Japan Questions and Answers
March 17, 2011

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. We do 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, we are collecting information on all FDA regulated food products exported to the U.S. from Japan, including where they are grown, harvested, or manufactured, so we 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, we 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 US 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 US from Japan?

Imports from Japan include human and animal foods, medical devices and radiation emitting products, cosmetics, animal and human drugs and biologics, and dietary supplements. 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 US 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?

While FDA does not track fields or fishery areas in foreign countries, 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.

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) (http://www.fernlab.org/) . 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 travel by vessel, the typical transit time for products to reach the US 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 US 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 US coast or affect US fishing waters. Please see www.epa.gov for more information about monitoring efforts.

Hypothetically, if they were needed, what are the FDA-approved products for radiation exposure?

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
- ThyroSafe Tablets (65 mg), Recipharm AB, Jordbro, Sweden, http://

www.thyrosafe.com
- ThyroShield Solution (65 mg/mL), Fleming & Company Pharmaceuticals, Fenton, Mo. http://www.thyroshield.com

When administered in the recommended dose, KI is effective in reducing the risk of thyroid cancer in individuals or populations 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, which are subsequently excreted in the urine. Potassium iodide works only to prevent the thyroid from uptaking radioactive iodine. It is not a general radioprotective agent.

Is potassium iodide the only medication available for radiation exposure?

Potassium iodide is the only FDA-approved medication available for exposure to 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 is aware of an increased demand for KI products. FDA is working with these companies to facilitate increased production. We can't provide an exact date on when that might happen, but it will occur as quickly as possible.

Several components of the federal government maintain stockpiles of medical supplies for emergency situations. For instance, the CDC maintains the Strategic National Stockpile for civilian use, while the Department of Defense maintains their own supplies for support of military operations. The respective federal organizations should be contacted with any additional requests about the specific items and quantities in those stockpiles. Deployment of these stockpiles is governed by policies and procedures developed by the individual organizations based on available information and potential benefits and risks to public health.

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

No. There is no public health event requiring anyone in the US 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 we are working with them on their supply issues.

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

Due to the public concern related the nuclear incident in Japan, there has been an increased demand for drugs, such as Potassium iodide (KI), used to prevent and treat the harmful effects of radiation.

According to the Nuclear Regulatory Commission, all the available information continues to indicate that the United States, including U.S. Territories, are not expected to experience any harmful levels of radiation from the event in Japan.

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 . To determine if a particular drug is FDA approved, check The Orange Book (http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm) or Drugs@FDA (http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm).

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 or by calling 800-332-1088 .