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Citation	Justin Ben-Asher, Regulating in a Radioactive World: the FDA and Radionuclide Contamination (May 2011)
Accessed	February 19, 2015 9:19:54 AM EST
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Regulating in a Radioactive World: the FDA and Radionuclide Contamination

Abstract: This paper traces the historical development of FDA regulation of radionuclide contamination of food, a subject that received surprisingly scant attention in the legal literature. As the agency has remolded its policies in response to successive crises, it has had to be particularly mindful of the public relations implications of its actions, given the fears surrounding nuclear radiation. This paper argues that in light of the unique challenges posed by radionuclide contamination—namely, the persistent scientific uncertainty about the effects of radiation, and the cognitive biases that lead the public to overestimate the risks involved—the FDA should seek to better coordinate its radiation contamination policy with other agencies, and, more controversially, develop a policy of greater circumspection in release of information to the public.

To place the radiation levels from Fukushima in brief perspective, it is important to recognize that we live in a radioactive world. A banana, for example, has 10 Bq of activity, that is, 10 radioactive potassium atoms decay every second. . . . Bricks and granite contain radioactive materials that result in radiation exposures to the public The Capitol Building was constructed with granite and is frequently cited as having some of the highest radiation levels in all of the United States. . . . Not only do we live in a radioactive world, our bodies are radioactive.

- John D. Boice, Jr., Sc.D., Scientific Director of the International Epidemiology Institute, in testimony before the U.S. House of Representatives¹

¹ House Committee on Science, Space and Technology, Subcommittee on Investigations and Oversight, Statement of John D. Boice, Jr., Sc.D., Scientific Director, International Epidemiology Institute, CONG. Q. CONG. TESTIMONY, May 13, 2011.

The Tohoku Earthquake that struck northern Japan on March 11 with a magnitude of 9.0,² creating a powerful tsunami and soon after a devastating cascade of failures at the Fukushima Daiichi nuclear power plant, left a sorrowful human and economic toll. Moreover, as the nuclear crisis at the Fukushima Daiichi plant deepened, global speculation swirled about the dangers posed by the release of radiation from the damaged plant, not only to Japan but to the rest of the world. The United States was no exception; indeed, the nation's own surgeon general, Regina Benjamin, suggested in an interview on March 15 that it was no overreaction for Americans to stock up on potassium iodide pills—which protect against thyroid cancer in the event of exposure to radioactive iodine-131—as a “precaution.”³

While Benjamin's advice was retracted two days later,⁴ her statement both contributed to and signaled deep public unease about the health implications of the nuclear crisis. It should come as no surprise, then, that the disaster prompted a flurry of responses by regulators. In particular, following Japanese regulators' announcement that they had discovered higher than normal levels of radiation in spinach and milk up to 90 miles away from the site of the accident,⁵ Americans looked to the Food and Drug Administration to ensure that the nation's food supply was safe.

The FDA's response to the Fukushima crisis appears to have thus far been successful in the narrow sense of ensuring, through testing of both domestic and imported food, that the

² USGS Updates Magnitude of Japan's 2011 Tohoku Earthquake to 9.0, U.S. GEOLOGICAL SURVEY (March 14, 2011, 5:35 PM), <http://www.usgs.gov/newsroom/article.asp?ID=2727>.

³ William J. Broad, *Drumbeat of Nuclear Fallout Fear Doesn't Resound With Experts*, N.Y. TIMES (May 2, 2011), <http://www.nytimes.com/2011/05/03/science/03radiation.html?scp=7&sq=japan%20radiation%20release&st=cse&wh=96E1C12E5813D49ED173F21803B0F535>.

⁴ *Id.*

⁵ Ken Belson and Hiroko Tabuchi, *Japan Finds Tainted Food Up to 90 Miles From Nuclear Sites*, N.Y. TIMES (March 19, 2011), <http://www.nytimes.com/2011/03/20/world/asia/20japan.html?ref=milk&gwh=49D77450DB83E168EC5FF82B38594DCA>.

nation's food supply is free of harmful levels of radionuclide⁶ contamination. However, the FDA has perhaps not been as successful in terms of public relations.

This difficulty, this paper will argue, has accompanied the historical development of the agency's regulation of radionuclide contamination of food from the start. In Part I, the paper will trace the development—heretofore not chronicled in the legal literature—of FDA regulation of radionuclide contamination, from nuclear testing in the early Cold War through three prominent nuclear accidents, one in the United States and two overseas: the crises at Three Mile Island, Chernobyl, and Fukushima. Part II will argue that FDA regulation of radionuclide contamination faces two major problems which impede its effectiveness: the insufficiently advanced state of scientific knowledge about the long-term effects of radionuclide exposure on human health, and the cognitive biases which lead the public to overestimate the risks posed by radiation. Finally, Part III will argue that in order to surmount these challenges, the FDA should seek to better coordinate its regulation of radionuclide contamination with other agencies; and, more controversially, should be more circumspect in the way it releases information to the public.

I. The History of FDA Regulation of Radionuclide Contamination

A. The Origins of FDA Regulation

1. Regulation Prior to FDA Involvement

The harmful effects of large doses of radiation on the human body became known soon after the discovery of x-rays; beginning in 1928, the International Commission on Radiation

⁶ Radionuclides are elements with unstable nuclei, capable of emitting radiation in the form of alpha, beta, or gamma rays, and sometimes more than one of these. See *Commonly Encountered Radionuclides*, EPA (March 24, 2011), <http://www.epa.gov/radiation/radionuclides>. Radionuclides monitored by the FDA include iodine-131, cesium-134, cesium-137, ruthenium-103, ruthenium-106, strontium-90, plutonium-238, plutonium-239, and americium-241. See *Supporting Document for Guidance Levels for Radionuclides in Domestic and Imported Foods*, FDA (May 25, 2009), <http://www.fda.gov/Food/FoodSafety/FoodContaminantsAdulteration/ChemicalContaminants/Radionuclides/UCM078341>.

Protection, a scientific body, began to issue exposure standards applicable to those who are exposed to smaller doses over a long period of time, and in particular to those exposed occupationally.⁷ A national scientific body, the National Committee on Radiation Protection and Measurements, was formed (in a reorganization from a prior body) in 1946 to serve a similar purpose.⁸

Although the first nuclear weapon was tested in 1945, significant Congressional attention would not be directed toward the threat to public health posed by long-term exposure to radiation produced by nuclear energy until the late 1950s, following a dramatic expansion of nuclear testing spurred by the escalating arms race of the Cold War: between 1955 and 1957, the United States, the Soviet Union, and the United Kingdom detonated a total of 112 nuclear devices, compared to only 45 in the three years prior.⁹ In 1957, Congress's Joint Committee on Atomic Energy held public hearings addressing "The Nature of Radioactive Fallout and Its Effects on Man."¹⁰ In its report, the Committee concluded that while there were differences of opinion among those who testified as to the biological effects of radiation, "it would appear from the information presented that the consequences of future testing over the next several generations at the level of testing over the last 5 years could constitute a hazard to the world's population."¹¹ A series of similar hearings followed, and in 1959 Congress created the Federal Radiation Council (FRC) to provide "guidance for all Federal agencies in the formulation of radiation standards and in the establishment and execution of programs of cooperation with States."¹² The FRC was

⁷ FEDERAL RADIATION COUNCIL, FEDERAL GUIDANCE REPORT NO. 1: BACKGROUND MATERIAL FOR THE DEVELOPMENT OF RADIATION PROTECTION STANDARDS 1 (May 1960), *available at* http://www.epa.gov/radiation/docs/federal/frc_rpt1.pdf [hereinafter FRC REPORT 1].

⁸ *Id.*

⁹ *Table of Known Nuclear Tests Worldwide*, NATURAL RESOURCES DEFENSE COUNCIL (Nov. 25, 2002), <http://www.nrdc.org/nuclear/nudb/datab15.asp>.

¹⁰ FRC REPORT 1, *supra* note 7, at 1.

¹¹ 104 CONG. REC. 7973 (daily ed. May 5, 1958) (statement of Sen. Clinton Anderson).

¹² *Id.*

created at President Eisenhower's direction in order to resolve a perceived conflict of interest between the two purposes of the Atomic Energy Commission—to promote the development of atomic weapons and energy, and to protect the public from nuclear hazards.¹³

The FRC produced a series of eight reports in the 1960s focused on the health effects of long-term exposure to radiation, in particular from fallout from the detonation of nuclear devices. (The concern over nuclear fallout was reflected at the international level in the signing of the Limited Test Ban Treaty of 1963, which prohibited nuclear testing in the atmosphere, in space, or under water, but permitted underground testing).¹⁴ The reports predicted the amounts of specific radionuclides to which Americans would be exposed, noting that “[t]here is a special interest in those radionuclides that enter the body through the diet” and describing the mechanism by which fallout could reach humans through the food chain either directly from plants or via ingestion by animals.¹⁵ Ultimately, the reports concluded that “the health risk from radioactivity in food over the next several years would be too small to justify protective actions to limit the intake of radionuclides either by diet modifications or by altering the normal distribution and use of food, particularly milk and dairy products,”¹⁶ and asserted that nationwide programs to reduce the population's exposure to fallout were unnecessary.¹⁷ However, the FRC

¹³ COMMITTEE FOR REVIEW AND EVALUATION OF THE MEDICAL USE PROGRAM OF THE NUCLEAR REGULATORY COMMISSION, *RADIATION IN MEDICINE: A NEED FOR REGULATORY REFORM* (Kate-Louise D. Gottfried & Gary Penn eds., 1996) [hereinafter *RADIATION IN MEDICINE*].

¹⁴ *Treaty Banning Nuclear Weapon Tests in the Atmosphere, in Outer Space and Under Water*, U.S. DEP'T OF STATE, <http://www.state.gov/www/global/arms/treaties/lbtt1.html>.

¹⁵ FEDERAL RADIATION COUNCIL, FEDERAL GUIDANCE REPORT NO. 4: ESTIMATES AND EVALUATION OF FALLOUT IN THE UNITED STATES FROM NUCLEAR WEAPONS TESTING CONDUCTED THROUGH 1962 11, *available at* http://www.epa.gov/radiation/docs/federal/frc_rpt4.pdf.

¹⁶ FEDERAL RADIATION COUNCIL, FEDERAL GUIDANCE REPORT NO. 7: BACKGROUND MATERIAL FOR THE DEVELOPMENT OF RADIATION PROTECTION STANDARDS 43 (May 1965), *available at* http://www.epa.gov/radiation/docs/federal/frc_rpt7.pdf [hereinafter *FRC REPORT 7*].

¹⁷ *Id.* at 44.

recommended that “[s]urveillance of the radionuclide content in food products contaminated with worldwide fallout be continued at levels appropriate to the situation.”¹⁸

In these reports, the FRC established the framework that would be the basis of later FDA regulation. Crucially, the severe limitations on the agency’s knowledge of risks were quickly apparent. The Council acknowledged that while immediate radiation effects had been directly observed, delayed effects must be “inferred from consideration of experimental knowledge in animals, from available epidemiological statistical observations, and from a limited number of medical and industrial case observations.”¹⁹ Moreover, the delayed effects of radiation exposure, in isolation, were indistinguishable from ordinary human illnesses.²⁰ And while there was agreement among scientists that the relation of dose to effect was linear for genetic effects, scientists could not agree on the dose-effect relationship for somatic effects.²¹ For both categories, it was becoming increasingly accepted by scientists that there was no “threshold” at which danger from exposure began; rather, lower levels of radiation could only mean lower levels of risk. As a result, standards “must be established by a process of balancing biological risk and the benefits derived from radiation use.”²²

With these limitations in view, the FRC introduced the Protective Action Guide (PAG), representing a consensus as to when “intervention” was required to prevent most of the exposure of the public to a radiation risk that would otherwise occur. The types of intervention considered by the agency included 1) “[a]ltering production, processing or distribution practices,” 2) “[d]iverting affected products to uses other than human consumption,” and 3) condemning the

¹⁸ *Id.* at 43.

¹⁹ FRC REPORT 1, *supra* note 7, at 4.

²⁰ *Id.*

²¹ *Id.* at 8.

²² *Id.* at 37.

products affected.²³ The FRC acknowledged that PAGs did not represent a pure evaluation of risk, but rather, took account of “health, economic, sociologic and political factors,” including “agricultural policies, the known feasibility of protective actions, related health impacts and similar considerations involved in the national interest.”²⁴ Moreover, the PAGs introduced by the FRC were not detailed enough to serve as a practical guide to other agencies as to when to take protective action with regard to a given food that might be contaminated, since they only provided a single number (actually three numbers, given different categories of radiation contamination pathways²⁵) representing the mean *dosage* of radiation to a member of the general public that would warrant intervention.²⁶

In 1970, President Nixon issued an executive order disbanding the FRC and placing its functions within the new EPA.²⁷ Thereafter, the EPA produced environmental standards for the operation of nuclear power facilities, and was responsible for long-term regulation of radioactivity in the environment.²⁸

2. *The FDA Steps In*

In 1975, the Federal Preparedness Agency (FPA) led an interagency effort to guide radiological incident emergency response planning, and assigned to the Department of Health, Education and Welfare the responsibility of issuing “guidance on appropriate planning actions necessary for evaluating and preventing radioactive contamination of foods and animal feeds and

²³ FRC REPORT 7, *supra* note 16, at 2.

²⁴ *Id.* at 6.

²⁵ The three categories of PAGs were for contamination through milk supplies; transmission through other dietary pathways within the first year after a contaminating event; and “long-term transmission of strontium-90 through soil into plants in the years following a contaminating event,” respectively. *Id.* at 1–2.

²⁶ *Id.* at 2.

²⁷ RADIATION IN MEDICINE, *supra* note 13.

²⁸ Accidental Radioactive Contamination of Human Food and Animal Feeds, 43 Fed. Reg. 58,790, 58,790–91 (Dec. 15, 1978) (to be codified at 21 C.F.R. pt. 1090).

the control and use of such products should they become contaminated.”²⁹ Within the Department, that responsibility was delegated to the FDA.³⁰

In 1978, taking up the FPA’s call,³¹ the FDA took its first step into regulating radionuclide contamination, issuing standards on “Accidental Radioactive Contamination of Human Food and Animal Feeds.”³² The standards were issued as a proposed rule in the Federal Register, but never became a final rule, therefore never entering the Code of Federal Regulations³³; thus, they did not have the binding force of law, but constituted an informal policy document that suggested how the FDA would respond in the event of a nuclear accident.³⁴ The FDA used the FRC’s general PAGs as a basis for developing more detailed standards, noting that since the publication of the FRC reports, “data on radiation risks have been reviewed in light of additional information on biological effects that became available.”³⁵ Because the FDA had been assigned authority exclusively with regard to exposure to radiation from nuclear events through the food pathway, it proposed recommendations on the presumption that the exposed population receives only insignificant doses through other pathways.³⁶

The FDA expanded on the PAG structure provided by the FRC in two important ways. First, it bifurcated the FRC’s PGA analysis into a two-tiered standard, with different responses

²⁹ *Id.* at 58,790.

³⁰ *Id.*

³¹ In the same year, FPA was made part of the newly created Federal Emergency Management Agency (FEMA). See Radiological Emergency Planning and Preparedness, 47 Fed. Reg. 10,758 (March 11, 1982) (to be codified at 44 C.F.R. pt. 351).

³² Accidental Radioactive Contamination of Human Food and Animal Feeds, *supra* note 28, at 58,790.

³³ The FDA reconsidered the proposal to codify the recommendations in 1982, ultimately deciding to issue them in the form of a notice in the Federal Register rather than as a formal rule. Accidental Radioactive Contamination of Human Food and Animal Feeds; Recommendations for State and Local Agencies, 47 Fed. Reg. 47,073, 47,074 (Oct. 22, 1982).

³⁴ *Cf.* Sec. 560.750 Guidance Levels for Radionuclides in Domestic and Imported Foods (CPG 7119.14), FDA (April 30, 2009), <http://www.fda.gov/Food/FoodSafety/FoodContaminantsAdulteration/ChemicalContaminants/Radionuclides/UCM078331> [hereinafter *Sec. 560.750 Guidance Levels for Radionuclides in Domestic and Imported Foods*].

³⁵ *Id.*

³⁶ *Id.* at 58,791.

called for depending on the tier.³⁷ The “Preventive PAG” level was one at which only “protective actions causing minimal impact on the food supply are appropriate,” where responsible officials should take action to prevent or reduce radioactivity concentrations in food.³⁸ The higher “Emergency PAG” was the level at which “protective actions of great impact on the food supply are justified because of the projected health hazards.”³⁹ At this level, the FDA said, officials should isolate food and consider condemnation.

Second, the FDA extrapolated from PAGs to “derived response levels,” allowing for officials to compare radioactivity measurements directly to a relevant standard rather than have to predict how a measured radioactivity level would translate into a mean dosage to the population, as would be required if interpreting the FRC’s standards. Derived response levels were established for several sources of measurement: “initial ground deposition ([radioactive] activity per unit of area), the concentration of radioactivity in milk (activity per unit of volume) or pasture (activity per unit of weight), and total dietary intake (total activity)” corresponding to the two PAG levels.⁴⁰ Moreover, beyond these categories, the FDA also provided guidance on how to apply the PAG levels to other kinds of food.⁴¹

3. *The FDA’s Statutory Authority to Act*

The statute from which the FDA derives the bulk of its regulatory authority—the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA)⁴²—was drafted before radioactivity in food was seriously considered as a potential danger; indeed, the first nuclear device had not yet been

³⁷ An original draft of the regulation also included a third proposed PAG level at a lower threshold, the “Alert PAG.” After the FDA received comments questioning the need for the Alert PAG on the basis that the regulation did not recommend protective action in such cases and that the invocation of an Alert PAG might unnecessarily alarm the public, among other considerations, the proposal was shelved. *Id.* at 58,792.

³⁸ *Id.* at 58,791.

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² 21 U.S.C. § 301 (2006).

detonated in 1938. Where did regulation of radionuclide contamination of food fit into FDA's statutory authority?

The FDA was able to claim authority to regulate radionuclide contamination because of the broad authority granted by the FDCA. Namely, section 402(a) of the Act⁴³ bestowed upon the FDA the authority to take enforcement actions against food that met the statutory definition of an “adulterated” food—namely, food that “bears or contains any poisonous or deleterious substance which may render it injurious to health.”⁴⁴ Such authority might be more limited if radionuclides were not considered an “added substance” under the Act, in which case the food could not be considered adulterated “if the quantity of such substance in such food does not ordinarily render it injurious to health.”⁴⁵ Indeed, given the uncertainties involved in forecasting the effects of a given level of radiation, it might be difficult to show that it is “ordinarily” “injurious to health.” However, fortunately for the FDA, it had already begun to successfully regulate even naturally occurring contaminants as “added” substances under the Act. For example, the FDA had previously enforced a regulation of mercury levels in swordfish on this basis.⁴⁶ Despite its environmental and (typically) nondeliberate provenance, then, radionuclide contamination could be subject to the full extent of FDA regulation as a contaminant.

Moreover, according to the FDA in its proposed rule in 1978, the agency had established in a prior regulation⁴⁷ that when a food contaminant is unavoidable but cannot be approved under

⁴³ 21 U.S.C. § 342(a).

⁴⁴ 21 U.S.C. § 342(a)(1).

⁴⁵ *Id.*

⁴⁶ See PETER BARTON HUTT, RICHARD A. MERRILL & LEWIS A. GROSSMAN, *FOOD AND DRUG LAW: CASES AND MATERIALS* 368–69 (3d ed. 2007).

⁴⁷ 21 C.F.R. 109.6 (1977).

the “food additives” provision of the FDCA,⁴⁸ regulatory procedures to control the contaminant are still available.⁴⁹

Alternatively, the FDA could rely on a different provision of the FDCA as the basis for its authority to regulate contaminated food, which seems to extend even broader discretion for the agency to take action. Section 402(a) of the act also permits the FDA to classify as adulterated food that “has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.”⁵⁰ So, for example, the agency could take action to protect the public from food that may have been exposed to unsafe levels of radionuclides in the agency’s estimation because of proximity to a nuclear accident, even if there is no evidence directly establishing unsafe levels of radiation in the food itself.⁵¹

Once a food that has been contaminated with radionuclides has been determined by the FDA to be adulterated, the agency has two primary enforcement mechanisms available to protect the public. First, the agency can seize domestic foods under section 304 of the Act, “on libel of information.”⁵² (It may then file suit in federal district court for condemnation.⁵³) Second, the agency can refuse admission of goods to be imported, and detain them, under section 801 of the Act.⁵⁴

B. The Three Mile Island Accident

1. *The Accident and Immediate Responses*

⁴⁸ 21 U.S.C. § 348 (2006).

⁴⁹ Accidental Radioactive Contamination of Human Food and Animal Feeds, 43 Fed. Reg. 58,790, 58,791–92 (Dec. 15, 1978) (to be codified at 21 C.F.R. pt. 1090).

⁵⁰ 21 U.S.C. § 342(a)(1).

⁵¹ See Sec. 560.750 Guidance Levels for Radionuclides in Domestic and Imported Foods, *supra* note 34.

⁵² 21 U.S.C. § 334(a)(1). See Sec. 560.750 Guidance Levels for Radionuclides in Domestic and Imported Foods, *supra* note 34.

⁵³ 21 U.S.C. § 334(a)(1).

⁵⁴ 21 U.S.C. § 381(a)(3). See Sec. 560.750 Guidance Levels for Radionuclides in Domestic and Imported Foods, *supra* note 34.

In the early morning hours of March 28, 1979, the Three Mile Island nuclear power facility, 10 miles south of Harrisburg, Pennsylvania, suffered a series of breakdowns in the cooling system of the plant's No. 2 reactor.⁵⁵ Technical problems delayed notification of the plant's troubles to monitoring personnel, leading to extensive damage:

The main feedwater pumps stopped running, caused by either a mechanical or electrical failure, which prevented the steam generators from removing heat. First the turbine, then the reactor automatically shut down. Immediately, the pressure in the primary system (the nuclear portion of the plant) began to increase. In order to prevent that pressure from becoming excessive, the pilot-operated relief valve (a valve located at the top of the pressurizer) opened. The valve should have closed when the pressure decreased by a certain amount, but it did not. Signals available to the operator failed to show that the valve was still open. As a result, cooling water poured out of the stuck-open valve and caused the core of the reactor to overheat.

...

Because adequate cooling was not available, the nuclear fuel overheated to the point at which the zirconium cladding (the long metal tubes which hold the nuclear fuel pellets) ruptured and the fuel pellets began to melt. It was later found that about one-half of the core melted during the early stages of the accident.⁵⁶

⁵⁵ *Major Accident Occurs At Three Mile Island Nuclear Plant, Radiation Released; Crisis Said To Be Easing; Explosion, Meltdown Threatened Pa.*, FACTS ON FILE WORLD NEWS DIGEST, April 6, 1979, at 241 A1.

⁵⁶ *Backgrounder on the Three Mile Island Accident*, U.S. NUCLEAR REGULATORY COMMISSION (March 15, 2011), <http://www.nrc.gov/reading-rm/doc-collections/fact-sheets/3mile-isle.html>.

In the wake of the partial meltdown at Three Mile Island, regulators converged on Pennsylvania to evaluate the public health risk posed by the accident. Indeed, no fewer than eight federal agencies contributed to monitoring the effects of radiation in the vicinity of the plant.⁵⁷ The FDA began testing milk and other food.⁵⁸ Immediately after the incident, the Nuclear Regulatory Commission served as the single spokesman for the agencies involved, but did not direct the collection of data or distribute the findings of one agency to other agencies.⁵⁹ An NRC official estimated that the cumulative radiation dose to local residents would be less than 100 millirems,⁶⁰ roughly equivalent to the annual dosage from natural background radiation.⁶¹

Finally, on April 13, more than two weeks after the accident began, the White House designated the EPA as the coordinator for the agencies involved, suggesting that the public would be assured by “the most credible environmental data.”⁶² The Department of Energy and the Department of Health, Education and Welfare (home of the FDA) were reportedly ruled out because of opposing institutional perspectives on the health risks posed by radiation.⁶³

The FDA collected and tested a large number of milk samples⁶⁴ from farms and dairies near the accident site, within a 20-mile radius.⁶⁵ The highest level of iodine-131 recorded was 31 picocuries per liter,⁶⁶ which corresponded with a projected dose commitment of 0.005 rem over

⁵⁷ Walter Pincus, *EPA Named Head Monitor On Radiation*, WASH. POST, April 14, 1979, at A4.

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ *Backgrounder on the Three Mile Island Accident*, *supra* note 56.

⁶¹ Pincus, *supra* note 57.

⁶² *Id.* (internal quotation marks omitted).

⁶³ *Id.*

⁶⁴ More than 500 samples were collected. Kevin L. Ropp, *FDA to the Rescue*, 26 FDA CONSUMER (Oct. 1992).

⁶⁵ This Week In FDA History - March 28, 1979, FDA (May 20, 2009), <http://www.fda.gov/AboutFDA/WhatWeDo/History/ThisWeek/ucm117712.htm>.

⁶⁶ *Backgrounder on the Three Mile Island Accident*, *supra* note 56.

the course of an individual's lifetime, assuming an infant drinking one liter of milk daily.⁶⁷ This represented a figure 300 times smaller than the protective PAG for a projected dose commitment to the thyroid gland of 1.5 rem.⁶⁸ Minute traces of cesium-137 were also found in some samples.⁶⁹

Despite indications that radiation emanating from Three Mile Island did not pose an appreciable threat to the public, FDA took precautions to ensure its ability to respond in case of greater danger in the future. Most importantly, the agency acted to ready supplies of potassium iodide. Coincidentally, in late 1978, just a few months prior to the Three Mile Island incident, the agency had published a notice in the Federal Register inviting drug manufacturers to submit New Drug Applications for potassium iodide products, suggesting that the compound was safe and effective for the purpose of preventing harm from radioactive iodine.⁷⁰ Research indicated that oral administration of the drug could achieve blockage of radioactive iodine uptake by the thyroid gland—a cause of thyroid cancer—with greater than 90 percent effectiveness.⁷¹ However, the NRC failed to take action to order any of the drug to prepare for future nuclear incidents.⁷²

Following the Three Mile Island incident, then, in order to ensure a sufficient supply of potassium iodide to the populated areas surrounding the plant, the FDA had to quickly contract with firms in Missouri, Michigan and New Jersey to supply it. The chief of the agency's Emergency Operations branch at the time, W. Remle Grove, has said, "We had people from what

⁶⁷ Bernard Shleien, *Protective Action Guides: Theory and Application: Lessons from the Three Mile Island Accident* 274, available at http://www.iaea.org/inis/collection/NCLCollectionStore/_Public/12/575/12575507.pdf.

⁶⁸ *Id.* at 273–74.

⁶⁹ Ropp, *supra* note 64.

⁷⁰ Bernard Shleien et al., *Recommendations on the Use of Potassium Iodide as a Thyroid Blocking Agent in Radiation Accidents: An FDA Update*, 59 BULLETIN OF THE N.Y. ACADEMY OF MEDICINE 1009, 1009–10 (1983), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1911939/pdf/bullnyacadmed00086-0155.pdf>.

⁷¹ *Id.* at 1010.

⁷² NIRS Fact Sheet-KI, NUCLEAR INFORMATION AND RESOURCE SERVICE (March 2002), <http://www.nirs.org/factsheets/nirsfactsheetki.htm>.

was then the Bureau of Drugs scurrying around trying to find possible sources of potassium iodide to manufacture, package, and be made available for the states and consumers.”⁷³

Ultimately, nearly 250,000 bottles of the drug were delivered to the area within 3 days of the accident.⁷⁴

2. Institutional Responses: Congressional and Executive

The difficulties in coordinating agencies to respond to the threat of radioactive contamination from the Three Mile Island incident prompted some in Congress to reconsider how regulators should respond to such incidents. Senators John Glenn and Abraham Ribicoff consequently introduced a bill entitled the Federal Radiation Protection Management Act of 1979.⁷⁵ In hearings on the bill in 1980, Senator Glenn noted, “It has been almost exactly 1 year since the Three Mile Island accident pointed out most compellingly the real need for better coordination of the Federal radiation protection and research apparatus. Events and studies since then, far from alleviating our concern, have confirmed and deepened it.”⁷⁶ Consequently, the announced purpose of the bill was “to insure adequate protection of workers, the general public, and the environment from harmful radiation exposure, to establish mechanisms for effective coordination among the various federal agencies involved in radiation protection activities, to develop a coordinated radiation research program, and for other purposes.”⁷⁷

To accomplish these objectives, the bill called for the creation of two federal “interagency groups,” to be called the Federal Council on Radiation Protection and the Federal

⁷³ Ropp, *supra* note 64.

⁷⁴ Significant Dates in U.S. Food and Drug Law History, FDA (Oct. 14, 2010), <http://www.fda.gov/aboutfda/whatwedo/history/milestones/ucm128305.htm>.

⁷⁵ S. 1938, 96th Cong. (1979).

⁷⁶ *Federal Radiation Protection Management Act of 1979: Hearing on S. 1938 Before the Subcomm. on Energy, Nuclear Proliferation and Fed. Services of the S. Comm. on Gov. Affairs*, 96th Cong. 2 (March 20, 1980) (statement of Senator Glenn).

⁷⁷ *Id.*

Conference on Research into the Biological Effects of Ionizing Radiation.⁷⁸ The former group would be chaired by the Administrator of the EPA and would be responsible for coordinating federal regulation of radiation; the latter group would be chaired by the Director of the National Institutes of Health and would oversee agency involvement in radiation research.⁷⁹ Senator Glenn saw the creation of these groups as necessary because no governmental body had possessed sufficient authority to coordinate government response: “Some have argued that [the abolishment of the FRC in 1970 and transfer of its guidance function to the EPA] occurred because the FRC lacked a mandate and organization strong enough to accomplish its missions effectively. We are concerned that that sense of weakness has persisted, notwithstanding transfers of authority.”⁸⁰

The bill failed to pass, however, largely because the energy behind legislative reform was dissipated by the Carter Administration itself having taken initiative in solidifying the government’s ability to respond to nuclear accidents. By executive order, President Carter established a Radiation Policy Council to advise on broad radiation policy; moreover, at the administration’s direction, the Secretary of HEW established an Interagency Radiation Research Committee to coordinate the planning, implementation, and evaluation of a research program on the biological effects of radiation.⁸¹ In light of these developments, the administration took the position that “legislation establishing [similar administrative bodies] in statute is unnecessary.”⁸²

3. FDA Regulation in the Wake of Three Mile Island

⁷⁸ *Id.* at 1.

⁷⁹ *Id.*

⁸⁰ *Id.* at 2.

⁸¹ *Id.* at 3 (statement of Donald S. Fredrickson, M.D., Director, National Institutes of Health, accompanied by John C. Villforth, Director, Bureau of Radiological Health).

⁸² *Id.* at 3–4.

The comment period for FDA's proposed regulation from 1978 introducing standards for radionuclide contamination of food, in the form of PAGs and derived response levels, actually closed shortly before the Three Mile Island accident. In light of the importance of the event and the extent to which it increased public awareness of the issues at stake, however, the agency considered comments submitted after the accident in its final regulation.⁸³

The regulation issued in 1982 did not depart radically from the proposed rule issued four years earlier, but the agency did reconsider its proposed rule in two important ways. First, as discussed above,⁸⁴ the FDA decided to issue its standards as a notice rather than a rule, “[b]ecause these recommendations are voluntary guidance to State and local agencies (not regulations).”⁸⁵ (As the agency demonstrated in its testing of foods after Three Mile Island, it also used the standards as guidelines for its own actions, though not legally bound to do so.)

Second, the FDA considered revising its PAG recommendations in an upward direction (toward higher threshold levels) with respect to specific organs in light of new scientific evidence, which indicated that risks to specific organs were “quite different from the earlier assumptions.”⁸⁶ However, a recent revision of EPA radiation standards for occupational exposures along the same lines had recently “been subject to considerable controversy.”⁸⁷ As a result, the FDA declined to revise the organ PAGs, at least until such time as “a consensus in the United States emerges.”⁸⁸ It seems reasonable to conclude that its hesitation was also influenced by the outpouring of public concern with radiation levels following the Three Mile Island accident; given the regulatory confusion after that event, the agency's easing of some standards

⁸³ Accidental Radioactive Contamination of Human Food and Animal Feeds; Recommendations for State and Local Agencies, 47 Fed. Reg. 47,073, 47,074 (Oct. 22, 1982).

⁸⁴ *Supra* note 33.

⁸⁵ Accidental Radioactive Contamination of Human Food and Animal Feeds; Recommendations for State and Local Agencies, *supra* note 83, at 47,074.

⁸⁶ *Id.* at 47,075.

⁸⁷ *Id.*

⁸⁸ *Id.*

without an unassailable foundation might be viewed with increased skepticism by at least some segments of the public.

The agency emphasized its specificity as to what kinds of action should be taken at Preventive and Emergency PAG levels. In the case of milk containing radionuclides at the level of Preventive PAGs, the agency suggested “transfer of dairy cows from fresh forage (pasture) to uncontaminated stored feed;” in addition, it recommended “the diversion of whole milk potentially contaminated with short-lived radionuclides to products with a long shelf life to allow radioactive decay of the radioactive material.”⁸⁹ In contrast, at the Emergency PAG level, the FDA recommended that officials “isolate food to prevent its introduction into commerce and determine whether condemnation or other disposition is appropriate.”⁹⁰

B. The Chernobyl Accident

1. *The Accident and Immediate Responses*

The threat to the public from Three Mile Island proved to be illusory—the “primary fallout” was financial rather than radioactive⁹¹—but a far more serious nuclear accident in the Ukraine (in the former U.S.S.R.) in 1986 would have a severe impact in Europe, unsettle the American public more deeply, and test the FDA’s ability to ensure the public’s confidence in the safety of the nation’s food supplies.

The accident was sparked on April 26 when the crew at the Unit 4 of the Chernobyl plant, roughly 80 miles north of Kiev, was conducting a test to determine how the plant would respond in the event of a loss of power:

⁸⁹ *Id.* at 47,074.

⁹⁰ *Id.*

⁹¹ See Joseph P. Tomain & Constance Dowd Burton, *Nuclear Transition: From Three Mile Island to Chernobyl*, 28 WM. & MARY L. REV. 363, 365 (1987).

A series of operator actions, including the disabling of automatic shutdown mechanisms, preceded the attempted test By the time that the operator moved to shut down the reactor, the reactor was in an extremely unstable condition. A peculiarity of the design of the control rods caused a dramatic power surge as they were inserted into the reactor.

. . . .

The interaction of very hot fuel with the cooling water led to fuel fragmentation along with rapid steam production and an increase in pressure. The design characteristics of the reactor were such that substantial damage to even three or four fuel assemblies can — and did — result in the destruction of the reactor. The overpressure caused the . . . cover plate of the reactor to become partially detached, rupturing the fuel channels and jamming all the control rods, which by that time were only halfway down. Intense steam generation then spread throughout the whole core (fed by water dumped into the core due to the rupture of the emergency cooling circuit) causing a steam explosion and releasing fission products to the atmosphere. About two to three seconds later, a second explosion threw out fragments from the fuel channels and hot graphite.⁹²

Following the explosions in Unit 4, massive amounts of radiation were released into the environment—at least five percent of the reactor core.⁹³ To prevent further release of radionuclides, boron and sand were poured onto the reactor from the air, and the unit was ultimately entombed in a concrete “sarcophagus.”⁹⁴ These measures, however, were insufficient to prevent radionuclides from spreading across a broad area. Initial exposure was to iodine-131,

⁹² *Chernobyl Accident 1986*, WORLD NUCLEAR ASSOCIATION (April 2011), <http://www.world-nuclear.org/info/chernobyl/inf07.html>

⁹³ *Id.*

⁹⁴ *Backgrounder on Chernobyl Nuclear Power Plant Accident*, U.S. NUCLEAR REGULATORY COMMISSION (February 4, 2011), <http://www.nrc.gov/reading-rm/doc-collections/fact-sheets/chernobyl-bg.html>.

but cesium-137 became the more far-reaching hazard, with five million Europeans living in areas considered contaminated—200,000 of whom were ultimately resettled.⁹⁵

Once the extent of the radiation release began to come into focus, the FDA moved to protect American food supplies. Some early tests were actually performed for the protection of Americans abroad; the first worrisome FDA test results came from a sample of Moscow milk in May that contained double the derived intervention level for infants and pregnant women, leading the U.S. Embassy there to recommend that pregnant American women and infants there avoid drinking local milk.⁹⁶ Also in May, the FDA announced that it would begin routinely monitoring food imports from twelve European nations for radiation.⁹⁷ The agency began to test import samples on May 5; it also began to test domestic milk samples.⁹⁸ The FDA detected low levels of iodine-131 in Italian mushroom and fennel shipments, but not enough to trigger protective action.⁹⁹

The FDA's approach to safeguarding the food supply was criticized by some environmentalists. This was perhaps inevitable given that its screening policy was dramatically less restrictive than the actions taken by the European Common Market nations: those countries blocked all imports of a number of food products from Eastern Europe.¹⁰⁰ Likewise, Canadian officials rejected substantial quantities of European imported food, and tested all shipments of

⁹⁵ *Chernobyl Accident 1986*, *supra* note 92.

⁹⁶ *U.S. Women, Infants Urged Not to Drink Milk in Moscow*, LEXINGTON HERALD-LEADER, May 25, 1986.

⁹⁷ Marilyn Marter, *Nuke Accident May Cut Supplies of Some Foods*, MIAMI HERALD, May 22, 1986.

The affected countries were Austria, Czechoslovakia, Denmark, East Germany, Finland, Hungary, Japan, Norway, Poland, the Soviet Union, Sweden and West Germany.

⁹⁸ Broderick Perkins, *No Decline Of Imports Because Of Chernobyl Testing By FDA Reveals Little Risk*, SAN JOSE MERCURY NEWS, May 21, 1986.

⁹⁹ *Id.*

¹⁰⁰ *Id.*

food imported from Europe.¹⁰¹ One prominent environmentalist was quoted in a major newspaper criticizing the FDA's response:

The European and Canadian approach "is much more sensible and conservative from the point of view of protecting the public health of their citizens," said Robert Alvarez of the Environmental Policy Institute in Washington. "You have to assume a conservative posture when you're dealing with a lot of uncertainties."¹⁰²

¹⁰¹ Larry Tye, *Food From Europe Being Tested*, BOSTON GLOBE, May 13, 1986.

¹⁰² *Id.*