPA's method involved waiting for "good. . .science" before undertaking regulatory action of a particular substance.⁷⁴ Accordingly, EPA's approach provides risk-based advice for consumption.⁷⁵ In its risk analysis, EPA follows four steps: (1) hazard identification, (2) evaluation of dose-response kinetics for a particular compounds, (3) exposure assessment and (4) risk characterization.⁷⁶ This practice, however, can pose a significant problem if no scientific study adequately captures the danger associated with a toxin.⁷⁷ Further compounding this problem is the slow pace at which carcinogenic information is discovered.⁷⁸

For salmon, however, EPA has already set safe limits on PCB intake.⁷⁹ While EPA's overall method of regulation has received criticism, studies do exist, and the PCB contamination limits for salmon adequately protect the public and consumers from products potentially laden with such compounds.⁸⁰

3. Food and Drug Administration's Standards for Regulating PCBs

FDA regulates PCB contaminants in farmed salmon.⁸¹ The Federal Food, Drug, and Cosmetic Act ("FFDCA") provides FDA with authority to regulate PCB contamination in commercially sold fish.⁸² FDA considers PCBs "toxic, industrial chemicals" that "[b]ecause of their widespread, uncontrolled industrial applica-

74. See Wagner, *supra* note 57, at 1683 (stating EPA guidelines were promulgated after sixteen years of administrative efforts and after reliable, complete science was available before enacting guidelines).

75. See Hites, *supra* note 10, at 228 (citing EPA method of regulation, using example where specific species should be consumed on specified amount per week and per month).

76. See UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *Risk Assessment Methods*, available at <http://www.epa.gov/ost/fishadvice/volume2/v2ch2.pdf> (last visited, Mar. 01, 2004) (detailing EPA's method of risk assessment for potential carcinogenic substances).

77. See Wagner, *supra* note 57 at 1683 (noting danger of waiting for enough information to use weight-of-evidence method).

78. See *id.* (discussing compounding of problem by slow rate in which scientific data is generated, which can delay proper regulation by several decades).

79. See Avril, *supra* note 1 (stating that EPA implemented strict criteria to regulate PCBs).

80. See *id.* (noting that EPA standards are more stringent than FDA standards); Wagner, *supra* note 57 (criticizing EPA's regulatory policy, at times, when determining safe quantities of carcinogenic substances).

81. See generally Avril, *supra* note 1 (discussing FDA regulation of farmed salmon, which is unlike EPA regulation of contaminants in wild salmon).

82. See 21 U.S.C. §§ 321, 336, 342, 346a, 348, 371 (2000) (granting FDA authority to regulate commercially sold fish).

tions. . . [have] become a persistent and ubiquitous contaminant in the environment.”⁸³ FDA determined that PCB contamination is unavoidable in certain foods and animal feeds and limited PCB contamination in fish and fish feed to two parts per million, or two thousand ppb.⁸⁴

Though FDA utilizes a similar approach as EPA does with regard to risk assessment, it also employs a non-scientific balancing method to determine acceptable levels of carcinogens.⁸⁵ In setting its PCB limits, FDA weighed multiple interests to determine the proper balance “between adequately protecting the public health and avoiding excessive losses of food to American consumers.”⁸⁶ FDA stated that “it is important that the agency’s decision be based on all currently known relevant information.”⁸⁷ Nonetheless, with respect to PCB regulation, FDA factored into account what was referred to as potential “food loss” of 9.6 million to consumers when setting its limits.⁸⁸

Regulatory approaches are not static, as illustrated by several changes in FDA’s approach since the last update of PCBs in farmed salmon.⁸⁹ An example of one such change is the Food Quality Protection Act of 1996 (FQPA), which significantly altered certain FDA regulatory philosophies.⁹⁰ The FQPA modified FDA’s regulatory approach by shifting away from bright-line rules for carcinogens in

83. See 21 C.F.R. pt. 109.30(a) (2004) (explaining briefly problems associated with PCB contamination and purpose of regulation).

84. See *id.* (stating PCB limits for fish and fish feed). In the regulation, PCBs encompass various mixtures of chlorinated biphenyl compounds. See *id.* “The temporary tolerances for residues of PCB’s are as follows: . . . 2 parts per million in animal feed components of animal origin, including fishmeal and other by-products of marine origin” and “2 parts per million in fish and shellfish.” See *id.* at 109.30(a)(6),(7).

85. See Mark Eliot Shere, *The Myth of Meaningful Environmental Risk Assessment*, 19 HARV. ENVTL. L. REV. 409, 422 (1995) (noting that FDA and EPA employ similar methods to determine carcinogenicity for risk assessment purposes). For EPA guidelines on Carcinogen Risk Assessment, see 51 Fed. Reg. 33,992 (1986).

86. See Polychlorinated Biphenyls (PCBs) in Fish and Shellfish; Reduction of Tolerances; Final Decision, 49 Fed. Reg. 21,514 (1984) (citing 44 Fed. Reg. 38,330-31) (discussing competing interests when regulating PCBs in fish and shellfish).

87. See *id.* (stating decisions should be based on most current scientific data).

88. See *id.* at 21,517 (noting balancing of interests and factors considered though there was uncertainty surrounding food loss number).

89. See Andrew J. Miller, *The Food Quality Protection Act of 1996: Science and Law at a Crossroad*, 7 DUKE ENV. L. & POL’Y. F. 393 (1997) (discussing enactment of FQPA and significant change in regulatory philosophy).

90. See *id.* (discussing details of FQPA).

food additives.⁹¹ These clauses are known as the Delaney Clauses.⁹² They were enacted at a time when current scientific techniques could not determine a safe level of carcinogens, and it was determined that all carcinogens should be banned.⁹³ Despite setting forth bright-line rules, the clauses have become a “relic” because new technology exists that provides better estimates for regulating carcinogens.⁹⁴ As technology evolved, the foundation for the Delaney Clauses eroded.⁹⁵ The FQPA did not eliminate this legislation, but limited its reach by establishing a “more uniform regulatory scheme for pesticides that is grounded in modern toxicological science and that balances risks with the social and economic well-being of our nation.”⁹⁶

The FQPA approach represents a shift in regulatory philosophy resulting from the availability of more sophisticated technology, allowing for a more accurate assessment of risk and health hazards.⁹⁷ The FQPA moved FDA away from the bright-line rules for risk assessment established in the Delaney Clauses towards a more flexible approach based on changes in technology.⁹⁸ While these changes do not deal directly with PCB limits in farmed salmon, they are illustrative of how FDA can adapt to new information when regulating consumer products.⁹⁹

IV. ANALYSIS

With the existing disparity, the issue becomes whether FDA should be flexible and revise its PCB standards in light of new scientific evidence.¹⁰⁰ In the recent Global Study, researchers from sev-

91. *See id.* at 396 (providing brief history and effect of FFDCAs’ Delaney Clauses).

92. *See id.* at 395-96 (noting purpose of regulation).

93. *See id.* (describing technology and science available when Delaney Clauses were enacted).

94. *See* Miller, *supra* note 89, at 395-96 (noting criticism of Delaney Clauses as archaic).

95. *See id.* (explaining legislative need to better assess risk in light of then current technology).

96. *See id.* at 401 (citing Food Quality Protection Act of 1996 402(b), Pub. L. No. 104-170, 110 Stat. 1489, 1513 (1996) (citations omitted)).

97. *See id.* (discussing changes in regulatory philosophy).

98. *See id.* at 403 (discussing FQPA’s effect on FDA regulation).

99. *See* Miller, *supra* note 89, at 401 (noting that FQPA pertains solely to food additives, but represents overall shift in philosophy).

100. *See* Avril, *supra* note 1 (discussing disparity between FDA and EPA regulatory standards concerning PCBs and salmon consumption).

eral universities noted that FDA uses an outdated 1984 standard.¹⁰¹ The authors based this analysis on the more stringent EPA guidelines.¹⁰² In response, FDA implied that the standard is not outdated, and that it balanced all health impacts that may result from eating fish.¹⁰³ Some, however, were not persuaded by FDA's contentions.¹⁰⁴ A public health professor at John Hopkins and former EPA assistant administrator for toxic substances stated that "the [standard] 'doesn't pass any sort of scientific scrutiny.'"¹⁰⁵

Accordingly, FDA should reevaluate its standard based on: (1) new technological information available from recent studies, (2) EPA's standard, (3) the time lapse since FDA's last revision, (4) the detrimental health impacts of PCBs and (5) the increasing consumption of salmon.

A. Recommendations Made to the FDA in Response to Study Results

The EWG's study suggested corrective actions in response to the high PCB quantities in farmed salmon.¹⁰⁶ The legal recommendations made include: (1) Congress increase FDA funding to support extended testing of PCBs in farmed salmon, (2) FDA conduct a definitive study to update its regulations and (3) FDA issue a health advisory for seafood consumption that comports with EPA guidelines for PCBs.¹⁰⁷ The common theme among these recommendations is to ensure a corrective action to the allegation that FDA set relaxed standards for PCB levels in farmed salmon.¹⁰⁸

101. See Hites, *supra* note 10, at 228 (discussing study's argument that FDA standards are outdated).

102. See *id.* (noting that Global Study authors based their conclusions from more current EPA standards which recommended minimum number of salmon meals per month).

103. See *id.* (quoting FDA in response to study results). In particular, referring to FDA director of plant and dairy foods who stated, "[W]e do not see a public health concern here." *Id.*

104. See *id.* (noting that FDA response is not fully accepted).

105. See Avril *supra* note 1 (criticizing FDA's 20 year old standards while FDA dismissed study results). The Environmental Working Group also stated that FDA "was not doing its job." See EWG Study, *supra* note 7.

106. See EWG Study, *supra* note 7, at 3, 16 (stating six recommendations to address potential health problems resulting from high PCB levels).

107. See *id.* (providing legal recommendations). Other recommendations targeting the farmed salmon industry included: (1) preservation of the Alaskan salmon habitat where preliminary reports indicate that fish contain lower PCB levels, and (2) monitoring salmon feed for PCB contamination or refining feed sources to produce lower PCB levels in fish. *Id.*

108. See *generally id.* (setting forth ecological problems with salmon farming, thus, setting forth rationale for making recommendations on salmon regulation).

FDA should strongly consider these recommendations in light of the new information available and the importance of flexibility when setting regulatory standards.¹⁰⁹ Regulatory agencies commonly receive criticism for making non-scientific decisions, including decisions regarding carcinogen regulation.¹¹⁰ Critics have also accused agencies of making expedient risk-reward management decisions rather than science-based decisions.¹¹¹ Further, agencies are often suspected of over-regulating well studied compounds and under-regulating lesser studied hazardous compounds.¹¹²

For example, Congress acknowledged this problem in the FQPA, which put a greater emphasis on science to effectively regulate risk.¹¹³ In enacting the FQPA, Congress acknowledged that “science is now capable and responsible. . . [to] better serve society.”¹¹⁴ Furthermore, new legislation has shifted away from the Delaney Clauses, which relaxed the alleged unreasonable and unscientific methods to regulate carcinogens.¹¹⁵ This example of recent legislation, which incorporated new scientific understanding, lends support to the recommendation that FDA reevaluate its standard for PCB contamination.¹¹⁶

Finally, FDA’s own admissions are contrary to its position.¹¹⁷ In the legislative history for the 1984 PCB tolerance amendment, FDA admitted that, “[i]n view of the changing nature of scientific knowledge and the public health importance of a tolerance for

109. See generally Vern Walker, *The Myth of Science as a “Neutral Arbiter” for Triggering Precautions*, 26 B.C. INT’L & COMP. L. REV. 197, 220-21 (2003) (generalizing that regulation of carcinogens in US law is another example of legislature and agencies making decisions that are not always based on science).

110. See *id.* (discussing lack of science based decisions when regulating carcinogens). For example, the article discusses FDA and EPA reluctance to strictly adhere to the Delaney Clauses because these clauses stripped agencies of discretion once a compound was found to cause cancerous effects in animal studies. See *id.*

111. See *id.* at 221 (claiming that risk management decisions may outweigh decisions based on science).

112. See Wagner, *supra* note 57, at 1664-65 (discussing EPA difficulties in properly regulating hazardous compounds due to lack of available scientific data).

113. See Miller, *supra* note 89, at 409 (claiming science now has greater role in toxic regulation).

114. See *id.* (noting how scientific advances can better serve in regulation).

115. See Shere, *supra* note 85, at 421 (asserting that scientific advances led to certain regulations and better equipped agencies to regulate carcinogens). The author also noted FDA’s reluctance to comply with literal interpretation of Delaney Clauses. *Id.*

116. See generally Avril, *supra* note 1 (demanding for more current evaluation of PCB contamination).

117. See Polychlorinated Biphenyls (PCBs) in Fish and Shellfish; Reduction of Tolerances; Final Decision, 49 Fed. Reg. 21,514 (May 22, 1984) (to be codified at 21 C.F.R. pt. 109) (noting scientific basis underlying shifts in regulation).

PCBs in fish and shellfish, it is important that the agencies base [their] decision[s] on currently known relevant information.”¹¹⁸

Unlike FDA regulations, it appears that EPA regulations for PCBs are based on more recent scientific information, which better represents the risk associated with PCBs.¹¹⁹ In the legislative history, EPA refused to allow economic factors to dictate its regulation of PCBs because it was contrary to congressional intent.¹²⁰ By comparison, FDA’s standard, used twenty years ago, did not take these recent studies into account.¹²¹ Thus, FDA can now perform a better scientific analysis.¹²²

B. Avoiding Litigation Due to EPA and FDA Disparity

FDA should also consider updating their standards to avoid lawsuits.¹²³ For example, in *Natural Resources Defense Council v. Environmental Protection Agency (Natural Res. Def. Council)*,¹²⁴ plaintiffs filed a claim because EPA failed to issue and revise dioxin standards that reach “all identifiable health and environmental effects” based on the latest available scientific data.¹²⁵ The District Court for the Eastern District of Virginia deferred to EPA and ultimately concluded that EPA had adequately researched the health effects of dioxins and made proper regulatory decisions.¹²⁶

118. See *id.* at 21,517 (discussing need to incorporate most recent studies related to dangers of PCBs, and noting “the submissions are relevant to the toxicity of PCBs and a final decision on the tolerance”).

119. For a discussion on EPA’s regulation of wild salmon, see *supra* notes 64-80 and accompanying text.

120. See Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants; States’ Compliance, 57 Fed. Reg. 60,848, 60,891 (Dec. 22, 1992) (to be codified as 40 C.F.R. pt. 131) (noting that “[w]hile EPA acknowledges that prevailing economic conditions affect individual business decisions concerning investment in pollution control, Congress clearly intended the Agency to move expeditiously when Federal action is warranted”).

121. See *generally id.* (noting more scientific information is available as opposed to twenty years ago).

122. See *generally id.* (reflecting proposition that better science is currently available).

123. See *generally id.* (noting that current science should be used to avoid legal issues).

124. *Natural Res. Def. Council v. Envntl. Prot. Agency*, 806 F. Supp. 1263 (E.D. Va. 1992) (discussing plaintiff’s claim that EPA failed to adequately regulate dioxin levels based on most current scientific data). The plaintiff brought the action under the CWA and under the Administrative Procedures Act. *Id.*

125. See *id.* (stating cause of action regarding Maryland’s dioxin water quality).

126. See *id.* at 1277 (granting EPA’s motion for summary judgment).

Even though EPA prevailed, the significance of this case lies not in its outcome.¹²⁷ The significance lies in the issues being strikingly similar to the current farmed salmon issue, which signifies that future litigation is likely for several reasons.¹²⁸ First, the dispute in *Natural Res. Def. Council* focused on EPA's loose regulations and lack of scientific evidence.¹²⁹ Second, FDA and EPA had different standards, which further complicated the issue.¹³⁰ While the court held that EPA had performed sufficient research, and that differing EPA and FDA standards were not relevant, the outcome might be different concerning farmed salmon.¹³¹ That is, a court may find that FDA did not perform adequate scientific evaluation of PCBs in farmed salmon and that the more stringent EPA standards may be considered evidence of this.¹³² By keeping a 1984 regulation despite new scientific data, FDA is faced with a greater risk of liability.¹³³

Similarly, *Chemical Manufacturer Association v. Natural Resource Defense Council, Inc.* (Chemical)¹³⁴ illustrates the potential for agency liability from a different perspective. In *Chemical*, the court gave EPA considerable deference in interpreting statutes that EPA had the responsibility to administer.¹³⁵ While this generally favors agencies, it also requires the agency to be in firm command of relevant problems regarding the specific issue presented.¹³⁶ Moreover, the dissent noted that when enacting the 1977 CWA amendments,

127. *See id.* (noting court's holding).

128. *See generally id.* (discussing plaintiffs' claims).

129. *See Natural Res. Def. Council*, 806 F. Supp. at 1274 (stating one of plaintiff's main arguments).

130. *See id.* at 1275 (discussing plaintiff's contention concerning initial difference between EPA and FDA standards, and EPA's subsequent adoption of FDA standards).

131. *See id.* at 1274-75 (noting EPA and FDA standards were both scientifically acceptable).

132. *See id.* at 1263 (evaluating argument concerning differing agency standards).

133. *See generally Hites, supra* note 10, at 228 (noting FDA regulation does not address health risks, implying potential liability).

134. *See Chemical Mfr. Ass'n v. Natural Res. Def. Council, Inc.*, 470 U.S. 116, 126 (1985) (resolving dispute over water quality standards though litigated before most recent CWA revision).

135. *See id.* (stating court's view that it will "defer to [EPA] unless the legislative history or the purpose and structure of the statute clearly reveal a contrary intent on the part of Congress").

136. *See id.* at 132, n.24 (stating that EPA typically engages "in an extensive data-collection effort, compiling information on the pollutants discharged by an industry, the process employed, the treatment technologies used by the industry or available for use, the 'treatability' of the pollutants, and the economics of the industry").

Congress acknowledged the potential danger presented by PCBs in fish and shellfish and that “the more we find out, the more cause there is for concern.”¹³⁷ Hence, though FDA may receive deference from the court, it could still face liability by failing to use current science to evaluate PCB risk factors.

Finally, *In re: Paoli Railroad Yard PCB Litigation* (Paoli)¹³⁸ illustrates that the tension between FDA and EPA regulations can also enhance the risk of liability.¹³⁹ In *Paoli*, the district court denied defendant’s summary judgment request because FDA and EPA standards were different, permitting the jury to resolve the disparity.¹⁴⁰ This case is significant because the court refused to grant summary judgment, explaining that the differing standards created a genuine issue of fact which could not be resolved without a trial.¹⁴¹ The disparity of FDA and EPA standards for PCB regulation in farmed salmon poses a significant problem for the farmed salmon industry, and ultimately, a liability risk if the disparate FDA standards do not ensure consumer safety.¹⁴²

There is a stark contrast between EPA and FDA standards when dealing with PCB levels in salmon.¹⁴³ EPA’s recommendation of only one meal per month would result in only one cancer case per one hundred thousand people.¹⁴⁴ FDA’s comparatively less stringent standard encompasses a higher risk of cancer.¹⁴⁵ FDA, therefore, has a duty to perform studies evaluating the safety of PCB levels in farmed salmon to avoid future litigation and to protect

137. *See id.* at 141 (Marshall, J., dissenting) (quoting 123 CONG. REC. H39,181 (1977), Legislative History of the Clean Water Act of 1977, at 454 (1977), which states that empirical evidence has shown that “PCBs are pervasive and have ruined the fishing in the Hudson River and the Great Lakes” and that “[i]t is imperative that these materials be controlled”).

138. *See In re: Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 796 (E.D.PA 1994) (stating basis of CERCLA claim involving, among other things, PCB levels in water runoff).

139. *See id.* at 796 (noting dispute between parties).

140. *See id.* (stating that EPA’s normal practice of “cleaning up property to the point where the risk is 1 in 1,000,000 creates a genuine issue of material fact as to whether a cancer risk of 1 in 100,000 constitutes permanent damage; the tension with . . . FDA standards is for the jury to resolve”).

141. *See id.* (refusing to grant summary judgment due to agency differences in regulation).

142. *See Avril, supra* note 1 (discussing problem concerning FDA and EPA disparity).

143. *See generally* Hites, *supra* note 10, at 226 (comparing agency standards for PCB limits).

144. *See Kay, supra* note 32 (describing risks of salmon consumption based on EPA standards).

145. *See id.* (noting disparity between EPA and FDA standards).

consumers from relying on what is otherwise known as a health food.

V. IMPACT

The most recent study of farmed salmon is indeed controversial and raises many questions concerning whether salmon is safe for consumption.¹⁴⁶ The Global Study authors admitted that contaminants found in farmed salmon present a “confusing message for the consumer.”¹⁴⁷ Salmon with high PCB levels pose potentially serious health problems, including ailments other than cancer risks, such as impairment of fetal brain development.¹⁴⁸ More significantly, the half-life of many PCBs can last a decade, rendering recent warnings regarding salmon intake as “too late” for expecting mothers.¹⁴⁹

Concern is worldwide, as illustrated in Great Britain, where a news publication wrote: “levels of cancer-causing toxins in Scottish farmed salmon are so high that consumers are being advised not to eat more than one portion every two months,” and “women of child bearing age would be advised not to eat Scottish salmon at all for fear of causing birth defects and brain damage in their unborn children.”¹⁵⁰ With regard to FDA standards, a Global Study co-author stated that “[j]ust because the contaminants we found do not exceed FDA levels, that doesn’t mean they are safe for consumers.”¹⁵¹ The executive director of Salmon of the Americas industry groups concedes “[t]he fact is that PCBs don’t belong in any food,” and that “we are working very hard to get [PCBs] out.”¹⁵²

Some believe that this study does nothing more than unnecessarily alarm people in the United States because it is an undocumented risk.¹⁵³ Nonetheless, those who support the study indicate

146. See Avril, *supra* note 1 (noting that Global Study was initially rejected for publication until authors “toned it down slightly”).

147. See *id.* (quoting author’s comments concerning Global Study).

148. See *id.* (describing risks stemming from PCBs aside from cancer).

149. See *id.* (stating risks associated with PCB intake, specifically adverse effects on pregnant mothers).

150. See ECES *New study recommends eating farmed salmon once a month at most after finding that they are significantly more contaminated with PCBs, dioxins and the banned pesticides toxaphene and dieldrin than wild salmon*, available at, <http://www.eces.org/articles/000727.php> (last modified Jan. 09, 2004) (summarizing various articles examining Global Study).

151. See *id.* (noting author’s criticism in Global Study).

152. See *id.* (stating concern and imminent action by industry groups).

153. See Avril, *supra* note 1 (quoting Harvard School of Public Health official denouncing most recent global study, and noting commentary from Rutgers University toxicologist who supported results but equated study to “political polemic”).

that the measurement data is sound.¹⁵⁴ Addressing this issue quickly is imperative because of farmed salmon's growing popularity which, in part, is due to that fact that it costs less than wild salmon.¹⁵⁵ In addition, more than ninety percent of the fresh salmon purchased in the U.S. is farmed, and sales have been growing from ten to twenty percent each year.¹⁵⁶

EPA seems to have considered recent scientific data with their regulation of salmon, and FDA should do the same.¹⁵⁷ Unfortunately, as the director of Salmon of the Americas commented, "until we hear differently from the FDA, we assume that theirs are the regulations we need to follow," and that "EPA and FDA should work their differences out."¹⁵⁸

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154. *See id.* (noting Global Study's supporters consider its scientific basis and results as "sound").

155. *See id.* (illustrating price difference between wild and farmed salmon – five versus fifteen dollars); *see also* Kay, *supra* note 32 (citing San Francisco price difference of one dollar between wild and farmed salmon).

156. *See* ECES, *supra* note 150 (illustrating increase in farmed salmon consumption).

157. *See generally* Avril, *supra* note 1 (noting disparity between FDA and EPA standards).

158. *See* Suwol, *supra* note 47 (discussing EPA and FDA disparity and resulting criticism).

