

(Note: This import alert represents the Agency's current guidance to FDA field personnel regarding the manufacturer(s) and/or products(s) at issue. It does not create or confer any rights for or on any person, and does not operate to bind FDA or the public).

**Import Alert # 99-33**

**Published Date:** 03/22/2011

**Type:** DWPE

Import Alert Name:

Detention Without Physical Examination of Products from Japan Due to Radionuclide Contamination

Reason for Alert:

This import alert represents the Agency's current guidance to FDA field personnel regarding the manufacturer(s) and/or product(s) at issue. It does not create or confer any rights for or on any person, and does not operate to bind FDA or the public.

On March 11, 2011, an 8.9 magnitude earthquake triggering a 30 ft tsunami struck the Pacific Coast of Japan. The force of the tsunami destroyed a great deal of the infrastructure along portions of the Japanese coast. The most notable damage from the tsunami has affected the Fukushima Daiichi nuclear plant. The following prefectures are in the closest proximity to the Fukushima Daiichi nuclear plant: Fukushima, Gunma Ibaraki, and Tochigi.

The Fukushima Daiichi nuclear plant houses several nuclear reactors that have posed signs of a potential threat of radiological contamination to the surrounding areas. Due to the public health concerns that are associated with radiation and nuclear contamination, FDA has increased surveillance of regulated products from Japan.

On March 19, 2011 the Japanese Ministry of Health, Labour and Welfare confirmed the presence of radioactive iodine contamination in dairy, fresh produce, and infant formula products. Japanese data analyses revealed that the food products measured from March 16-18, 2011 indicated the presence of radioactive iodine was five times the acceptable levels. The elevated levels were identified in products tested in Kawamata Town, Fukushima Prefecture and Ibaraki Prefecture, areas around the Fukushima Daiichi nuclear power plant.

Though radioactive iodine has a short half-life of about 8 days and decays naturally within a matter of weeks, there is a risk to human health if radioactive iodine in food is absorbed into the human body. If ingested, it can accumulate in and cause damage to the thyroid. Children and young people are particularly at risk of thyroid damage due to the ingestion of radioactive iodine.

On March 21, 2011 the Japanese Prime Minister ordered the Governors of the affected prefectures of Fukushima, Gunma, Ibaraki, and Tochigi to stop the distribution of spinach and kakina (a local Japanese vegetable) into the market, and ordered the Governor of Fukushima prefecture to stop the distribution of raw milk. This means no such products may lawfully be placed in the domestic or export markets.

FDA recognizes that the government of Japan is taking steps to address this issue and FDA will continue to provide support to their efforts.

**Guidance:**

Districts may detain, without physical examination, the specified products from firms in the Fukushima, Ibaraki, Tochigi, and Gunma prefectures.

FDA and the Japanese government will continue to collaborate to ensure products from the affected prefectures do not pose a health risk to U.S. consumers. FDA will continue monitoring the public health risks due to radionuclide contamination, and when appropriate will remove the Import Alert and resume routine coverage of entries.

Questions or issues involving operations should be addressed to the Division of Import Operations & Policy contact identified in the listing.

For questions or issues concerning science, science policy, sample collection, analysis, preparation, or analytical methodology, contact the Division of Field Science at 301-796-5992.

**Product Description:**

All specified products from the affected prefectures in Japan:

Fukushima

Gunma

Ibaraki

Tochigi

**PROBLEM:**

Radionuclide Contamination

**Charge:**

**CHARGES:**

For the above specified products from the affected prefectures of Fukushima, Gunma, Ibaraki, and Tochigi in Japan:

The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to contain a radionuclide, a poisonous or deleterious substance which may render it injurious to health [Adulteration, Section 402(a)(1)].

OASIS Charge Code: RADIONUC

AND

For spinach and kakina (a local Japanese vegetable) from the affected prefectures of Fukushima, Gunma, Ibaraki, and Tochigi in Japan; AND

For milk from the Fukushima prefecture:

The article is subject to refusal of admission pursuant to Section 801(a)(2) in that it appears to be forbidden or restricted in sale in the country in which it was produced or from which it was exported.

[Section 801(a)(2)].

OASIS Charge Code: FORBIDDEN

**Countries**

JAPAN

(09 - - - -) Milk/Butter/Dried Milk Prod

Desc:Milk /Butter/Dried Milk Products

(14 - - - -) Filled Milk/Imit Milk Prod

Desc:Filled Milk/Imitation Milk Products

(20 - - - -) Fruit/Fruit Prod

Desc:Fruit/Fruit Prod

(21 - - - -) Fruit/Fruit Prod

Desc:Fruit/Fruit Prod

(22 - - - -) Fruit/Fruit Prod

Desc:Fruit/Fruit Prod

(24 - - - -) Vegetables/Vegetable Products

Desc:Vegetables/Vegetable Prod

(25 - - - -) Vegetables/Vegetable Products

Desc:Vegetables/Vegetable Prod

(40 C - - 01) Milk Base Formula Product (Similac, Enfamil, Etc) (Baby)

Desc:Milk based formula

(40 C - - 99) Formula Products (Milk and Milk Substitutes) (Baby)

Desc:Formula Products (Milk) Baby