SOMETHING'S IN THE WATER: ALTERING RADIATION REGULATIONS AND SEAFOOD IMPORT ALERTS BY THE FDA IN THE WAKE OF THE FUKUSHIMA DISASTER

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I. INTRODUCTION

In general, everyone has an idea of what radiation is and a healthy fear of its effects. This fear, however, does not take into account the sinister effects of radiation upon the human body. Without any accompanying visuals, sounds, smells, taste, or any other physical manifestation, radiation is a true silent killer. As smaller fish are consumed by larger fish, their contaminants and toxins are absorbed by the larger fish, and so-on up the food chain. This is called "bioaccumulation."[1]

Just as these bioaccumulated fish are passed up the food chain, so are the risks, which are passed from fisherman to market to buyer and, eventually, to consumer. The consumer stands the most to lose from seafood contaminated with radioactive materials. A consumer on the West Coast could unwittingly eat seafood from the coastal waters of Japan, near Fukushima, without knowing and continue to do so day after day. After all, isn't Japanese seafood said to be a mark of quality?[2] This consumer could then, after a period of some years, develop highly dangerous cancers as a result of eating fish contaminated with cesium, iodine, plutonium, or strontium, all chemical elements leaked from Fukushima,[3] bioaccumulated up the food chain. This silent killer could strike without warning, and it could all stem back to a 2011 incident off the coast of Japan.

March 11, 2011 marked the start of Japan's nuclear nightmare, when the Fukushima Daiichi nuclear power station ("Fukushima") was rocked by both earthquake and tsunami .[4] Nearly 16,000 people died in the wake of the devastation.[5] Off the Eastern coast of Honshu, Japan's largest island, a 9.0 magnitude earthquake rocked the Earth, with an epicenter

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[1] *What is Bioaccumulation?*, MICH. DEPT. OF CMTY. HEALTH (2020), https://www.michigan.gov/documents/mdch/Bioaccumulative__Persistent_Chemicals_FINAL_354016_7.pdf.

[2] *See Norwegian Seafood Takes Off in SE Asia*, THE NATION (Apr. 21, 2018), https://www.nationthailand.com/Economy/30343606 (Consumers are more likely to patronize restaurants that they believe is serving Japanese seafood, even though the seafood they are eating is actually from Norway. The restaurant in the article has used the popularity of the "high quality of Japanese seafood" idea to its own advantage to draw in picky consumers.).

[3] Ed Vitz et al., *Radiation Contamination from Fukushima*, CHEMISTRY LIBRETEXTS, https://chem.libretexts.org/Ancillary_Materials/Exemplars_and_Case_Studies/Exemplars/Environmental_and_Green_chemistry/Radiation_Contamination_from_Fukushima (last visited Dec. 20, 2018).

[4] MARK HOLT ET AL., CONG. RESEARCH SERV., R41694, FUKUSHIMA NUCLEAR DISASTER 1 (2012).

[5] Jotaro Yokoyama, *Fukushima Disaster and Reform*, 43 ENVTL. POL'Y & L. 226, 226 (2013).

approximately eighty miles out to sea from the coastal city of Sendai.[6] The earthquake was the largest event ever recorded in Japan.[7] It was a rare and complex double-quake, shifting the Earth so much that Japan moved a few feet to the east.[8] The massive earthquake triggered an automatic shutdown of eleven reactors at four[9] of Japan's fifty-five operational nuclear power plants, most of which suffered little to no damage.[10] However, when the resulting forty-nine foot high tsunami[11] struck the coast, it obliterated everything in its path and easily overtopped a twenty foot high seawall at Fukushima, one of the nuclear power plants closest to the epicenter.[12]

Fukushima was rocked by two explosions in the days following the earthquake and the tsunami.[13] These explosions resulted in high radiation levels outside Fukushima, where only a moment's exposure equaled one year's worth of allowable radiation.[14] To save the dangerously overheating nuclear power plant, Fukushima's operators flooded the damaged reactors with water in a "last-ditch" effort to cool the plant.[15] In the aftermath of the damage to Fukushima, water contaminated with radioactive material had not only leaked into the ocean, but had also been intentionally dumped directly into it.[16] All varieties of sea creatures, many of which are consumed by humans the world over, were impacted by the radioactive materials spilled into the ocean.[17]

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[6] Michael Faure & Jing Liu, *The Tsunami of March 2011 and the Subsequent Nuclear Incident at Fukushima: Who Compensates the Victims*, 37 WM. & MARY ENVTL. L. & POL'Y REV. 129, 131 (2012).

[7] P. Carydis, A. Pomonis & K. Goda, *Fukushima Daiichi Nuclear Power Plant: A Retrospective Evaluation*, 15TH WORLD CONG. ON EARTHQUAKE ENG'G 1 (Sept. 2012), https://www.iitk.ac.in/nicee/wcee/article/WCEE2012_2832.pdf.

[8] *Fukushima Daiichi Accident*, WORLD NUCLEAR ASS'N, http://www.world-nuclear.org/information-library/safety-and-security/safety-of-plants/fukushima-daiichi-accident.aspx (last updated June 2018).

[9] *Id.*

[10] RICHARD J. CAMPBELL ET AL., CONG. RESEARCH SERV., R41694, FUKUSHIMA NUCLEAR CRISIS 1 (2011).

[11] *Fukushima Daiichi Accident*, *supra* note 8.

[12] Campbell, *supra* note 10, at 2.

[13] Darian Ghorbi, *There's Something in the Water: The Inadequacy of International Anti-Dumping Laws as Applied to the Fukushima Daiichi Radioactive Water Discharge*, 27 AM. U. INT'L L. REV. 473, 475 (2012).

[14] *Id.* Nuclear workers are normally allowed to receive a dose of 20 mSv of radiation per year, and up to 100 mSv in emergency situations. *See Japan to Raise Worker Emergency Radiation Exposure Limits*, WORLD NUCLEAR NEWS (May 21, 2015), http://www.world-nuclear-news.org/RS-Japan-to-raise-worker-emergency-radiation-exposure-limits-2101154.html. Radiation dose rates of up to 1,000 mSv per hour were reported following the disaster, before stabilizing between 600 and 800 mSv per hour. *See Radiation Spike Hinders Work at Japan Nuke Plant*, CBS NEWS (Mar. 16, 2011), https://www.cbsnews.com/news/radiation-spike-hinders-work-at-japan-nuke-plant/.

[15] Ghorbi, *supra* note 13, at 475.

[16] *Id.*

[17] EUGENE H. BUCK & HAROLD F. UPTON, CONG. RESEARCH SERV., R41751, EFFECTS OF RADIATION FROM FUKUSHIMA DAI-ICHI ON THE U.S. MARINE ENVIRONMENT 1-4 (2012).

While the nuclear materials from Fukushima may not impact U.S. fisheries in the near future, both ocean currents and atmospheric winds have the potential to carry radiation over and into the territorial waters of the United States.[18] Further, those fish that make it to American markets from the seas around Japan may bring radioactive contamination with them.[19] Some sea creatures harvested by Japanese fishers have been found to have elevated levels of radiation.[20] Higher than normal levels of radioactive iodine-131, cesium-137, and cesium-134[21] were all measured in the ocean adjacent to Fukushima in the days since the earthquake-tsunami.[22] To head this issue off at the pass, rather than wait decades down the line when the human cost will be too great, the Food and Drug Administration ("FDA") should pass binding regulations that would prevent products with elevated levels of radiation from coming into U.S. markets, rather than promoting toothless import alerts that may not actually protect American consumers when challenged in court.

First, this article will describe the history of nuclear power in Japan, the effect of the Fukushima disaster on sea life, and the mechanisms by which radiation from Fukushima continues to contaminate the ocean. Second, this article will discuss Japanese regulations in reaction to this disaster and the role they play compared to the American regulations through the FDA. Third, this article will use case law and precedent to lay out a step-by-step recommendation of how the current FDA import alert system should be improved. The dangerous fallout from Fukushima has potential to impact populations not only across Japan and East Asia, but may rear its head in the United States' own coastal population, and thus must be acted upon in a preventative manner rather than a reactive one.

II. BACKGROUND

A. Nuclear Power in Japan

Despite being the only country that has experienced the devastation of nuclear weapons, Japan has embraced nuclear power to provide a substantial portion of its energy needs.[23] Following the atomic

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[18] *Id.* at 1-2.

[19] *Id.* at 2.

[20] *Id.* at 2-3.

[21] These are radioactive isotopes, also known as radioisotopes or radionuclides, which are unstable forms of their parent elements. These isotopes have a different atomic mass compared to the parent form of their parent elements, denoted by the number affixed to the end of the element name. These isotopes are created via the production of nuclear energy and emit dangerous radiation. *See Radioisotopes: What Are They and How Are They Made?*, DEP'T OF ENERGY, https://ehss.energy.gov/ohre/roadmap/achre/intro_9_4.html.

[22] Buck, *supra* note 17, at 2.

[23] *Nuclear Power in Japan*, WORLD NUCLEAR ASS'N, http://www.world-nuclear.org/information-library/country-profiles/countries-g-n/japan-nuclear-power.aspx (last updated Mar. 2020).

bombing that ended the Second World War, anti-nuclear sentiment in Japan was extremely high, with depictions across the entire spectrum of Japanese culture, from politics to cinema.[24] Although other countries were also greatly devastated by the war, the atomic bombings of Hiroshima and Nagasaki imprinted themselves on the Japanese national psyche, echoing into the modern era with their longstanding national ban on nuclear weaponry.[25] Consequently, it was a surprising turn of events when the Japanese embraced nuclear technology, albeit for peaceful purposes, with open arms.[26] Up until the Fukushima disaster in 2011, Japan had been generating 30% of its electricity from its fifty-four nuclear reactors.[27] By comparison, the United States produced about 20% of its electricity from nuclear power plants in 2018.[28] Before the Fukushima disaster skewed the projections, Japan was slated to produce 50% of its electricity from nuclear power plants by 2030.[29] However, after the disaster, public sentiment regarding nuclear energy in Japan shifted markedly.[30]

Following the disaster at Fukushima, widespread public protests called for nuclear power to be abandoned altogether.[31] With total costs of the Fukushima disaster reaching into the hundreds of billions of dollars, a predictably unhappy public now faces the reality of a fallout clean-up plan that makes them shoulder a part of that burden.[32] As a result, there have been renewed calls for the closing of all Japanese nuclear power plants.[33] In a poll conducted by the pro-nuclear Japan Atomic Energy Relations

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[24] *See* Masakatsu Ota, *Conceptual Twist of Japanese Nuclear Policy: Its Ambivalence and Coherence Under the US Umbrella*, 1 J. FOR PEACE & NUCLEAR DISARMAMENT 193, 193-98 (2018).

[25] Shigenori Matsui, *T-Rex, Jurassic Park and Nuclear Power: Nuclear Power Plants and the Courts After the Fukushima Nuclear Accident*, 42 WM. & MARY ENVTL. L. & POL'Y REV. 145, 145 (2017); *Japan*, NUCLEAR THREAT INITIATIVE, https://www.nti.org/learn/countries/japan/nuclear/ (last updated Oct. 2018).

[26] Ota, *supra* note 24, at 197.

[27] Matsui, *supra* note 25, at 148; *Nuclear Power in Japan*, *supra* note 23.

[28] *Nuclear Power in the USA*, WORLD NUCLEAR ASS'N, http://www.world-nuclear.org/information-library/country-profiles/countries-t-z/usa-nuclear-power.aspx (last updated Apr. 2020).

[29] *Nuclear Power in Japan*, *supra* note 23.

[30] Mari Saito & Sophie Knight, *Thousands in Japan Anti-Nuclear Protest Two Years After Fukushima*, REUTERS (Mar. 10, 2013, 5:40 AM), https://www.reuters.com/article/us-japan-protest/thousands-in-japan-anti-nuclear-protest-two-years-after-fukushima-idUSBRE92903Y20130310.

[31] Mari Saito and Sophie Knight, *Thousands in Japan anti-nuclear protest two years after Fukushima*, REUTERS (Mar. 10, 2013), https://www.reuters.com/article/us-japan-protest/thousands-in-japan-anti-nuclear-protest-two-years-after-fukushima-idUSBRE92903Y20130310.

[32] Tatsujiro Suzuki, *Six Years After Fukushima, Much of Japan Has Lost Faith in Nuclear Power*, THE CONVERSATION (Mar. 9, 2017, 10:30 AM), http://theconversation.com/six-years-after-fukushima-much-of-japan-has-lost-faith-in-nuclear-power-73042.

[33] *Id.*

Organization, only 10.1% of polled Japanese citizens said that the use of nuclear energy should be maintained.[34]

Prior to the disaster at Fukushima, some Japanese citizens protested and filed lawsuits to stop the operation of nuclear power plants, but Japanese courts were typically reluctant to intervene, essentially siding with the government and nuclear power companies.[35] However, the disaster at Fukushima clearly demonstrated that nuclear power is fraught with risks and nuclear accidents could cause serious damage; enough damage to cause a change in the judicial attitude towards nuclear power plants in Japan.[36]

This change in attitude towards nuclear energy in Japan manifested a major effect on the reality of Japanese energy production, and, since 2011, Japan has shuttered many of its nuclear power plants.[37] In 2017, Japan produced only about 3% of its electricity from nuclear power plants, a far cry from the 30% in 2011,[38] demonstrating that fears regarding nuclear energy in Japan have clearly manifested into its electricity production policy.

B. Damage to the Fukushima Power Plant

The Fukushima power plant complex consists of two separate nuclear plants, Fukushima Daiichi (first) and Fukushima Daini (second), with Daiichi being about 6.8 miles to the north of Daini.[39] The Fukushima Daiichi plant began construction in 1967[40] and was designed to withstand tsunamis based on an assessment of the 1960 Chile tsunami,[41] a tsunami that resulted from the most powerful earthquake ever recorded.[42] The Fukushima power plant was built on the coast of Japan, thirty-three feet above sea level, with its seawater pumps thirteen feet above sea level.[43] In 2002, the seawater pumps, meant to cool the reactor, were redesigned, sealed, and raised to nineteen feet above sea level.[44] However, the 2011 tsunami created waves approximately 49 feet high, and the power plant's turbine halls were submerged under over sixteen feet of seawater until the

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[34] *Id*.

[35] Matsui, *supra* note 25, at 145-46.

[36] *See id.* at 189 (Several courts granted injunctions against the restart of nuclear reactors following the Fukushima disaster.).

[37] *Nuclear Power in Japan*, *supra* note 23.

[38] *Id*.

[39] *Fukushima Daiichi Accident*, *supra* note 8.

[40] *See* Carydis, *supra* note 7, at 2. The Fukushima reactors are boiling water reactors designed by the General Electric Company, similar to ones in use in the United States. *See* Stephen G. Burns, *The Fukushima Daiichi Accident: The International Community Responds*, 11 WASH. U. GLOBAL STUD. L. REV. 739, 742 (2012).

[41] *Fukushima Daiichi Accident*, *supra* note 8.

[42] *1960 Chile Tsunami*, WESTERN STATES SEISMIC POLICY COUNCIL, https://www.wsspc.org/resources-reports/tsunami-center/significant-tsunami-events/1960-chile-tsunami/.

[43] *Fukushima Daiichi Accident*, *supra* note 8.

[44] *Id*.

ocean subsided.[45] As such, the 2002 redesign proved to be grossly ineffective, as everything was submerged, creating a toxic slurry of contaminated radioactive water.[46]

Like Fukushima, many nuclear plants are built along the coast in other countries, as the vast amounts of seawater make for an easily accessible resource to keep the plants cool.[47] However, when such power plants are constructed near the ocean, it follows that they should be built to withstand whatever elements the sea may throw at them.

Earthquakes and their resulting tsunamis are a recurring problem in the Japanese archipelago, so much so that Japanese architects and building planners have become adept at earthquake proofing new constructions. However, failing to update older buildings with new earthquake proofing technology has been a problem in Japan.[48] In fact, TEPCO, the electric utility company that operated the Fukushima nuclear power plant facility, was found guilty of negligence in 2017 by a Japanese court for failure to prevent meltdowns at the facility during the 2011 catastrophe.[49] The court found that TEPCO should have been able to predict and prevent the disaster at Fukushima and ordered TEPCO to pay damages to victims of the disaster.[50] The National Diet of Japan Fukushima Nuclear Accident Independent Investigation Commission ("NAIIC"), in a damning report on the actions taken by TEPCO in maintaining the Fukushima power plant, stated that TEPCO, as the nuclear operator, and a host of Japanese

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[45] *Id.*

[46] *Id.*

[47] *See Map of Power Reactor Sites*, U.S. NUCLEAR REGULATORY COMM'N, https://www.nrc.gov/reactors/operating/map-power-reactors.html (demonstrating numerous American nuclear power plants are constructed along the coast); John Vidal, *What are Coastal Nuclear Power Plants Doing to Address Climate Threats?*, ENISIA (Aug. 8, 2018), https://ensia.com/features/coastal-nuclear/ (using the Fukushima disaster to address the preventable problem and dangers posed by coastal nuclear power plants in the event of flooding).

[48] *See 28% of Municipal Government Buildings Still at Risk from Earthquakes: Survey*, JAPAN TIMES (Mar. 11, 2018), https://www.japantimes.co.jp/news/2018/03/11/national/28-municipal-government-buildings-still-risk-earthquakes-survey/#.XEOSNy2ZPOQ (stating that, according to a survey by the internal affairs ministry, nearly 30 percent of the nation's municipalities had not completed seismic reinforcement work on their main buildings as of the end of 2017); James M. Acton & Mark Hibbs, *Why Fukushima Was Preventable*, THE CARNEGIE ENDOWMENT FOR INT'L PEACE 1 (Mar. 2012), https://carnegieendowment.org/files/fukushima.pdf (asserting that a major tsunami caused accident at Fukushima could have been prevented if the power plant's outdated disaster prevention mechanisms and reinforcements had been updated).

[49] Motoko Rich, *Japanese Government and Utility Are Found Negligent in Nuclear Disaster*, N.Y. TIMES (Mar. 17, 2017), https://www.nytimes.com/2017/03/17/world/asia/japan-fukushima-nuclear-disaster-tepco-ruling.html.

[50] *Id.*

regulatory bodies failed to correctly prepare and implement the most basic safety requirements needed to avoid the disaster.[51]

Fukushima had six reactor units.[52] This is a relatively large number of reactors for one plant,[53] which heightened the chance for catastrophe in the event of a meltdown. Comparatively, current and planned U.S. nuclear power plants typically have only two or three reactors.[54] At the time of the 2011 earthquake and tsunami, Fukushima's reactor units one, two, and three were operational, while reactor units five and six were shut down as part of routine maintenance work.[55] Only unit four had no fuel in its reactor.[56]

When the earthquake hit in 2011, it triggered an automatic shutdown of the three operating reactors at Fukushima, causing the reactor control rods to be inserted to stop the fission reaction from generating electricity.[57] The same automatic process occurred at eight other reactors in Japan, causing a "sudden loss of power across Japan's power grid" and cutting crucial electricity supplies to Fukushima.[58] Because external power supply sources to the power plant were disabled when the national power grid was affected, the on-site emergency diesel generators at the power plant had to be activated in order to keep the reactors cooled.[59] However, these on-site emergency diesel generators were knocked out of commission when the forty-nine foot waves from the tsunami breached the power plant's sea wall and flooded the facility.[60] The tsunami also drowned the electrical switchgear and batteries located in the basements of the turbine building, with the one surviving air-cooled generator serving units five and six.[61]

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[51] Kiyoshi Kurokawa & Andrea Ryoko Ninomiya, *Examining Regulatory Capture: Looking Back at the Fukushima Nuclear Power Plant Disaster, Seven Years Later*, 13 U. PA. ASIAN L. REV. 47, 53-54 (2018).

[52] Carydis, *supra* note 7, at 1.

[53] *See U.S. Operating Nuclear Reactors*, WORLD NUCLEAR ASS'N, http://world-nuclear.org/information-library/country-profiles/countries-t-z/appendices/nuclear-power-in-the-usa-appendix-1-us-operating-n.aspx.

[54] *See id.*; *Westinghouse, Blue Castle Working to Bring Benefits of AP1000® Plant Technology to Western Us*, WESTINGHOUSE NUCLEAR (Aug. 20, 2014), http://www.westinghousenuclear.com/About/News/View/ArticleId/447/Westinghouse-Blue-Castle-Working-to-Bring-Benefits-of-AP1000-Plant-Technology-to-Western-US (discussing plans for a new, two-unit nuclear power plant).

[55] Burns, *supra* note 40, at 742.

[56] *Id.*

[57] Carydis, *supra* note 7, at 1.

[58] *Id.*; Antonios Pomonis et al, *The M_W 9.0 Tōhoku Earthquake and Tsunami of 11th March 2011*, THE INSTITUTION OF STRUCTURAL ENGINEERS 132 (2011), https://www.istructe.org/IStructE/media/Public/Resources/report-eefit-mission-japan-20111203.pdf.

[59] Carydis, *supra* note 7, at 1.

[60] *Id.*

[61] *Fukushima Daiichi Accident*, *supra* note 8.

As a consequence, four of the reactor units entered a state known as "station blackout," where "the only electric power comes from station batteries, which are capable of providing power only in terms of hours, not days."[62] In this station blackout, the reactors were isolated from their ultimate heat sink.[63] Without a functional heat removal system connected to the facility, "the reactor cores increased in temperature, evaporating the surrounding water and, once there was no more water left to evaporate, the cores began to melt down."[64] Even after the reactors were finally shut down, they continued to produce heat.[65] "To cool down the nuclear fuel, plant workers tried to do everything they could."[66] They attempted "to cool down the reactor cores as well as the fuel stored in the fourth reactor by supplying water from outside."[67] The workers were so desperate to stop the reactors from melting down that they resorted to using seawater to cool the reactors, "knowing that the use of seawater would ruin the system" and potentially contaminate the environment.[68] The tsunami had further damaged and obstructed roads, making outside access difficult for emergency cleanup and repair crews, prolonging the resulting damage.[69]

Despite the best efforts of plant facility workers to cool the reactors, unit one lost its cooling status within hours.[70] The initial loss of cooling in unit one was followed by unit three, which lost its cooling status within thirty-six hours, and unit two, which lost cooling within seventy-one hours.[71] The loss of cooling damaged the fuel in all three reactors.[72] Damaged fuel within a nuclear reactor has the potential to release catastrophic amounts of radiation by triggering a meltdown.[73] At Fukushima, the damaged fuel caused the release of hydrogen gas, which then ignited and exploded, "impair[ing] the functionality of the equipment and the integrity of structures at the site," further complicating already challenging recovery operations at the power plant.[74] This caused the reactors to suffer meltdowns, with subsequent explosions polluting the air

[62] Burns, *supra* note 40, at 742.
[63] *Id.* at 744. The ultimate heat sink of a nuclear power plant is the source of the water that provides cooling for the reactors: the ocean, river, or lake that provides ultimate cooling. It is imperative that the ultimate heat sink remain stable in order for the reactors to avoid melting down. *See* Kari Lydersen, *Amid Climate Concerns, Nuclear Plants Feel the Heat of Warming Water*, ENERGY NEWS NETWORK (Sept. 9, 2016), https://energynews.us/2016/09/09/midwest/nuclear-plants-feel-the-heat-of-warming-water/.
[64] Matsui, *supra* note 25, at 175.
[65] *Id.*
[66] Matsui, *supra* note 25, at 175.
[67] *Id.*
[68] *Id.*
[69] Burns, *supra* note 40, at 743; *Fukushima Daiichi Accident*, *supra* note 8.
[70] Burns, *supra* note 40, at 743.
[71] *Id.*
[72] *Id.*
[73] *See id.*
[74] *Id.*

and ocean around the power plant with massive doses of radioactive material.[75]

In a last-ditch effort to cool the plant, Fukushima's operators flooded the damaged reactors with water, but this had the unfortunate side-effect of greatly contaminating the water with massive amounts of radiation.[76] In the aftermath of the catastrophe, this contaminated water did more than just leak into the ocean; it was intentionally dumped directly into it.[77]

The Japanese government announced in mid-December 2011 that the three damaged reactors had entered a state of cold-shutdown.[78] This would ostensibly be a significant step in maintaining the long-term stability of the damaged reactors,[79] but in 2013 it was announced that a toxic mix of highly radioactive water being used to cool melted fuel at Fukushima continued to seep into the ocean at a rate of 300 tons per day.[80] In fact, it was further revealed in 2018 that TEPCO failed to adequately contain radiation leaking from the plant, contrary to what had previously been reported.[81] Despite being responsible for cleaning and maintaining the damaged facility, TEPCO revealed that contaminated water around the plant's reactors has continued to seep into the ground, causing major difficulties in the decommissioning process.[82] In February 2018, damaged fuel at Fukushima continued to leak radioactive particles into the environment, despite best efforts to contain and clean the area around the power plant.[83] TEPCO admitted that it could take until 2020 for the contamination issue to be resolved; however, in the meantime, exposure to the radiation leaking from the plant could kill a human in just one hour.[84]

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[75] Geoff Brumfiel, *Fukushima's Doses Tallied*, 485 NATURE 423, 423 (May 24, 2012).

[76] Ghorbi, *supra* note 13, at 475.

[77] *Id*.

[78] Burns, *supra* note 40, at 745.

[79] *Id*.

[80] Mari Saito & Antoni Slodkowski, *Japan Says Fukushima Leak Worse Than Thought, Government Joins Clean-Up*, REUTERS (Aug. 7, 2013, 10:16 PM), https://www.reuters.com/article/us-japan-fukushima-pm/japan-says-fukushima-leak-worse-than-thought-government-joins-clean-up-idUSBRE97601K20130808; Justin McCurry, *Fukushima Radiation Levels 18 Times Higher Than Previously Thought*, THE GUARDIAN (Sept. 1, 2013 5:22 PM), https://www.theguardian.com/environment/2013/sep/01/fukushima-radiation-levels-higher-japan.

[81] Jeff Farrell, *Fukushima Nuclear Disaster: Lethal Levels of Radiation Detected in Leak Seven Years After Plant Meltdown in Japan*, THE INDEPENDENT (Feb. 2, 2018, 3:16 PM), https://www.independent.co.uk/news/world/asia/fukushima-nuclear-disaster-radiation-lethal-levels-leak-japan-tsunami-tokyo-electric-power-company-a8190981.html.

[82] *Id*.

[83] *See New Evidence of Nuclear Fuel Releases Found at Fukushima*, UNIV. OF MANCHESTER (Feb. 28, 2018), https://www.manchester.ac.uk/discover/news/new-evidence-of-nuclear-fuel-releases-found-at-fukushima/.

[84] Farrell, *supra* note 81.

C. Radiation and its Effects on Sea Life

Higher than normal levels of radioactive iodine-131, strontium-90, cesium-134, and cesium-137 were all measured in the ocean adjacent to Fukushima in the time following the catastrophe.[85] The highest concentrations of radiation were found close to the coast, mainly of iodine-131 and cesium-137.[86] The occurrence of cesium-137 is of greater concern because of its longer half-life.[87] A longer half-life means, for example, that "radioactive iodine decays naturally within weeks but [cesium] can stay in the environment for many years."[88] The effects of this are severe, as exposure to radioactive cesium can result in an increased risk of cancer.[89] Cesium has no known taste or odor accompanying it, and can accumulate in humans from food contaminated with the element.[90]

At least seventy-three species of sea creatures are known to have been affected by radiation as a result of the Fukushima disaster.[91] Some of these species include flounder, cod, blue crab, squid, sea urchins, clams, mackerels, pollock, salmon, and sardines.[92] Seafood affected by Fukushima has been sold in Japanese markets[93] and, in March 2018, began to be exported to markets abroad for the first time since the 2011 disaster.[94] One month after the disaster, a sand lance fish caught near Fukushima was found to have cesium isotope levels twenty-five times the legal consumption

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[85] Buck, *supra* note 17, at 2; *FAQs: Radiation from Fukushima*, WOODS HOLE OCEANOGRAPHIC INST. (June 6, 2019), https://www.whoi.edu/press-room/news-tip/faqs-radiation-from-fukushima/.

[86] Buck, *supra* note 17, at 2.

[87] *Id.*

[88] *Fukushima's Fish Industry Yet to Recover*, U.N. OFFICE FOR DISASTER RISK REDUCTION (Mar. 31, 2015), https://www.unisdr.org/archive/43503.

[89] *Id.*

[90] *Public Health Statement: Cesium*, DEP'T OF HEALTH AND HUMAN SERVS., AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY 2-3 (Apr. 2004), https://www.atsdr.cdc.gov/ToxProfiles/tp157-c1-b.pdf.

[91] Hiroki Wakamatsu & Tsutom Miyata, *Reputational Damage and the Fukushima Disaster: An Analysis of Seafood in Japan*, 83 FISHERIES SCI. 1049, 1050 (2017).

[92] *Id.* For more information on the affected species, *see id.* Table 1.

[93] *Id.*

[94] *Fukushima Exports First Fish Consignment Since Nuclear Disaster*, EFE (Mar. 1, 2018), https://www.efe.com/efe/english/world/fukushima-exports-first-fish-consignment-since-nuclear-disaster/50000262-3539377.

limit.[95] Other fishery products including "cherry salmon, rock fish, flounder, sea urchin, [and] seabass" were also found to be contaminated.[96]

In trying to scrub and contain the radiation from the environment, one problem is that the very sands of the beaches around Fukushima and the brackish waters inland from the ocean are hindering clean-up efforts.[97] Radioactive cesium contains properties which make it stick to grains of sand like glue, which makes clean-up difficult.[98] The high levels of radioactive cesium-137 released in 2011 were transported along the coast by ocean currents and, in the weeks after the disaster, the waves and tides brought the cesium in these highly contaminated waters onshore, where the cesium "stuck" to the surfaces of sand grains.[99] The cesium-enriched sands on the beaches and the brackish mixture of fresh water and salt water underneath the beaches act together as a mechanism constantly transporting cesium back out to sea.[100]

As cesium contaminates the water surrounding Fukushima and spills into the greater Pacific Ocean off the coast of Japan, the radioactive cesium in marine fish can become concentrated 5 to 100 times the concentration of radioactive cesium in seawater.[101]

As radiation makes its way into the bodies of various species of sea life, it has cascading effects up through the food chain.[102] This bioaccumulation is how a relatively minor bit of radiation in the bottom of the food chain can make its way up through the food chain, from smaller fish to larger species like tuna and other species that humans eat and, eventually, settling into the human microbiome.[103]

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[95] Gijs Berends and Megumi Kobayashi, *Food after Fukushima - Japan's Regulatory Response to the Radioactive Contamination of Its Food Chain*, 67 FOOD & DRUG L.J. 51, 52 (2012). The Fisheries Agency of Japan is the body responsible for monitoring levels of radiation in seafood. *See The Solution of Stop the Contaminated Water and The Safety of Fishery Products at TEPCO's Fukushima Daiichi Nuclear Power Station*, FISHERIES AGENCY OF JAPAN (Sept. 2018), https://web.archive.org/web/20181114211604/http://www.jfa.maff.go.jp/pdf/181102English.pdf.

[96] Berends, *supra* note 95, at 51.

[97] Lonny Lippsett, *Radioactivity Under the Beach? Pollution from Fukushima Disaster Found in Unexpected Spot*, 53 OCEANUS 8 (2017).

[98] *Id.*

[99] *Id.*

[100] *Id.*

[101] *Questions and Answers about Fishery products (Monitoring for radioactive materials), Fisheries Agency of Japan*, *https://web.archive.org/web/20181114212645/http://www.jfa.maff.go.jp/e/q_a/index.html*.

[102] *See* Elizabeth Grossman, *Radioactivity in the Ocean: Diluted, But Far from Harmless*, YALE ENVIRONMENT 360 (Apr. 7, 2011), https://e360.yale.edu/features/radioactivity_in_the_ocean_diluted_but_far_from_harmless.

[103] *Id.*

In the Pacific Ocean, plankton, a class of waterborne microorganisms that includes both plants and animals,[104] have been detected containing high levels of radioactive cesium originating from Fukushima.[105] If plankton are contaminated with cesium, then this presents a very large problem, as they are eaten by all manner of sea creatures up the food chain.[106] Dangerous levels of both cesium and strontium have been found in species of fish at varying levels of the food chain off the coast near Fukushima.[107] With regards to strontium, it has been found to have substantially impacted smaller, bony fish, like sardines, due to its bone-seeking properties.[108] Since strontium's chemical makeup resembles calcium, it assimilates in bones and teeth, where it causes radiation injury by damaging bone marrow, impairing the process of forming new blood cells, and possibly inducing cancer.[109] This presents a significant danger to humans, as these small, bony fish are often consumed whole: bones and all.[110] Further, when these fish are consumed by other, larger fish, radioactive materials cascade up the food chain, eventually ending up on the dinner plate of an American.

D. Japanese Regulations and Reaction

The Japanese government had regulations in place in case of disaster.[111] Unfortunately, the scope of these regulations was not wide enough to be an effective and preventative tool for stopping all contaminated seafood from entering the market, as fish with high levels of radioactive iodine were not covered by the provisional values.[112] In response to the Fukushima disaster, the Japanese government imposed new regulations regarding radioactivity, but some radioactive products had already slipped into the market via the unregulated stream of commerce.[113] Since April 2012, the Japanese government lowered the allowable standard limit of radioactive cesium in fishery products from 500 becquerels per kilogram (or "bq/kg," a becquerel being the standard unit of radioactivity)

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[104] *Plankton*, WOODS HOLE OCEANOGRAPHIC INSTITUTION, https://www.whoi.edu/science/B/people/kamaral/plankton.html.

[105] *Researchers Find High Cesium in Some Pacific Plankton*, JAPAN TIMES (May 22, 2013), https://www.japantimes.co.jp/news/2013/05/22/national/researchers-find-high-cesium-in-some-pacific-plankton/#.XEUUjy2ZPOS.

[106] *Id.*; *Plankton*, *supra* note 104.

[107] *See* Claire Wright, *Blueprint for Survival: A New Paradigm for International Environmental Emergencies*, 29 FORDHAM ENVTL. L. REV. 221, 232 (2017); Ken Buesseler, *FAQs: Radiation from Fukushima*, WOODS HOLE OCEANOGRAPHIC INST. (Mar. 11, 2011), http://www.whoi.edu/page.do?pid=127297 (last updated Mar. 2016).

[108] Buesseler, *supra* note 107.

[109] *Id.*; *Strontium*, ENCYCLOPEDIA BRITANNICA, https://www.britannica.com/science/strontium.

[110] Buesseler, *supra* note 107.

[111] Berends, *supra* note 95, at 55.

[112] *Id.* at 56.

[113] *Id.* at 59.

to 100 bq/kg.[114] Further restrictions were added, and restrictions on fish were imposed so that "when the fishes [sic] concerned can no longer be captured in the restricted zones due to the migration of fishes [sic] from the restricted zones to the outside or the end of the fishery seasons, the restrictions of distribution can be cancelled, based on inspection results obtained before the next fishery season."[115] When a sand lance, a sea fish, was found contaminated near Fukushima one month after the disaster, the Japanese government blocked distribution from the entirety of Fukushima prefecture.[116] Similarly, when a cherry salmon, a river fish, was found contaminated in the Fukushima prefecture, the government further imposed restrictions on lakes and river systems in Fukushima prefecture.[117] This is significant as it demonstrates that the spread of radiation from Fukushima is not contained to one area or region, and, just as it spreads throughout the rivers and waterways of the Japanese archipelago, so too does it spread across the ocean.[118]

The Japanese government has tried to compel consumers to be more confident in the safety of Japanese fisheries,[119] but, in 2012, elevated levels of radiation were still present in fish caught off the coast near Fukushima.[120] In January 2013, a fish was caught that contained 2,500 times the legal amount of radiation.[121] Also in 2013, radiation levels at Fukushima were found to be eighteen times higher than had been previously reported.[122]

Between the disaster in 2011 and March 2018, fish caught off the coast near Fukushima were not exported.[123] Exporting seafood is an important part of Japan's overall economy, accounting for $14 billion annually, or 20 percent of the agricultural industry, at the time of the Fukushima disaster.[124] However, the confidence of Japanese seafood stock

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[114] *Questions and Answers about Fishery Products*, *supra* note 101.

[115] Berends, *supra* note 95, at 63.

[116] *Id.* at 61.

[117] *Id.*

[118] Indeed, in 2014 and 2015, radiation from Fukushima was found in seawater collected off the coasts of Canada and California. *See* Wright, *supra* note 107, at 233.

[119] *Cf.* Youkyung Lee & Mari Yamaguchi, *South Korea to Fight WTO Ruling on Fukushima Seafood Ban*, SEATTLE TIMES (Feb. 23, 2018, 12:46 AM), https://www.seattletimes.com/business/south-korea-to-fight-wto-ruling-on-fukushima-seafood-ban/ (describing how multiple countries in East Asia and around the world have enacted flat bans on products from Fukushima and efforts the Japanese government has undertaken to use the WTO to compel South Korea to overturn its ban on products from Fukushima).

[120] Jim Haw, *Challenges Facing Japan's Marine Fisheries*, SCI. AM. (June 26, 2013), https://blogs.scientificamerican.com/expeditions/challenges-facing-japans-marine-fisheries/.

[121] *Id.*

[122] McCurry, *supra* note 80.

[123] *See Fukushima Exports First Fish Consignment Since Nuclear Disaster*, *supra* note 94.

[124] RENEE JOHNSON, CONG. RESEARCH SERV., R41766, JAPAN'S 2011 EARTHQUAKE AND TSUNAMI: FOOD AND AGRICULTURE IMPLICATIONS 1 (May 18, 2011).

holders was shaken by this disaster.[125] In the aftermath, Japan was estimated to have sustained $11 billion in damages to its fisheries sector.[126] It stands to reason that the Japanese would be eager to get the fishery sector of their economy running normally again as soon as possible.[127]

The Japanese government and the Fukushima Prefectural Fisheries regulatory body has, as of September 2018, allowed for certain species of marine fish to be caught and inspected for human consumption.[128] The fish, once caught, are inspected on the ship immediately by the fishermen.[129] Afterwards, they are sent to a middle-man processor, where they are inspected again, this time more closely, for radioactive contamination.[130] If they pass these double-inspections, they are then ready for the commercial distributer and sale to the consumer.[131] However, sometimes the fish skip the second stage of inspection, are sold directly to the distributer, and then to the consumer.[132] Herein lies a problem, especially as more and more potentially contaminated fish are prepared for export. This porous inspection system allows for a fish laced with a radioactive isotope of cesium, strontium, or iodine to swim its way up the food chain and end up on a plate in an American restaurant.

E. American Regulations and Reaction

U.S. food imports are regulated by the FDA, which monitors the safety of most types of food imports, including seafood.[133] The FDA uses a variety of interconnected regulations in order to monitor for and screen out contaminated products, such as seafood.[134] One tool the FDA uses in these regulatory schemes is import alerts.[135] Import alerts are guidelines used to inform both FDA field staff and the public that the agency may, without a physical examination, detain products that appear to be in violation of FDA laws and regulations.[136] "These violations could be related to the product, manufacturer, shipper, and/or other information."[137] Before importing

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[125] *See id.* at 3.

[126] *Id.*

[127] *See id.*

[128] *The Solution of Stop the Contaminated Water and The Safety of Fishery Products at TEPCO's Fukushima Daiichi Nuclear Power Station*, *supra* note 95.

[129] *Id.*

[130] *Id.*

[131] *Id.*

[132] *Id.*

[133] *See Imported Seafood Safety Program*, FDA, https://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/ucm248706.htm (last visited Apr. 27, 2020).

[134] *See id.*

[135] *Id.*; *Import Alerts*, FDA, https://www.fda.gov/ForIndustry/ImportProgram/ActionsEnforcement/ImportAlerts/default.htm.

[136] *Import Alerts*, *supra* note 135.

[137] *Id.*

products into the United States, the onus is on importers to know if their products are subject to detention without physical examination.[138] The purpose of import alerts is multi-faced, as they are used to: ensure potentially violative products are not distributed in the United States; free-up agency resources to examine other, more pertinent imports; provide a uniform guideline across the country; and ensure that the importer maintains compliance with FDA laws and regulations for products being imported into the United States.[139] In the wake of the Fukushima disaster, the FDA implemented regulatory schemes, including an import alert, which sought to prevent Americans from consuming potentially contaminated products sourced from Japan.[140]

FDA Import Alert #99-33 is one such living guideline, ever evolving since the 2011 disaster.[141] Import Alert #99-33 provides "guidance" to FDA field personnel to detain, without examination, a comprehensive list of products from Japan due to radioactive iodine particles.[142] Import Alert #99-33 contains all manner of seafood products, as well as produce and meat products, and it specifically states that its reason for promulgation was the 2011 Fukushima disaster.[143] However, Import Alert #99-33 is not binding according to its language.[144] Rather, it is described as a guideline for FDA field personnel to detain, without examination, anything contained within the alert.[145] The nonbinding language of Import Alert #99-33, combined with its substantive language, may present a problem in the future.[146] Import Alert #99-33 has not, to date, been published in the Federal Register and, as will be discussed below, this poses a problem as it may violate notice-and-comment requirements.[147]

The FDA heavily regulates additives and, as part of its duties, monitors what can and cannot be added to food sold in the United States. The Federal Food, Drug, and Cosmetic Act ("FDCA") establishes the legal framework within which the FDA operates and regulates food standards and food additives.[148] The FDCA also gives the FDA broad authority in matters

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[138] *Import Alerts*, *supra* note 135.

[139] *Id.*

[140] *See FDA Import Alert #99-33*, FDA (Jan. 30, 2020), https://www.accessdata.fda.gov/cms_ia/importalert_621.html (last visited Apr. 27, 2020).

[141] *Id.*

[142] *Id.*

[143] *Id.*

[144] *Id.*

[145] *Id.*

[146] *Cf.* Benten v. Kessler, 799 F. Supp. 281, 288-89 (E.D.N.Y. 1992); Bellarno Int'l Ltd. v. Food & Drug Admin., 678 F. Supp. 410, 414-15 (E.D.N.Y. 1988).

[147] *Cf. Benten*, 799 F. Supp. at 288-89; *Bellarno Int'l Ltd* 678 F. Supp. at 414-15; *Notice-and-Comment Rulemaking*, CTR. FOR EFFECTIVE GOV'T, https://www.foreffectivegov.org/node/2578.

[148] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (2018); 21 U.S.C. §§ 341-348 (2018).

involving adulterated products which can harm health of the public.[149] For instance, the Food Additives Amendment states that a food is adulterated (and thus cannot be marketed legally) if it has been intentionally irradiated, unless that irradiation is carried out in conformity with a regulation prescribing safe conditions of use.[150] It is of note that, according to the language of the amendment, only intentionally irradiated products not in compliance with regulations are to be deemed adulterated.[151] Products that may have been unintentionally irradiated are not deemed adulterated.[152] The FDA does not define the form of energy or the process of irradiation as an additive, instead focusing on the equipment used to irradiate the food.[153] The equipment used is itself what may affect the characteristics of the food, according to the FDA, with the definition of radiation as an additive in food focusing on the particular method of irradiating the food.[154] This is problematic, as potential, unintentional radiation that can bioaccumulate in humans is not labeled as an additive and, thus, may not be regulated as stringently as it could be.

It is important that any future regulatory schemes also be able to evolve, like Import Alert #99-33, as radiation in the ocean can traverse vast distances both on the currents of the ocean as well as through the movement of sea life it contaminates via bioaccumulation.[155] As stated above, in 2014 and 2015, radiation from Fukushima was found in seawater collected off the coasts of Canada and California.[156] Every single bluefin tuna tested off the California coast was found to contain trace radiation from Fukushima.[157] Further, while this article does not address the effects of Fukushima's radiation on all aspects of American life, it does acknowledge that there are many.[158]

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[149] United States v. Blue Ribbon Smoked Fish, Inc., 56 F. App'x 542, 543 (2d Cir. 2003).

[150] *See* 21 U.S.C. § 321 (2018); 21 U.S.C. § 341 *et seq.* (2018); *see also* 21 U.S.C. §§ 331-333 (2018). Governmental regulation of irradiated food varies from country to country. This author notes that Japan has more stringent radiation standards for foodstuffs than both the U.S. and Europe. *See Tokyo Food Safety Information Center*, TOKYO METRO. GOV'T, BUREAU OF SOCIAL WELFARE & PUB. HEALTH, https://www.fukushihoken.metro.tokyo.lg.jp/shokuhin/eng/faq/category01/17.html (last visited Apr. 27,2020). "Most countries approve food irradiation on a case-by-case basis." *See Overview of Irradiation of Food and Packaging*, FDA, https://www.fda.gov/food/ingredientspackaginglabeling/irradiatedfoodpackaging/ucm081050.htm.

[151] 21 U.S.C. § 342 (2018).

[152] *See id.*

[153] *Food Additive Status List*, FDA, https://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm091048.htm#ftnR.

[154] *Id.*

[155] *See* Grossman, *supra* note 102.

[156] Wright, *supra* note 107, at 233.

[157] *Id.* at 233.

[158] *See, e.g.*, Jessica Campisi & Saeed Ahmed, *There May Be Traces of Radioactive Particles from Fukushima in Your California Red Wine*, CNN (July 26, 2018, 11:48 AM),

Eating a piece of tuna contaminated with cesium-137 would not make someone drop dead at the sushi bar, but it would build up in their body. The internal contamination level of a carcinogenic radioactive substance takes at least 110 days for half of it to clear out of the body.[159] This sort of internal contamination is "worse than external contamination," and, if a consumer is continually eating contaminated food from one or many sources, it could quickly add up and become a life-threatening problem, especially in the very young or very old.[160] Although experts state that "these traces are too small to endanger human health,"[161] the problem remains that, just as in sea life, trace radiation can build in humans over time, with radioactive iodine accumulating in, for example, the thyroid.[162] In Japan, there have been hundreds of cases where relatively young and healthy people have developed thyroid cancer as a result of the Fukushima disaster.[163] There is even evidence of those most vulnerable to radiation being affected. Data gathered by a French NGO, the Association for the Control of Radioactivity in the West ("ACRO"), found significant increases over time in the amount of radioactive cesium in the urine of young Japanese children.[164] These children were located not only in Fukushima prefecture, but in other areas around the country as well.[165] It is believed that elevated levels of cesium could be attributed to diet, and, when people become more selective in their food choices, their internal contamination levels decrease.[166] There is a justified cause for alarm, however preventable, that American consumers could find themselves confronted with elevated levels of cesium or other radioactive elements from seafood contaminated by the Fukushima disaster in their own bodies, despite the flimsy protections put in place by the FDA.

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https://www.cnn.com/2018/07/23/health/california-wine-radioactive-fukushima-trnd/index.html (describing how bottles of California wine produced after the 2011 Fukushima disaster contain much higher levels of radioactive cesium than experts believed they would when tested); Julian Ryall, *Japanese Dealers Selling 'Radioactive Cars'*, THE TELEGRAPH (Oct. 26, 2011), https://www.telegraph.co.uk/news/worldnews/asia/japan/8849664/Japanese-dealers-selling-radioactive-cars.html (describing how unwitting consumers purchased cars originating in Fukushima province that later on turned out to be contaminated with radiation).

[159] *Sorry Charlie, There's Cesium-137 In Your Tuna*, THE FUKUSHIMA PROJECT (May 29, 2012), http://www.fukuleaks.org/web/?p=6171.

[160] *Id.*

[161] Wright, *supra* note 107, at 233.

[162] *See FDA Import Alert #99-33*, *supra* note 140; *Fish Sampling Shows Widespread Problems from Nuclear Disaster*, THE FUKUSHIMA PROJECT (Oct. 26, 2012), http://www.fukuleaks.org/web/?p=8070.

[163] *See Japanese Woman Breaks Silence on Fukushima-Related Cancer*, CBS NEWS (June 7, 2016, 5:46 AM), https://www.cbsnews.com/news/japan-fukushima-thyroid-cancer-patient-is-first-to-speak-out/.

[164] *See Fish Sampling Shows Widespread Problems from Nuclear Disaster*, *supra* note 162; *Results of ACRO's Monitoring in Japan*, ASS'N POUR LE CONTRÔLE DE LA RADIO-ACTIVITÉ DANS L'OUEST, https://www.acro.eu.org/Archives/OCJ_en.html (last updated Mar. 6, 2013).

[165] *Results of ACRO's Monitoring in Japan*, *supra* note 164.

[166] *See Fish Sampling Shows Widespread Problems from Nuclear Disaster*, *supra* note 162.

The FDA has a host of regulatory schemes to complement Import Alert #99-33.[167] To import seafood into the United States, the FDA requires compliance with its Hazard Analysis and Critical Control Points ("HACCP") regulations, which entails the analysis and control of biological, chemical, and physical hazards.[168] The HACCP regulations require seafood processors to identify safety hazards that are reasonably likely to occur in food production and to develop plans for the control of those hazards, and, in this way, it serves as a guidance to the FDA's Fish and Fishery Products regulation.[169] The FDA's Fish and Fishery Products regulation also applies to seafood importers and requires importers of certain seafood products to comply with requirements designed to help ensure that imported products are processed in accordance with the seafood HACCP regulation.[170]

However, the FDA also has some rules that are outdated or ineffectual when it comes to proactive protections against radiation. Import alerts, such as Import Alert #99-33, are one such example. Import alerts have easily been adjudicated as unlawful, as this article shall discuss in detail.[171] Chapter 19 of the seafood HACCP regulation deals with prohibited food and color additives, specifying a variety of additives that are prohibited in the processing of seafood while conspicuously leaving absent irradiation.[172] However, monitoring for prohibited additives is usually done merely via visual examination.[173] The onus is on seafood processors to conduct such examinations. Domestic seafood processors are "required to establish and implement HACCP plans pursuant to 21 C.F.R. § 123.6(b)."[174] Importers of fish or fishery products must verify that their products are not adulterated, and that their products comply with HACCP regulations.[175]

If the FDA detects that a potentially carcinogenic material has been used as a food additive, then it can decisively ban it from use, even if the FDA has previously stated that those additives are not cancer causing.[176] In

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[167] *See Imported Seafood Safety Program*, *supra* note 133; *FDA Response to the Fukushima Dai-Ichi Nuclear Power Facility Incident*, FDA, https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm247403.htm#food (last visited Apr. 27, 2020).

[168] *See Imported Seafood Safety Program*, *supra* note 133; *Seafood HACCP*, FDA, https://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006764.htm.

[169] 21 C.F.R. §§ 123, 1240 (2018); *Seafood HACCP*, *supra* note 168.

[170] *See* 21 C.F.R. §§ 123.12, 1240 (2018).

[171] *See Benten*, 799 F. Supp. at 288; *Bellarno Int'l Ltd.*, 678 F. Supp. at 411.

[172] *See Undeclared Major Food Allergens and Certain Food Intolerance Causing Substances and Prohibited Food and Color Additives*, FDA (Apr. 2011), https://www.fda.gov/downloads/Food/GuidanceRegulation/UCM252439.pdf.

[173] *See id.* at 15.

[174] United States v. Blue Ribbon Smoked Fish, Inc., 179 F. Supp. 2d 30, 34 (E.D.N.Y. 2001), *aff'd*, 56 F. App'x 542 (2d Cir. 2003); *see also* 21 C.F.R. § 123.6(b) (2018).

[175] 21 C.F.R. § 123.12 (2018).

[176] 21 U.S.C. § 348(c)(3)(A) (2018).

October 2018, the FDA amended food additive regulations and banned the use of six different synthetic flavoring substances, despite the FDA's own scientific analysis and determinations that those substances did not pose a risk to public health under the conditions of their intended use.[177] These additives were banned because petitioners provided data to the FDA that these additives induced cancer in laboratory animals.[178] As a result, the FDA could not, as a matter of law, maintain the listing of these substances in food additive regulations.[179]

III. CASE AND PROBLEM ANALYSIS

A. Bellarno and Benten

While the FDA has a network of regulatory schemes in place, ostensibly to stop radioactive contaminated seafood from reaching American dinner plates, these regulations have been shown in the past to be easily challenged. In *Bellarno Int'l Ltd. v. Food & Drug Admin.* ("*Bellarno*"), a corporation had its goods detained at import by the FDA pursuant to an import alert.[180] The alert stated that the FDA could automatically detain all imports of a certain class of pharmaceuticals.[181] The import alert was issued one year before the date of import, and the government had not followed notice-and-comment procedures.[182]

In appealing the detention of its imports, the plaintiff corporation argued that the automatic detention and imposition of certain requirements to have goods returned exceeded the statutory authority of the FDA, and, further, that the detention was arbitrary and capricious.[183] The FDA argued that it was not required to conduct notice-and-comment procedures for detention because the import alert in question was an "interpretive rule" or a "general statement of policy."[184] Normally, agency rules are required to be issued only after notice-and-comment procedures are completed, but "an exception to the procedures is provided when an agency is adopting merely an 'interpretive rule' or a 'general statement of policy.'"[185] The decision in *Bellarno* hinged on whether the import alert in question was unlawful as a "legislative rule" or was permitted as either an "interpretive rule" or a "general statement of policy."[186]

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[177] *See* Food Additive Regulations; Synthetic Flavoring Agents and Adjuvants, 83 Fed. Reg. 50490 (Oct. 9, 2018) (to be codified at 21 C.F.R. §§ 172, 177).
[178] *Id.*
[179] *Id.*
[180] *Bellarno Int'l Ltd.*, 678 F. Supp. at 411.
[181] *Bellarno Int'l Ltd.*, 678 F. Supp. at 411.
[182] *Id.* at 416.
[183] *Id.* at 411-12.
[184] *Id.* at 412.
[185] *Id.*; *see also* 5 U.S.C. § 553(b)(3)(A) (2018).
[186] *Bellarno Int'l Ltd.*, 678 F. Supp. at 412.

The court in *Bellarno* laid out four general factors to distinguish between these rules: "the binding effect of the pronouncement; the degree of discretion accorded the agency in applying the pronouncement; deference to the agency's characterization, and the language of the pronouncement itself."[187] Although the language of the import alert in *Bellarno* suggested that it was not binding, the FDA essentially had "*carte blanche*" to detain these pharmaceuticals, rendering the first factor against the FDA.[188] The FDA also argued that the import alert was merely "a statement directed primarily to agency staff advising them how to conduct an agency discretionary function."[189] However, the court found that other language in the import alert suggested that the FDA sought to create "a substantive rule of general applicability," impacting a wide class of pharmaceuticals, "rather than a discretionary statement of general policy."[190] Finally, the court in *Bellarno* stated that, although the import alert was entitled "guidance" by the FDA, this "[did] not mitigate the tone of the language" that followed. [191] As a result, the court held the import alert was unlawful and that, rather than a statement of policy or interpretive rule, the import alert was meant as a binding legislative rule.[192]

Four years after *Bellarno*, the court in *Benten v. Kessler* ("*Benten*"), handed down a similar ruling on "substantive regulations" and their need to follow notice-and-comment procedures.[193] *Benten* was, as the court described, "a lawsuit waiting to happen," due to "political and bureaucratic timidity mixed with well-intentioned blundering."[194] In *Benten*, as in *Bellarno*, the FDA detained a pharmaceutical under the authority of an import alert it had issued without following notice-and-comment procedures.[195] The plaintiff argued that the pharmaceutical had been illegally banned.[196] The import alert in *Benten* stated that the drug was to be subject to "automatic detention" and that agents should "automatically detain all shipments of [the class of drug]," for reasons of public safety.[197] The *Benten* court cited *Bellarno* and noted that the language of the import alert at issue was similar in its "automatic detention" language, while different with its lack of even "guidance" language to mitigate its substantive effects.[198] The court in *Benten* held that the import alert was unlawful, as the language was clearly that of a substantive rule, and, as a substantive rule, it was required to follow notice-and-comment

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[187] *Id.* at 413.
[188] *Id.* at 413-14.
[189] *Bellarno Int'l Ltd.*, 678 F. Supp. at 414 (internal quotations omitted).
[190] *Id.* at 415.
[191] *Id.*.
[192] *Id.* at 416.
[193] *Benten*, 799 F. Supp. at 288.
[194] *Id.* at 282.
[195] *Id.* at 284.
[196] *Id.* at 283-85.
[197] *Id.* at 286.
[198] *Id.* at 288-89.

procedures.[199] Further, even if the import alert in *Benten* was not a substantive rule, notice-and-comment procedures would have been required.[200] Under the agency's own rules in effect on the date the alert was promulgated, notice-and-comment procedures were required even if the alerts were interpretive rules or agency practices, and an agency is bound to follow procedures required by its own regulations.[201]

B. Blue Ribbon Smoked Fish and N.Y. Fish

Despite the holdings in *Bellarno* and *Benten*, courts are still willing to give the FDA broad powers in imposing sanctions on producers who commit statutory violations. In *United States v. Blue Ribbon Smoked Fish, Inc.* ("*Blue Ribbon Smoked Fish*"), the Second Circuit held that the FDA may choose to set a zero-tolerance policy for potentially hazardous substances in foods.[202] In the preceding District Court opinion, it was stated that because of the health risk to the young and elderly, a zero-tolerance policy was necessary to enjoin the risk to public health.[203] The Second Circuit then found that enjoining the New York manufacturer from producing adulterated products was also within the scope of the FDA, but the FDA could not employ language so broad as to stop the manufacturer from producing seafood at facilities which had not been proven to be adulterating products.[204]

In *United States v. N.Y. Fish* ("*N.Y. Fish*"), just as in *Blue Ribbon Smoked Fish*, the FDA had found a seafood production company to be in violation of the FDCA and attacked it on the grounds of produced adulterated seafood products.[205] Again, similarly to *Blue Ribbon Smoked Fish*, the facility and its finished products were found to contain amounts of an adulterous substance.[206] The court in *N.Y. Fish* held that the government must prove there is a "reasonable likelihood that [the] defendants will violate the FDCA in the future unless enjoined."[207] This reasonable likelihood of continued violations could be "some cognizable danger of recurrent violation, [but] something more than the mere possibility that serves to keep the case alive."[208] Thus, the FDA has rather broad powers to determine whether or not a future violation may occur. As in *Blue Ribbon Smoked Fish*, the court in *N.Y. Fish* held that the defendant's seafood

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[199] *Benten*, 799 F. Supp. at 289-91.
[200] *Id.* at 289-90.
[201] *Id.* (citing United States v. Nixon, 418 U.S. 683, 694-95 (1974)).
[202] *Blue Ribbon Smoked Fish, Inc.*, 56 F. App'x at 544 (citing Young v. Cmty. Nutrition Inst., 476 U.S. 974 (1986)).
[203] *Blue Ribbon Smoked Fish, Inc.*, 179 F. Supp. 2d at 37.
[204] *Blue Ribbon Smoked Fish, Inc.*, 56 F. App'x at 543-544.
[205] United States v. N.Y. Fish, Inc., 10 F. Supp. 3d 355, 359 (E.D.N.Y. 2014).
[206] *N.Y. Fish Inc.*, 10 F. Supp. 3d at 361-69.
[207] *Id.* at 374.
[208] *Id.* at 370 (internal quotations omitted) (citing *United States v. W. T. Grant Co.*, 345 U.S. 629, 633 (1953)).

products had become adulterated when they were contaminated to such a degree that they became injurious to the public's health.[209] In such a situation, the FDA has "broad authority in manners involving adulterated products which can damage the health of the public."[210] This authority extends as far as potentially shutting down the business entirely via an injunction.[211]

IV. SOLUTION ANALYSIS

A. Banning of High Seas Fishing

One solution that would be effective, but perhaps a bridge too far, would be to wholly ban high seas fishing. At least two environmental experts have suggested that this would be the best solution to the problems currently facing the world's ocean populations.[212] While an interesting solution, it is one that is outside the scope of this article. While it would serve the purposes of keeping potentially irradiated fish off of American dinner plates, no current United States regulatory body would be prepared to wholesale ban high seas fishing, despite experts' argument that it would not collapse the fishing market.[213] Rather, experts argue that a temporary high seas fishing ban would allow struggling fishing populations to recover and, over a period of a few generations, become sustainable.[214] For purposes of this article, such a ban would also allow for sea life in the Pacific Ocean off of Fukushima to "self-regulate," and over time, allow for radioactive materials such as cesium to decay to even lower levels. However, as discussed above, such a solution is too broad for purposes of stopping potentially contaminated fish imports from reaching American consumers.

B. Adulteration and Irradiation

If food is intentionally irradiated, then it is considered adulterated and subject to being taken off the market.[215] However, unintentional irradiation is not considered an adulteration of food.[216] This article proposes one solution, which is to have the FDA include language that unintentional irradiation of seafood is also considered an adulteration. As discussed above, in the cases of *Blue Ribbon Smoked Fish* and *N.Y. Fish*,

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[209] *Id.* at 371; *see also* 21 U.S.C. § 342(a)(4) (2018).
[210] *N.Y. Fish, Inc.*, 10 F. Supp. 3d at 379 (internal citations omitted).
[211] *See id.* at 380.
[212] *See* Crow White & Christopher Costello, *Close the High Seas to Fishing?* PLOS BIOLOGY 12(3) (Mar. 25 2014), *available at* https://doi.org/10.1371/journal.pbio.1001826.
[213] *See* White, *supra* note 212.
[214] *Id.*
[215] 21 U.S.C. §§ 331-333, 342(a)(1) (2018).
[216] *See* 21 U.S.C. § 342(a)(1) (2018).

the FDA has broad authority in determining what is and is not adulterated. It would be simple to modify the language of what is included as adulterated under 21 U.S.C. § 342. Simply excising the word "intentionally" from "if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption…"[217] would provide the FDA with extremely broad authority to enjoin fish importers who are importing fish, which should otherwise not be sold for human consumption. This would incentivize Japanese fishermen off the Fukushima coast to not catch high-risk species of fish, such as sardines, or fish higher in the food chain which feed on those high-risk fish. By allowing these fish to roam free in the ocean, the radioactive contaminants in them will, over time, decay and be flushed out.

Such a proposition could be easily undertaken, but there would be some concerns as there are low levels of trace radiation present in almost all fish. The seafood market would likely react harshly to the idea that the FDA could deem their products adulterated if they had any amount of unintentional radiation. If a product is determined to be adulterated, then the FDA has broad authority in matters involving adulterated products which can damage the health of the public. However, this is where the role of the courts could step in and narrow such broad authority, as they did in *Blue Ribbon Smoked Fish.* Further, any questions of jurisdiction would be settled immediately, as the language of the FDCA allows the government to enjoin any producers engaged in interstate commerce. As the fish in question would be coming from Japanese territorial waters, the FDA would be allowed to maintain authority over the importers in this newly worded regulation.[218]

C. Radiation and Additives

While the FDA does not currently consider unintentional radiation to be a food additive,[219] another solution is for the FDA to deem cancer causing unintentional radiation a food additive. Radioactive particles are themselves "added" to the flesh of the fish and cannot be separated from it. As the fish swims up the food chain, so to speak, these problems become compounded, eventually ending up in the thyroid of an unwitting consumer. However, it is unlikely that the FDA would reclassify unintentional irradiation as a food additive. Considering radioactivity an additive may anger (currently legal) additive producers, for they would not wish to be lumped in with something perceived so deadly as radiation. Additionally, the FDA would likely prefer to have irradiated fish fall under the category

[217] *Id.*

[218] *See* 21 U.S.C. § 321(b) (2018); *see also Blue Ribbon Smoked Fish, Inc.*, 179 F. Supp. 2d at 42.

[219] *See* 21 U.S.C. § 342 (2018).

of adulterated food, as this could potentially take the products out of the stream of commerce altogether.

D. It is Unwise to Rely on Import Alerts

Therefore, since the other "solutions" are impractical, it is apparent that the solution would have to come in the form of modifying the current practice of FDA import alerts. It is not currently a viable solution to rely on import alerts as a safeguard from potentially dangerous products. As was shown in *Bellarno* and *Benten*, import alerts that do not follow notice-and-comment procedures (like Import Alert #99-33) have been known to be easily challenged, due to the nature and language of the alerts. Import Alert #99-33 is extremely similar in its language and effect to the import alerts that were held to be unlawful in *Bellarno* and *Benten*.[220] Import Alert #99-33 has not yet been challenged in court, most likely because Japan has not yet started to export seafood from Fukushima to the United States. But, as the court stated in *Benten*, there is a "lawsuit waiting to happen."[221] As soon as the first imported shipment of fish from Fukushima is automatically detained pursuant to Import Alert #99-33, an angry plaintiff would have a field day in court, and Import Alert #99-33 would likely be overturned as unlawful due to its substantive effects and failure to follow proper notice-and-comment procedures. If the import alert is overturned, the proverbial flood gates would open and potentially dangerous products from Fukushima could enter the U.S. market and cause harm to unwitting consumers. Japanese producers are eager to resume exporting products from Fukushima and, as such, would take full advantage of a newly opened U.S. market.[222]

E. A New Safety Net Solution

Just because the levels of radiation found in fish caught off the Fukushima coast may not be dangerous to the public at large, they would still be dangerous to the very old or very young. If a very young child living on the West Coast ate enough cesium-laced fish, the element could continue to build in his thyroid until it becomes cancerous, at which point it will have been too late. As in both *N.Y. Fish* and *Blue Ribbon Smoked Fish*, where the greatest health risk was to the very old or very young, the FDA

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[220] *Compare Benten*, 799 F. Supp. 281 (the import alert was declared unlawful because it was a substantive rule with regard to automatic detention and did not follow note-and-comment procedures) *and Bellarno Int'l Ltd.*, 678 F. Supp. 410 (the import alert was declared unlawful in spite of its "guidance" language because it was too substantive in effect with regard to automatic detention and did not follow note-and-comment procedures) *with FDA Import Alert #99-33*, supra note 140 (an import alert that claims to be a "guideline" but has potential substantive effects regarding automatic detention and that has not followed note-and-comment procedures).

[221] *Benten*, 799 F. Supp. at 282.

[222] *See Fukushima Exports First Fish Consignment Since Nuclear Disaster*, *supra* note 94.

could propose a zero-tolerance ban on potentially irradiated fish for reasons of public health concern. This could be done by adding the radioactive elements to the banned additives list or by including unintentional irradiation in the adulterated food list.

Additionally, a new regulation could be tied into this scheme of modifying a currently existing regulation. In recent years, many environmental advocacy groups have pushed for traceability in seafood.[223] "Traceability increases transparency and accountability in the seafood supply chain by ensuring that information such as how and where fish are caught or farmed follows the fish from boat to plate." [224] The United States has a fledging traceability program through the National Oceanic and Atmospheric Administration ("NOAA") that went into effect on January 1, 2018.[225] This NOAA program, entitled the Seafood Import Monitoring Program ("SIMP"), requires the importer to provide and report key data, "from the point of harvest to the point of entry into U.S. commerce."[226] However, SIMP is not consumer facing and only currently covers thirteen types of imported fish and fish products.[227] As such, this article proposes that consumer facing traceability requirements should implemented by the FDA in conjunction with NOAA. These requirements should be targeted towards species of fish that may have been most impacted by radiation, such as varieties of sardine or tuna. As Japan seeks to turn the flow of exports of fishery products from Fukushima back on, one can expect there to be pushback on the idea of consumer facing traceability. Even within Japan, consumers are wary of products from Fukushima,[228] and exports that were once lauded are now only just beginning to start back up. This proposed bundle of regulatory schemes would serve to protect the American consumer from start to finish, with unique consumer-facing traceability requirements giving consumers the ability to make informed choices about the source of their seafood.

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[223] *See Fish Stories: Success and Value in Seafood Traceability*, OCEANA (Mar. 2016), https://usa.oceana.org/publications/reports/fish-stories-success-and-value-seafood-traceability.

[224] *Id.*

[225] *U.S. Seafood Import Monitoring Program*, NOAA, https://www.iuufishing.noaa.gov/RecommendationsandActions/RECOMMENDATION1415/FinalRuleTraceability.aspx (last visited Apr. 27, 2020).

[226] *See U.S. Seafood Import Monitoring Program*, *supra* note 225.

[227] *Id.*

[228] *See* Jun Hongo, *One in Five Japanese Cautious About Fukushima Food*, Wall Street Journal (Oct. 2, 2014), https://blogs.wsj.com/japanrealtime/2014/10/02/one-in-five-japanese-cautious-about-fukushima-food/ (describing how, even years after the Fukushima disaster, many Japanese consumers are wary of products from Fukushima due to fears of radiation, despite knowing about Japan's stricter radiation standards on food compared to the U.S.A. and Europe); Chico Harlan, *Please Eat the Vegetables, Japan Tells Radiation-Wary Nation*, WASHINGTON POST (Apr. 15, 2011), https://www.washingtonpost.com/world/please-eat-the-vegetables-japan-tells-radiation-wary-nation/2011/04/15/AFkOfmkD_story.html?utm_term=.446cecb0bdda (describing how even those Fukushima producers of products deemed uncontaminated have had trouble finding consumers willing to purchase their products, requiring the Japanese government to try and incentivize them to trust products from Fukushima).

A truly novel and effective solution would be a mix of most of the proposed solutions discussed above, a "fishing net" solution creating a networking bundle of new or modified regulatory schemes. Combining the options to modify language in FDA definitions of additives and/or adulterated products with the lessening of reliance on potentially toothless import alerts, along with tracing measures to ensure that seafood is safe before it gets to a consumer's plate, would create a safety net that would not have the patchwork holes that currently exist. Rather than merely reacting to threats as they arise, the FDA should take proactive measures to ensure that, in the case of radiation entering the seafood market, from Fukushima or elsewhere, there is a broad network of new or modified regulatory schemes interacting with each other as a safeguard. The FDA has a duty to "protect[] the public health by ensuring the safety, efficacy, and security" of America's food supply.[229] Included in this duty is the responsibility to protect the public health from contaminated food, including products that contain radiation.[230] More than any other group of American consumers, the very old and the very young would be the ones to suffer from confusing seafood contaminated by Fukushima's radiation. It is their health that the FDA has to duty to protect, and their lives must be protected and allowed to grow. By implementing this article's proposed safety net solution, one could imagine the FDA crafting a "fishing net," with those contaminated fish that are caught in it allowed to return to the sea from whence they came.

V. CONCLUSION

The 2011 disaster and resulting meltdown at Fukushima created a massive challenge that will take decades to overcome.[231] Therefore, it is prudent to get ahead of this challenge now, rather than merely react years down the line when problems may rear their ugly head. Stronger regulations should be passed that promote import practices that pre-emptively screen out radioactive or contaminated sea life. While the FDA has passed Import Alert #99-33 to serve as a guideline for FDA field agents to detain products from Japan, without physical examination, due to radionuclide contamination, this import alert is a paper tiger, as it has not been published in the Federal Register. A court would likely follow precedent and declare it unlawful in violation of notice-and-comment requirements.

This article's proposed regulatory scheme would be focused on preventing both small and large-scale radioactive contamination of the American seafood supply from Japan. This article's proposed solution is to

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[229] *What We Do*, FDA, https://www.fda.gov/AboutFDA/WhatWeDo/ (last visited Apr. 27, 2020).

[230] *See id.*

[231] Farrell, *supra* note 81.

implement a new regulation that could be tied into a scheme of modifying currently existing regulations. By following the advice of environmental advocacy groups and implementing traceability in seafood products, transparency would be increased throughout the seafood supply chain, ensuring that information on how and where a fish was caught or farmed follows the fish throughout its journey from ocean waters into the stomach of a consumer. Preferably, a stomach untainted by radioactive isotopes from Fukushima. While a fledging traceability program does exist, it is not consumer facing and only currently covers thirteen types of imported fish and fish products.[232]

The FDA should be willing to recognize the utility in consumer facing traceability requirements and should begin to implement such a program in order to best protect the health of the average American consumer over a long period of time. These requirements should be targeted towards species of fish that may have been most impacted by radiation from Fukushima, such as varieties of sardine or tuna. This solution would also have the bonus of letting radioactive contaminates work themselves out of the ecosystem, by allowing fish populations to dilute it through successive generations. The half-lives of the contaminants would ensure that the fish are free of any harmful radiation for future generations.

The solution presented in this article is both novel and effective solution, as it proposes a networked bundle of new and modified regulatory schemes. This article's solution combines the ability to modify language in current FDA definitions of additives and/or adulterated products with the lessening of reliance on import alerts that may be found unlawful if challenged. Along with tracing measures to ensure that seafood is uncontaminated before it reaches the market, a safety net could be created that would not have the patchwork holes that currently exist. These measures would be designed to be preventative, so that the FDA can take proactive measures to ensure that only healthy fish enter the seafood market and not fish from Fukushima or some future coastal nuclear disaster. Lessening the reliance on reactive measures would be safer for the American consumer in the long run, ensuring that there is a broad network of proactive regulatory schemes interacting with each other as a safeguard against contaminates. This "fishing net" of regulations would ensure that no contaminated seafood slips through to injure the health of any American consumer.

As Japan prepares to re-commit to nuclear power, a future administration, rather than be wracked with a potentially incurable problem, should let the FDA enact a regulatory scheme to minimize the harm contaminated seafood may present to future generations. Rather than a forcing a terminally ill citizen to face the challenge of seeking relief against an unknown fish market from years past, let him be free of worry when he

[232] *U.S. Seafood Import Monitoring Program*, *supra* note 225.

goes to a restaurant or has Japanese tuna on his dinner plate. The life of any being has immense worth, whether it be a very old or a very young person. Rather than have that life cut short by cancer caused by the build-up of radioactive contaminants consumed in years past, the FDA should adhere to its duty to protect the American consumer from contaminated foodstuffs and implement this article's "fishing net" solution, in order to prevent such a nightmare scenario from affecting even one American family.