U.S. Food and Drug Administration

News & Events

Radiation Safety

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What is FDA doing to ensure the safety of products imported from Japan?

FDA's screening at U.S. borders will remain vigilant and will be augmented with radiation screening of shipments.

Because of the heavy damage caused by the earthquake and tsunami to the region, no products are currently being exported from the affected area. The Japanese Ministry of Health, Labour, and Welfare has also ordered a stop to the sale of all food products from the Fukushima Prefecture.

FDA's import tracking system has been programmed to automatically flag all shipments of FDA-regulated products from Japan, and the Agency maintains a registry of companies that prepare, pack, manufacture, or hold food for intended consumption in the U.S. The Agency will be paying special attention to shipments from those companies in the affected area.

Standard operating procedure requires shippers to submit and FDA to receive prior notice of a shipment before the arrival of any shipments of FDA-regulated food/feed products. FDA's Prior Notice Center (PNC) enables the agency to stop these products upon arrival at the U.S. border or before they are distributed in U.S. commerce if a credible threat is identified for any shipment.

United States Customs and Border Patrol (CBP) officers routinely use radiation detection equipment to screen food imports, cargo, and travelers. This screening helps identify and resolve potential safety or security risks. FDA is working with CBP to determine if their Automated Targeting System can assist in identifying shipments of FDA-regulated products, other than food, originating from Japan before they arrive so that these shipments can be better targeted for examination. FDA's import staff will review each shipment of regulated goods originating from Japan and determine if it should be examined and sampled or released.

Questions about Food Safety

What is FDA doing to assess the situation in Japan?

Based on current information, there is no risk to the U.S. food supply. FDA is closely monitoring the situation in Japan and is working with the Japanese government and other U.S. agencies to continue to ensure that imported food remains safe. FDA already has a very robust screening process for imports and has staff in place at the ports to monitor incoming products. FDA does not have concerns with the safety of imported food products that have already reached the U.S. and that are in distribution.

As part of our investigation, FDA is collecting information on all FDA regulated food products exported to the U.S. from Japan, including where they are grown, harvested, or manufactured, so the Agency can further evaluate whether, in the future, they may pose a risk to consumers in the U.S. As FDA assesses whether there is a potential health risk associated with FDA-regulated food products imported from Japan, the Agency will

develop a monitoring strategy that may include increased and targeted product sampling at the border.

What systems does FDA have in place to protect the U.S. food supply?

The U.S. enjoys one of the world's safest food supplies. FDA has systems in place to help assure that our food supply is wholesome, safe to eat, and produced under sanitary conditions.

FDA has a team of more than 900 investigators and 450 analysts in the Foods program who conduct inspections and collect and analyze product samples. FDA oversees the importation of the full range of regulated products, including food and animal feed, among other responsibilities.

Altogether, FDA electronically screens all import entries and performs multiple analyses on about 31,000 import product samples annually. During Fiscal Year (FY) 2010, the Agency performed more than 175,000 food and feed field exams and conducted more than 350 foreign food and feed inspections.

FDA works to inspect the right imports—those that may pose a significant public health threat – by carrying out targeted risk-based analyses of imports at the points of entry.

If unsafe products reach our ports, FDA's imports entry reviews, inspections, and sampling at the border help prevent these products from entering our food supply.

Although FDA doesn't physically inspect every product, the Agency electronically screens 100 percent of imported foods products before they reach our borders. Based on Agency risk criteria, an automated system alerts FDA to any concerns. Then inspectors investigate further and, if warranted, do a physical examination of the product.

FDA also works cooperatively with U.S. Customs and Border Protection and other agencies to help identify shipments that may pose a threat.

What products come to the U.S. from Japan?

Imports from Japan include human and animal foods, medical devices and radiation emitting products, cosmetics, animal and human drugs and biologics, dietary supplements, and animal feeds. Foods imported from Japan make up less than 4 percent of foods imported from all sources. (Food products from Canada and Mexico each make up about 29 percent of all imported foods.) Almost 60 percent of all products imported from Japan are foods. The most common food products imported include seafood, snack foods and processed fruits and vegetables.

Are there dairy products that come from Japan?

Foods imported from Japan constitute less than 4 percent of foods imported from all sources. Dairy products make up only one-tenth of one percent of all FDA-regulated products imported from Japan. Most dairy products in the U.S. market are produced domestically. FDA is consulting with USDA's Animal Plant Health Inspection Service (APHIS) to ensure the continued safety of dairy products.

Are there food harvesting (fields, fisheries) or processing facilities in the area of the Fukushima nuclear reactor?

It's important to note that the damage caused by the earthquake and ensuing tsunami has reportedly halted production prior to the explosion at the reactor. While FDA does not track fields or fishery areas in foreign countries, the Agency does have a list of companies and manufacturing facilities in the affected area and will be paying special attention to imports from those locations.

Is there any reason for concern about radiation from these products when they are imported into the US?

Right now, due to the damage to the infrastructure in Japan, FDA believes that export activity is severely limited. FDA is monitoring all import records for Japan to determine when importation will resume and will conduct

surveillance to assure safety. FDA does not have any concerns for products that were already in transit when the explosion occurred at the reactor.

What are the current procedures for measuring radiation contamination in food? How will these change? How will FDA ensure consumers' safety?

FDA has procedures and laboratory techniques for measuring radionuclide levels in food, and can also utilize the Food Emergency Response Network (FERN)[1]. FERN integrates the nation's food-testing laboratories at the local, state, and federal levels into a network that is able to respond to emergencies involving biological, chemical, or radiological contamination of food. FDA is working with Customs and Border Protection (CPB) to share resources and techniques for measuring contamination. FDA has the ability to measure contamination in products and issued guidance in 1998 regarding safe levels.

Will FDA issue an import bulletin? What sort of techniques will FDA use to measure radiation in food?

FDA will issue an import bulletin or an assignment to the field once an assessment is completed on products and appropriate testing that can be completed. Products generally travel by vessel, and the typical transit time for products to reach the U.S. is about 8 days. FDA and other domestic regulatory labs have validated analytical methods to detect radiological contamination in food.

Is FDA looking at products that might have traveled through Japan at the time of the explosion?

FDA will be examining both food products labeled as having originated in Japan or having passed through Japan in transit. The same is true for raw ingredients.

How will the radiation affect fish and seafood that have not yet been fished or harvested?

The great quantity of water in the Pacific Ocean rapidly and effectively dilutes radioactive material, so fish and seafood are likely to be unaffected. However, FDA is taking all steps to evaluate and measure any contamination in fish presented for import into the US.

What are the chances of radiation affecting growing areas in the US? What action will FDA take to ensure the safety of consumers of those products?

At this time, there is no public health threat in the U.S. related to radiation exposure. FDA, together with other agencies, is carefully monitoring any possibility for distribution of radiation to the United States. At this time, theoretical models do not indicate that significant amounts of radiation will reach the U.S. coast or affect U.S. fishing waters. Please see www.epa.gov[2] for more information about monitoring efforts.

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Questions about Medical Products

Hypothetically, if they were needed, what are the FDA-approved products for treatment of internal contamination with radioactive iodine?

There are three FDA-approved potassium iodide (KI) products for use as an adjunct to other public health protective measures in the event that radioactive iodine is released into the environment. The three over-the-counter products are:

- Iosat Tablets (130 mg), Anbex, Inc., Williamsburg, Va., http://www.anbex.com[3] [4]
- ThyroSafe Tablets (65 mg), Recipharm AB, Jordbro, Sweden, http://www.thyrosafe.com[5] [6]
- ThyroShield Solution (65 mg/mL), Fleming & Company Pharmaceuticals,

Fenton, Mo. http://www.thyroshield.com[7] [8]

When administered at the recommended dose, KI is effective in reducing the risk of thyroid cancer in people at risk for inhalation or ingestion of radioactive iodine. KI floods the thyroid with non-radioactive iodine and prevents the uptake of the radioactive molecules. Potassium iodide works only to prevent the thyroid from uptaking radioactive iodine. It is not a general radioprotective agent.

There are three FDA-approved potassium iodide drugs marketed as over the counter products. They are: Iosat Tablets (130 mg), manufactured by Anbex, Inc.; ThyroSafe Tablets (65 mg), manufactured by Recipharm and ThyroShield Solution (65 mg/mL), manufactured by Fleming & Company Pharmaceuticals.

Is potassium iodide the only medication available for radiation exposure?

Potassium iodide is the only FDA-approved medication available to treat contamination with radioactive iodine. There are FDA-approved products available that increase the rate of elimination of other radioactive elements. They include:

- **Calcium-DTPA and Zinc DTPA, Hameln Pharmaceuticals.** Approved to treat known or suspected internal contamination with plutonium, americium, or curium to increase the rates of elimination.
- **Radiogardase (Prussian blue insoluble capsules), HEYL Chemisch-Pharmazeutische Fabrik GmbH & Co. KG.** Approved to treat known or suspected internal contamination with radioactive cesium and/or radioactive or non-radioactive thallium to increase their rates of elimination.

We have heard that potassium iodide is in short supply. Is that correct?

FDA daily evaluates the pharmaceutical supply for a wide variety of drugs to assess shortage issues.

Despite the fact that there is no public health event in the U.S. requiring KI, FDA is aware of an increased demand for KI products. FDA is working with these companies to facilitate increased production. FDA can't provide an exact date on when that might happen but it will occur as quickly as possible.

Due to public concern related to the nuclear incident in Japan, there is an increased demand for drugs used to prevent and treat harmful effects caused by radiation exposure or contamination with radioactive materials. At this time, however, the U.S. Government is not recommending that residents of the United States or its territories take potassium iodide, even as a preventative measure. According to the Nuclear Regulatory Commission, all the available information continues to indicate that the U.S. Territories and the U.S. West Coast are not expected to experience any harmful levels of radioactivity. Based on this, it is not expected that U.S. citizens will need potassium iodide. Nonetheless, the FDA is working with manufacturers to facilitate increased production of this medicine as quickly as possible.

Does FDA recommend that consumers purchase potassium iodide as a protective step?

No. There is no public health event requiring anyone in the U.S. to take KI because of the ongoing situation in Japan.

With exports from Japan disrupted, is there any possibility that some medical products could be in short supply?

FDA has been contacted by a few companies who receive product from Japan and the Agency is working with them on their supply issues.

Have U.S. manufacturers of potassium iodide been asked to ship any products to Japan?

At this time, the FDA is not aware of any request from Japan for potassium

iodide. In addition, there is not a public health event requiring anyone in the U.S. to be taking KI because of the ongoing situation in Japan.

Drugs shipped to a foreign country, including as part of a humanitarian relief effort, are considered exports, and therefore, need to meet certain legal requirements under the Federal Food, Drug, and Cosmetic Act (FFDCA). If a drug is approved and is otherwise in compliance with the FFDCA's requirements, there are no additional restrictions by FDA on its exportation. Drugs that are not approved or that otherwise are not in compliance with the FFDCA's requirements may be exported if the exportation meets certain conditions and requirements.

If I see web sites advertising potassium iodide or alternative cures, should I buy the products?

Due to public concern related to the nuclear incident in Japan, there is an increased demand for drugs used to prevent and treat harmful effects caused by radiation exposure or contamination with radioactive materials. One drug, potassium iodide (KI), has been approved by the FDA to prevent thyroid cancer in people internally contaminated with radioactive iodine.

At this time, the U.S. Government is not recommending that residents of the United States or its territories take KI, even as a preventative measure. According to the Nuclear Regulatory Commission, all the available information continues to indicate that Hawaii, Alaska, the U.S. Territories, and the U.S. West Coast are not expected to experience any harmful levels of radioactivity.

The FDA is alerting consumers to be wary of internet sites and other retail outlets promoting products making false claims to prevent or treat effects of radiation or products that are not FDA-approved. These fraudulent products come in all varieties and could include dietary supplements, food items, or products purporting to be drugs, devices or vaccines.

Consumers should be wary of the following:

- claims that a product not approved by FDA can prevent or treat the harmful effects of radiation exposure;
- suggestions that a potassium iodide product will treat conditions other than those for which it is approved, i.e., KI floods the thyroid with non-radioactive iodine and prevents the uptake of the radioactive molecules, which are subsequently excreted in the urine;
- promotions using words such as "scientific breakthrough," "new products," "miraculous cure," "secret ingredient," and "ancient remedy";
- testimonials by consumers or doctors claiming amazing results;
- limited availability and advance payment requirements;
- promises of no-risk, money-back guarantees;
- promises of an "easy" fix; and,
- claims that the product is "natural" or has fewer side effects than approved drugs.

Don't be fooled by professional-looking Web sites. Avoid Web sites that fail to list the company's name, physical address, phone number, or other contact information. For more tips for online buying, visit Buying Medicines and Medical Products Online [9]. To determine if a particular drug is FDA approved, check The Orange Book [10] or Drugs@FDA [11].

Consumers and health care professionals are encouraged to report adverse side effects or medication errors from the use of both approved and unapproved radiation exposure products to the FDA's MedWatch Adverse Event Reporting program at www.fda.gov/MedWatch [12] or by calling 800-332-1088.

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