

**UNITED STATES DEPARTMENT OF HEALTH AND
HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

March 12, 2013

Division of Dockets Management)
Food and Drug Administration)
Department of Health and Human Services)
5630 Fishers Lane, rm. 1061)
Rockville, MD 20852)

Docket No. _____

Submitted by

FUKUSHIMA FALLOUT AWARENESS NETWORK

INCLUDING:

**ECOLOGICAL OPTIONS NETWORK
BEYOND NUCLEAR
CITIZENS FOR HEALTH**

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CITIZEN PETITION

Fukushima Fallout Awareness Network, a group of concerned citizens and watchdogs with varied backgrounds including science, public policy, and actual on-the-ground experience near Fukushima, Japan, submits this petition under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 321(s); 331(a), (c), & (g); 342; 346; 348; 371 – a non-exclusive list) to request the Commissioner of Food and Drugs to promulgate a series of regulations to protect U.S. consumers from Cesium 134 and Cesium 137 contamination.

No food, dietary supplements, or drugs commercially available in the U.S. should have more than 5 Bq/kg of Cesium 134/137 contamination. This standard is of practical convenience for current detection equipment; eventually, the amounts of Cesium 134/137 contamination permitted in our food and drug supply could be lowered further. To aid consumers in determining their own Cesium 134/137 intake, all food, dietary supplements, and drugs should be tested for and labeled with its exact Cesium 134/137 contamination. All tests of Cesium 134/137 contamination should be recorded in a publicly accessible database for common knowledge with further research into the safety of our food and drug supply. Any food, dietary supplement, or drug with more than 5Bq/kg of Cesium 134/137 contamination should be prohibited from commercial sale but still recorded in the public database for understanding the Cesium 134/137 threat.

The Commissioner of Food and Drugs should promulgate these regulations:

(1) prohibit the sale or distribution of any food, dietary supplements, and drugs which are contaminated with more than 5Bq/kg of Cesium 134/137 (either radioisotope individually or any combination of the two).

(2) require testing for Cesium 134 and 137 contamination in two levels in any and all food, dietary supplements, and drugs meant for commercial sale. The first level would be testing (most likely an assembly line) of all food, dietary supplements, and drugs for Cesium 134/137 contamination using a mass-market commercially affordable Germanium Detector similar to those used commonly in Japan. The second level would be more in-depth testing of samples of food, dietary supplements, drugs, and farm soil on a regular (once every two weeks to once a month) cycle in a laboratory using the best scintillation spectrometry equipment available to build a statistical history of products' and regions' susceptibility to contamination. Every two years FDA should reevaluate commercially available detection equipment and appropriately reassess its testing requirements.

(3) assign a tracking number to every food, dietary supplement, and drug containing Cesium 134/137 contamination which is then catalogued in a national database. Each catalogued item will contain the exact amount of Cesium 134/137 contamination found, crop/manufacture date, and the product's country or State of origin.

(4) ensure that the national database described in Item (3) directly above is publicly accessible for any and all consumers via the internet. A consumer should be able to read the tracking number off of the label of any commercially available food, dietary supplement, or drug and find the corresponding information in the national database described in Item (3) directly above.

(5) prohibit a listing of "below limit" in the national database for Cesium 134/137 contamination in a food, dietary supplement, or drug; there must always be a number. Items contaminated with more than 5 Bq/kg should still be listed with the amount of contamination found, even though these items will be prohibited from sale - the database would then serve researchers in determining the level of threat posed by ongoing Cesium 134/137 contamination.

(6) ensure that any established testing process for radioactivity has safeguards against co-mingling or dilution --- i.e. the mixing of products or samples to artificially meet a standard; no mixing contaminated and un-contaminated food, dietary supplements, or drugs so that both meet a standard.

(7) begin systematic testing of soil, trees, and waterways across the U.S. and especially on the west coast to determine our ecosystem's contamination and vulnerability. File all readings in the national database described in Item (3) above.

(8) label all food, dietary supplements, and drugs that are commercially available and contaminated with Cesium 134/137 with the amount of Cesium 134/137 contamination found.

A. ACTION REQUESTED

Initiate immediate rulemaking procedures to expand the FDA's response to the Fukushima disaster in order to address the domestic-based threat of radiation fallout in food, dietary supplements, and drugs.

First, we ask that FDA begin systematic testing in the U.S. to properly determine and catalogue the radiological threat of Cesium 134/137 contamination. Systematic testing should be performed on any and all food, dietary supplements, and drugs intended to enter a consumer's hands *along with* testing of soil, trees and waterways.

Second, we ask that FDA designate any food, dietary supplement, or drug containing more than 5 Bq/Kg of Cesium 134/137 contamination in its final form illegal.

Third, we ask that FDA require the labeling of any food, dietary supplement, or drug with its Cesium 134/137 contamination. This would empower consumers to manage their own chronic Cesium 134/137 intake.

Fourth, the information collected from testing should be placed in one publicly accessible database which consumers can use to find out more information about their

food and which researchers can use to properly tackle the Cesium 134/137 contamination threat.

Radioactive contamination in the food chain started with above ground testing in the 1950s, increased with Chernobyl, and is continuing to increase after Fukushima's triple meltdown on 3/11, the largest nuclear catastrophe in history. The official food monitoring system in place has become inadequate to deal with the growing problem of radioactive food contamination and is also inaccessible to citizens. The damaged Fukushima units continue to leak 10 million becquerels of Cesium 134 and 137 per hour into the environment with no sign of stopping,^{1,2} the accident is ongoing. Unfortunately, Cesium bioaccumulates³ and biomagnifies⁴ over time; since Cesium 134 has a hazardous life⁵ of about 10-20 years and Cesium 137 has a hazardous life of about 300-600 years, the threat of contamination in our food and drug supply is a long-term issue that deserves immediate attention.

We are alarmed at the lack of testing currently in place to meet the present-and-growing threat of Cesium 134 and 137 contamination in our food supply. The time is past-due for a comprehensive response to radiation present in our food supply from the Fukushima disaster. FDA's public actions and comments on preventing contaminated food from Japan entering our supply consists of steps in the right direction, however, the Fukushima disaster represents a threat that requires stronger, long-term action.

While countries have set different standards for Cesium 134/137 contamination in their food, the U.S. only has guidelines and recommendations.⁶ FDA should promulgate a binding U.S. threshold of 5 Bq/kg of Cesium 134/137 contamination in light of the dangers posed from the cumulative effect of Cesium 134/137 contamination (with the understanding that as technology and testing methods improve, an even lower level of Cesium 134/137 contamination, as per the BEIR VII report discussed below, would become the ultimate goal standard). Since current FDA standards use previous BEIR recommendations, we recommend that the most recent conclusion of BEIR VII of "no

¹ Iori Mochizuki, "10 million Bq of cesium-134/137 is still released every single hour from reactor1, 2 and 3," *Fukushima Diary*, (12/27/2012). Available at: <http://fukushima-diary.com/2012/12/10-million-bq-of-cesium-134137-is-still-released-every-single-hour-from-reactor1-2-and-3/>

² Tokyo Electric Power Company, "The Estimated Amount of Radioactive Materials Released into the Air and the Ocean Caused by Fukushima Daiich Nuclear Power Station Accident Due to the Tohoku-Chihou-Taiheiyoku-Okie Earthquake (As of May 2012)," Press Release, (5/24/2012). Available at: http://www.tepco.co.jp/en/press/corp-com/release/2012/1204659_1870.html

³ "The biological sequestering of a substance at a higher concentration than that at which it occurs in the surrounding environment or medium." - U.S. Geological Survey, 2007. Available at: <http://toxics.usgs.gov/definitions/bioaccumulation.html>

⁴ "Result of the process of bioaccumulation and biotransfer by which tissue concentrations of chemicals in organisms at one trophic level exceed tissue concentrations in organisms at the next lower trophic level in a food chain." - Environmental Protection Agency, 2010. Available at: <http://toxics.usgs.gov/definitions/biomagnification.html>

⁵ Using 10 half-lives of each isotope as one hazardous life.

⁶ Food and Drug Administration, "Supporting Document for Guidance Levels for Radionuclides in Domestic and Imported Foods," Docket No. 2003D-0558 (prepared 7/2004), *see* Footnote 4. Available at: <http://www.fda.gov/Food/FoodSafety/FoodContaminantsAdulteration/ChemicalContaminants/Radionuclides/ucm078341.htm>

safe dose” be a guiding principle, particularly after the ramifications of Fukushima’s ongoing nuclear meltdowns. Consumers should have the knowledge and a choice to manage their own Cesium 134/137 intake, so FDA should require the testing and labeling of Cesium 134/137 in food, dietary supplements, and drugs. Every two years FDA should reevaluate commercially available detection equipment and appropriate reassess the testing requirements of Item 2.

B. STATEMENT OF GROUNDS

1. THE U.S. FOOD SUPPLY HAS CESIUM RADIATION CONTAMINATION

Various products in the U.S. food supply have Cesium 134 and 137 contamination; these include pistachios,⁷ oranges from California,⁸ grapefruits from Florida (only cesium 137),⁹ prunes from California,¹⁰ and almonds from California.¹¹ These measures came from Japanese laboratory Security Tokyo and grocery store Maruetsu testing incoming food from the U.S.

The California coastline itself is now in danger of radiation contamination. “Scientists from California State University, Long Beach tested giant kelp collected in the ocean off Orange County and other locations after the March, 2011 accident, and detected radioactive iodine, which was released from the damaged nuclear reactor.”¹² Even more recently, scientists at Stanford University’s Hopkins Marine Station found levels of Cesium 134 and 137 from the Fukushima disaster in bluefin tuna caught off the California coast in Feb. 2013.¹³ The lingering question is, however, what additional levels of Cesium 134 and 137 contamination have occurred and how far up the food chain is the radiation going? University of California, Berkeley School of Nuclear Engineering found Cesium 134 and 137 in samples of topsoil, water, milk, vegetables and

⁷ Item 36, Maruetsu. Available at: <http://www.maruetsu.co.jp/brand/pdf/kensa120814.pdf>

⁸ Security Tokyo (4/4/2012). Available at: http://translate.google.com/translate?sl=auto&tl=en&js=n&prev=_t&hl=en&ie=UTF-8&eotf=1&u=http%3A%2F%2Fwww.securitytokyo.com%2Fdata%2Fc_orange.html&act=url

⁹ Security Tokyo (4/9/2012). Available at: http://translate.google.com/translate?sl=auto&tl=en&js=n&prev=_t&hl=en&ie=UTF-8&eotf=1&u=http%3A%2F%2Fwww.securitytokyo.com%2Fdata%2Fc_grapefruit.html&act=url

¹⁰ Security Tokyo (7/2012). Available at: http://translate.google.com/translate?sl=auto&tl=en&js=n&prev=_t&hl=en&ie=UTF-8&eotf=1&u=http%3A%2F%2Fsecuritytokyo.com%2Fdata%2Fc_prune.html&act=url

¹¹ Security Tokyo (7/2012). Available at: http://translate.google.com/translate?sl=auto&tl=en&js=n&prev=_t&hl=en&ie=UTF-8&eotf=1&u=http%3A%2F%2Fsecuritytokyo.com%2Fdata%2Fc_almonds.html&act=url

¹² Marla Cone, “Radioactive Iodine from Fukushima Found in California Kelp,” *Scientific American*, (3/30/2012). Available at: <http://www.scientificamerican.com/article.cfm?id=radioactive-iodine-from-from-fukushima-found-in-california-kelp>

¹³ “Tuna caught near California still have traces of Fukushima radiation,” (2/21/2013). Available at: <http://newsle.com/article/0/61369722/>

berries taken from the San Francisco Bay area.^{14,15} Due to the long-lived Cesium 134 and 137 radionuclides, it is likely that Cesium is continuing to bioaccumulate and biomagnify in the area.

Considering that the confidence in safety thus far was misplaced due to our own lack of knowledge and understanding of maritime ecosystems,¹⁶ the time has come to set up a system of observations and standards that will (1) monitor the situation appropriately, (2) prevent any problem from growing too big to handle, and (3) empower consumers with the necessary means to protect themselves if they so wish. Since the current level of Cesium contamination discovered in migratory fish near the U.S. and different land food products has ranged from barely detectable to almost 10 Bq/kg, we have the time to establish a thorough testing regime. While there is time to lay foundation, there is no time to lose because as recent as January 19, 2013, record high Cesium absorption rates have been found in the fish near Japan.¹⁷

2. NO LEVEL OF RADIATION IS SAFE – THE BEIR VII REPORT

In 2006, the National Academy of Sciences (NAS) published the seventh report in the Biological Effects of Ionizing Radiation (BEIR). This report specifically covers low level doses of ionizing radiation¹⁸ such as chronic, low-level intake of Cesium 134/137 contaminated food. FDA has previously referred to BEIR reports such as in 1998, when announcing its "Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations for State and Local Agencies," FDA relied upon BEIR IV.

The conclusion of the BEIR VII report weighs in favor of establishing a system to test our food and inform consumers of Cesium 134 and 137 levels. From the BEIR VII public summary:

“Despite the challenges associated with understanding the health effects of low doses of low-LET radiation, current knowledge allows several conclusions. The BEIR VII committee concludes that current scientific evidence is consistent with the hypothesis that there is a linear dose-response relationship between exposure to ionizing radiation and the development of radiation-induced solid cancers in humans. The committee

¹⁴ UCB “Food Chain Testing,” University of California-Berkeley, (dates of tests labeled). Available at: <http://www.nuc.berkeley.edu/UCBAirSampling/FoodChain>

¹⁵ UCB “Milk Sampling Results,” University of California-Berkeley, (dates of tests labeled). Available at: <http://www.nuc.berkeley.edu/UCBAirSampling/MilkSampling>

¹⁶ Delvan Neville, Jason Phillips, and Richard Brodeur, “Pacific Albacore Carry Barely Detectable Fingerprints of Fukushima Disaster,” Oregon State University (10/24/2012). Available at: <http://oregonstate.edu/ua/ncs/archives/2012/oct/pacific-albacore-carry-barely-detectable-fingerprints-fukushima-disaster>

¹⁷ Japan Today via News On Japan, “Record high radiation found in fish caught near Fukushima plant,” (1/20/2013). Available at: <http://newsonjapan.com/html/newsdesk/article/100555.php>

¹⁸ Committee to Assess Health Risks from Exposure to Low Levels of Ionizing Radiation, National Research Council, “Public Summary & Executive Summary,” *Health Risks from Exposure to Low Levels of Ionizing Radiation: BEIR VII Phase 2*. Washington, DC: The National Academies Press, 2006. Available at: <http://www.nap.edu/openbook.php?isbn=030909156X>

further judges it unlikely that a threshold exists for the induction of cancers but notes that the occurrence of radiation-induced cancers at low doses will be small.”¹⁹

3. THERE IS A WEALTH OF INFORMATION FROM THE LONG-TERM EFFECTS OF THE CHERNOBYL DISASTER THAT HAS HIGH RELEVANCE TO THE FUKUSHIMA DISASTER; THE EVIDENCE POINTS TOWARD THE NEED FOR GREATER ACTION BY FDA

The Chernobyl accident contained Cesium 134 and 137 leaks that continue to contaminate the lives of nearby residents.

Tokyo Electric Power Company, which operated the Fukushima plant, estimated on December 27, 2012 that the current Cesium 134 and 137 output from the damaged plant is at 10 million Bq/hr.²⁰ With that level of contamination output, there is great importance to gathering information on State-side fallout.

From the tragic fallout of Chernobyl, there has been a wealth of information learned about Cesium 134 and 137 contamination of human bodies. Out of Dr. Bandazhevsky’s research which included effects on children, we can see dramatic problems with relatively low (currently permissible) intakes of Cesium 134 and 137.²¹

Looking at the post-Chernobyl studies highlighted in the International Commission on Radiological Protection publication 111, cumulative low-dose intakes of Cesium 134 and 137 pose a real threat. Figure 2.2 from the publication shows a graph distinguishing between a person’s Cesium contamination after a singular one-time (episodic) dose vs two different daily low-dose amounts over a period of 3 years.

¹⁹ BEIR VII, page 10.

²⁰ See Footnote 1, *supra*.

²¹ Yuri Bandazhevsky, “Radioactive Caesium and heart – pathophysiologic aspects,” (2001), chapter 1. Available at: http://www.enfants-tchernobyl-belarus.org/doku.php?id=base_documentaire:articles-2001:etb-066

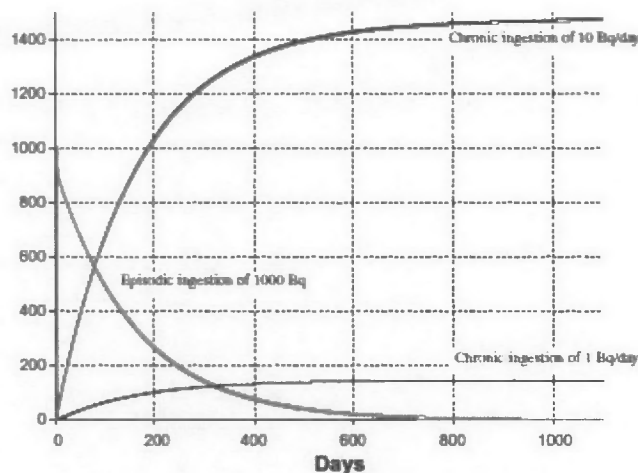


Fig. 2.2. Evolution over a pluri-annual period (1000 days) of whole-body activity (Bq) associated with an episodic intake of 1000 Bq and daily intake of 1 and 10 Bq of ^{137}Cs .

Ingesting 10 Bq/kg per day of Cesium 137 over three years results in a contamination of over 1400 Bq/kg.

Considering the study's recognition of how different the dose may be between individuals, families, and localities after a nuclear event, the importance of giving an individual consumer the ability to manage his or her own Cesium intake through diet is magnified.²²

Beyond the known cancer risk from Cesium, there are other risks such as kidney and bladder damage, cardiac abnormalities in children with doses as low as 11 Bq/kg, hormone imbalances, hypertension, angina, and diabetes.²³

C. ENVIRONMENTAL IMPACT

21 C.F.R. 25.30(a), (h), (j), & (k) and 21 C.F.R. 25.32(a), (m), & (n) categorically excludes the need of an environmental impact statement or analysis for this petition.

D. ECONOMIC IMPACT

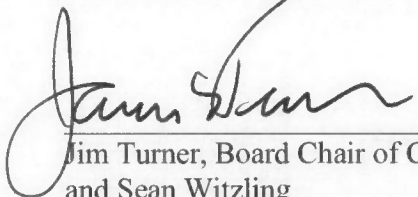
No request for this information has been made by the Commissioner.

²² International Commission on Radiological Protection, "Application of the Commission's Recommendations to the Protection of People Living in Long-term Contaminated Areas after a Nuclear Accident or Radiation Emergency," Vol. 39 No. 3 (2009), paragraph 16. Available at: <http://www.icrp.org/publication.asp?id=ICRP%20Publication%20111> and free download at: [www.icrp.org/docs/P111\(Special%20Free%20Release\).pdf](http://www.icrp.org/docs/P111(Special%20Free%20Release).pdf)

²³ See Footnote 21, *supra*.

E. CERTIFICATION

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

A handwritten signature in black ink, appearing to read "Jim Turner", is written over a horizontal line.

Jim Turner, Board Chair of Citizens for Health
and Sean Witzling
for Fukushima Fallout Awareness Network
(202) 462-8800
Sean@swankin-turner.com

Citizens for Health
1400 16th St., N.W., Ste. 101
Washington, D.C. 20036