MATURITY HEALTH MATTERS

FDA Health News for Older Adults, Their Families and Caregivers

Issue 10 **Winter/Spring 2009**

Food Import Safety – Keeping Consumers Healthy

FDA is responsible for the safety of most of the food Americans eat, everything except for meat, poultry, and processed egg products, which are regulated by the United States Department of Agriculture (USDA). Each year, FDA regulates about 49 billion dollars of imported food that comes from over 150 countries or territories and enters through more than 300 American ports. There are approximately 214,000 registered foreign facilities that manufacture, process, pack, or hold food that is consumed in the United States.

Approximately 15 percent of the United States' food supply by volume is imported. For some products, a much higher percentage is imported. For example, approximately 60 percent of fresh fruits and vegetables consumed in the United States are imported. Americans are eating fresh fruits and vegetables year-round, thanks to the imports that fill in the times when the United States is not producing certain fruits and vegetables.

How are consumers affected by imported food?

Some foods, whether domestic or imported, may contain bacteria that can be harmful. Among those at highest risk for foodborne illness are those who are very young, older adults, as well as others:

- with immune-compromised diseases such as those who are HIV positive
- who receive chemotherapy
- who receive other immunosuppressive treatments

Symptoms of foodborne illness range from mild stomach discomfort to life-threatening problems that can affect the nervous system, liver, and kidneys.

Foodborne illnesses are caused by 200 different agents such as viruses, bacteria, parasites, and toxins plus a vast number of chemical contaminants and metals. The agents associated with foodborne illness have steadily grown over the last few decades, and this trend is expected to continue.

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How are food imports changing?

In the past, a large percentage of FDA-regulated imports consisted of unprocessed food ingredients that would be subsequently processed domestically with FDA oversight. Today, the volume and complexity of imported food has increased. Because of this, FDA's approach to handling imports has changed.

How does FDA regulate imported food products?

Under the Federal Food, Drug, and Cosmetic Act (FFDCA), all food, whether imported or domestic, must be safe, clean, and produced under sanitary conditions.

Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (BT Act), prior notice is required for all imported human food and animal feed shipments to be submitted to the FDA before the food is allowed to enter the United States. This means that FDA must be notified in advance of when and where food shipments will enter the United States and what those shipments will contain as well as the facility and country where the food was manufactured and/or grown. This requirement helps increase the security and safety of the United States food supply.

Data on imported food products, with a few exceptions, are submitted and processed through United States Customs and Border Protection and/or FDA import systems. The data are electronically screened to assist in determining whether the food appears to present a significant risk to the public health. When necessary, FDA physically examines targeted import food shipments on the basis of apparent risk. Food products that pose higher risks or companies with a history of problems are physically inspected more frequently than those that pose little or no apparent risk.

FDA inspectors can refuse entry of imported food if there is the appearance that the food does not comply with applicable food safety laws. When products are detained, the burden to comply with FDA law falls on the importer. If the food cannot be brought into compliance with the law, it can be denied entry into the country.

FDA has a team of more than 2,000 staff (675 in food import safety) who are dedicated, scientifically trained specialists who:

- conduct inspections
- collect and analyze product samples
- perform investigations
- oversee recall of products
- take enforcement actions, when necessary, and
- monitor the entry of all FDA-regulated products at our country's borders.

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What more can FDA do to increase its oversight of imported foods?

In November 2007, FDA initiated its Food Protection Plan (FPP). The FPP is designed to further protect the nation's food supply. It identifies FDA's most critical needs and addresses the changing nature of global food sources, production systems, and consumption patterns.

The FPP provides a framework for FDA's efforts to prevent problems before they occur; to use risk-based measures to identify potential hazards and intervene before they cause harm; and to provide a rapid coordinated response if contaminated food is detected that could harm humans or animals.

The major components of this new initiative are based on prevention, intervention, and response. The FPP complements the United States Government's Import Safety Action Plan (ISAP), which makes short-term and long-term recommendations to improve imported product safety.

The FPP strengthens FDA's role and supports the Agency's continued partnership with other federal agencies that play a vital role in the safety of our nation's food supply. They include the Centers for Disease Control and Prevention (CDC), the USDA, and the Department of Homeland Security. The goal is to ensure a thorough, far-reaching, food safety and food defense program that meets the emerging risk posed by the types of foods that FDA regulates.

As a key part of the Import Safety Action Plan, FDA has established permanent offices in China (Beijing, Shanghai, and Guangzhou), Europe (Brussels), Latin America (Costa Rica), India (New Delhi and Mumbai) and plans to establish an office in the Middle East. Having staff stationed overseas will allow FDA personnel to work closely with local authorities as well as with industries that ship food and medical products to the United States to help ensure their safety, quality, and security.

What can consumers do to help protect themselves from potentially unsafe imported products?

FDA urges consumers to pay attention to the information reported in the media about imported food or any food products. FDA also encourages consumers to report problems they have with any FDA products by using, "Your Guide to Reporting Problems to FDA."
http://www.fda.gov/consumer/updates/reporting_guide061008.html.

To help stay current on consumer information, FDA offers a free e-mail subscription to FDA's Consumer Updates at: https://service.govdelivery.com/service/subscribe.html?code=USFDA_9

Irradiation: A Safe Measure for Safer Iceberg Lettuce and Spinach

FDA published a final rule on August 22, 2008, that allows the use of irradiation to make fresh iceberg lettuce and fresh spinach safer and last longer without spoiling. Irradiating fresh iceberg lettuce and spinach will help protect consumers from disease-causing bacteria. Infections from bacteria such as Salmonella and Escherichia coli (*E. coli*) continue to be a public health problem in the United States. Illnesses from these two bacteria range from uncomfortable symptoms to life-threatening health problems. Severe illness from *E. coli*, for example, can lead to kidney failure.

The foods affected by the final rule are

- loose, fresh iceberg lettuce and fresh spinach
- bagged iceberg lettuce and spinach

Irradiation and Safety

Irradiation (also sometimes termed “ionizing radiation”) is a process of treating products with a measured dose of radiation. Food irradiation is not new. FDA has conducted irradiation safety evaluations for more than 40 years and has determined that the process:

- is safe for use on a variety of foods
- retains the food’s nutritional value
- results in food that is safe to eat
- may result in food that lasts longer without spoiling
- kills insects found on vegetables
- kills many disease-causing bacteria, such as Salmonella and *E. coli*

Irradiation is not a replacement for, proper food-handling practices by producers, processors, and consumers. It is an additional tool that may be used to reduce the levels of disease-causing microorganisms on fresh iceberg lettuce and fresh spinach.

You should still wash fresh produce, even if irradiation has taken place. FDA continues to recommend that consumers wash fresh produce before eating. You should wash packaged lettuce and spinach unless the packaging specifically states that the product has been pre-washed.

How Will I Know if My Fresh Iceberg Lettuce or Spinach Has Been Irradiated?

Irradiation of iceberg lettuce and spinach is voluntary on the part of food processors. FDA requires that foods that have been irradiated bear the logo to the left (named the “radura”) along with the statement “Treated with radiation” or “Treated by irradiation.”

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What is FDA's Role in Safe Irradiation of Food?

FDA regulates the equipment used to irradiate foods as "food additives" and requires approval before the irradiated food is allowed on the market. The doses of radiation allowed are limited to doses that have been shown to be safe. FDA continues to evaluate the safe use of irradiation in additional foods.

Source: http://www.fda.gov/consumer/updates/irradiation082208.html, August 22, 2008

For More Information

FDA's Fact Sheet: Questions and Answers about Final Rule on Irradiation of Fresh Iceberg Lettuce and Fresh Spinach
http://www.cfsan.fda.gov/~dms/irradlet.html

USDA

Irradiation and Food Safety
Answers to Frequently Asked Questions

As part of its public health mission to reduce the risk of foodborne illness, the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) inspects meat, poultry, and egg products, including those that are irradiated.

FSIS recognizes irradiation as an important technology to protect consumers. Irradiation of food reduces the numbers of harmful bacteria that may be present in food, including *E. coli*, Salmonella, and Campylobacter. Many consumers want to know more about what food irradiation is and how it works. This article (September, 2005) answers questions that consumers frequently ask about food irradiation.

For the entire article, please go to:
www.fsis.usda.gov/Fact_Sheets/Irradiation_and_Food_Safety/index.asp

Recent News from the FDA

FDA Analysis Shows Cholesterol Lowering Medications Do Not Increase the Risk of "Lou Gehrig's Disease"

The Agency recommends no change in prescribing and use of statins. An FDA analysis provides new evidence that the use of statins does not increase incidence of amyotrophic lateral sclerosis (ALS), a neurodegenerative disease often referred to as "Lou Gehrig's Disease." (Sept. 29, 2008)
http://www.fda.gov/bbs/topics/NEWS/2008/NEW01892.html

FDA Approves Use of Temporary Pump to Assist Heart's Right Side

FDA approved the first heart pump that provides certain critically ill patients with temporary support for the right side of their heart. (Oct. 7, 2008)
http://www.fda.gov/bbs/topics/NEWS/2008/NEW01898.html

FDA Approves Rapaflo for the Treatment of Symptoms Due to an Enlarged Prostate Gland

FDA approved Rapaflo (silodosin) capsules for the treatment of symptoms due to benign prostatic hyperplasia (BPH), a condition also known as an enlarged prostate. BPH is a male disease where the prostate gland – located between the bladder (which stores urine) and the urethra (the tube through which urine exits the body) – enlarges in men as they age. By age 50, roughly 50 percent of all men suffer from BPH. By age 80, that number jumps to 75 percent. (Oct. 10, 2008)
http://www.fda.gov/bbs/topics/NEWS/2008/NEW01902.html

Information on Surgical Mesh for Pelvic Organ Prolapse and Stress Urinary Incontinence

FDA wants to inform you about the complications that can occur when surgical mesh is used to treat Pelvic Organ Prolapse (POP) and Stress Urinary Incontinence (SUI), and provide you with questions to ask your surgeon before having these procedures. This is part of our commitment to keep healthcare professionals and the public informed about the medical products we regulate.
(Oct. 21, 2008)
http://www.fda.gov/cdrh/consumer/surgicalmesh-popsui.html

Information on Surgical Mesh for Hernia Repairs
FDA wants to inform you about complications that may occur with the surgical mesh that is sometimes used to repair hernias, and to provide you with questions you may want to ask your surgeon before having this procedure. (Oct. 21, 2008)
http://www.fda.gov/cdrh/consumer/surgicalmesh-hernias.html

FDA Approves Lung Valve to Control Some Air Leaks after Surgery
FDA approved an implantable and removable valve system designed to control some air leaks in the lungs that persist after certain kinds of lung surgery. (October 24, 2008)
http://www.fda.gov/bbs/topics/NEWS/2008/NEW01906.html

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Recent News- Continued from page 6

FDA Approves Toviaz, a New Drug to Treat Overactive Bladder

FDA has approved a new drug to help patients suffering from overactive bladder (OAB). Toviaz (fesoterodine fumarate) works by relaxing the smooth muscle tissue of the bladder, thus reducing the urinary frequency, urge to urinate, and sudden urinary incontinence (leakage of urine), that are characteristic symptoms of OAB. (Oct. 31, 2008).
http://www.fda.gov/bbs/topics/NEWS/2008/NEW01910.html

FDA Reports Significant Progress in Protecting the Food Supply

FDA released a report on its implementation of the Food Protection Plan that was launched a year ago to protect both domestic and imported food from accidental and intentional contamination. The Plan, which outlines strategies for prevention, intervention and response, is designed to address food safety and food defense for both domestic and imported products and covers the full life cycle of food, by encouraging the building of safety into every step of the food supply chain. (Dec. 1, 2008)
http://www.fda.gov/bbs/topics/NEWS/2008/NEW01917.html

FDA Requires New Safety Measures for Oral Sodium Phosphate Products to Reduce Risk of Acute Kidney Injury

FDA announced that it will add a Boxed Warning to the prescription oral sodium phosphate products Visicol and OsmoPrep to warn consumers about the risk of acute phosphate nephropathy (a type of acute kidney injury). Patients routinely take OSP products to cleanse the bowel before a colonoscopy (colon examination) and other medical procedures. (Dec. 11, 2008)
http://www.fda.gov/bbs/topics/NEWS/2008/NEW01923.html

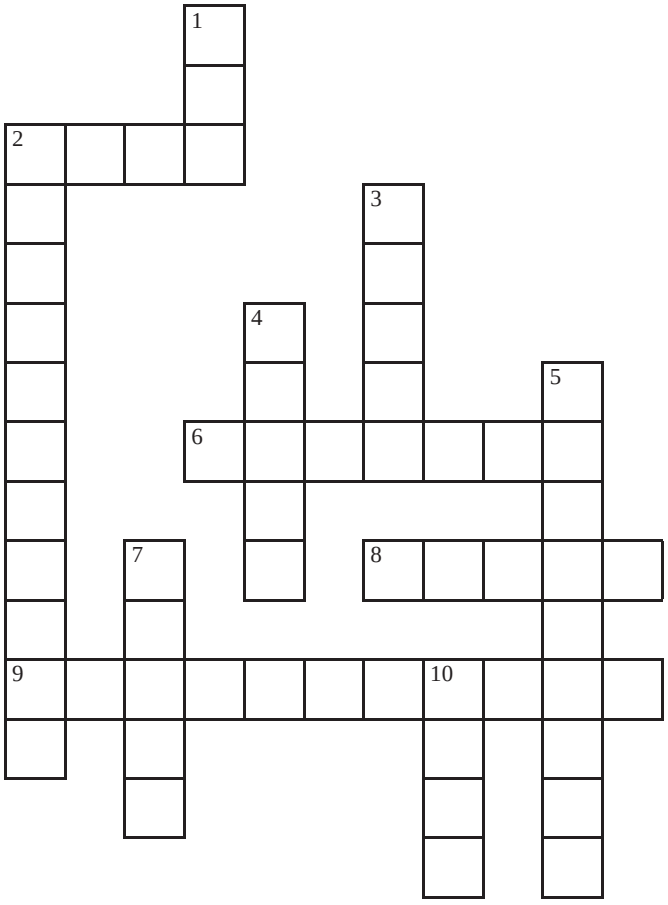
FDA Approves First Imaging Agent to Enhance Scans of Blood Flow

FDA approved Vasovist Injection (gadofosveset trisodium), the first contrast imaging agent for use in patients undergoing magnetic resonance angiography, or MRA, a minimally invasive test for examining blood vessels. Although MRA can be performed without the use of a contrast imaging agent, Vasovist administration provides a clearer image in patients who are suspected of having blockages or other problems with the blood vessels in their abdomen or limbs. The MRA is performed using magnetic resonance imaging (MRI) that relies on magnetic fields to create highly detailed images of the inside the body. (Dec. 24, 2008)
http://www.fda.gov/bbs/topics/NEWS/2008/NEW01934.html

FDA Approves Drug for Patients with Advanced Prostate Cancer

FDA approved the injectable drug degarelix, the first new drug in several years for prostate cancer. Degarelix is intended to treat patients with advanced prostate cancer. It belongs to a class of agents called gonadotropin releasing hormone (GnRH) receptor inhibitors. These agents slow the growth and progression of prostate cancer by suppressing testosterone, which plays an important role in the continued growth of prostate cancer. (Dec. 29, 2008)
http://www.fda.gov/bbs/topics/NEWS/2008/NEW01935.html

Crossword Puzzle*



ACROSS

2 A complement to FPP, this plan makes short and long-term recommendations for imported food safety. (Acronym)
6 Percent of U.S. food supply that is imported
8 Foodborne illness can affect this organ, as well as the kidney.
9 One of the populations at highest risk for foodborne illness from bacteria in food. (Two Words)

DOWN

1 Another protection plan for U.S. food supply that began in November 2007. (Acronym)
2 Since August 22, 2008, fresh iceberg lettuce and spinach may receive this treatment.
3 Exporters are required by this Act to give prior notice of intent to ship human and animal food to the U.S. (Acronym)
4 The U.S. has recently established an office in this country.
5 Irradiation can kill bacteria that cause this health problem.
7 Act that ensures food is safe, clean and produced under sanitary conditions. (Acronym)
10 Agency that regulates meat, poultry and processed egg products. (Acronym)

All answers are taken from this issue.

Maturity Health Matters

Maturity Health Matters is an FDA publication for older adults, their families and caregivers. We provide our readers with current information on FDA-regulated medical products. This publication can be freely reproduced and distributed. Comments about our publication should be sent to the editors. The information published in this issue was current as of the date of publication.

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To receive free email notices of new issues, go to http://www.fda.gov/cdrh/maturityhealthmatters.

Crossword Puzzle Answer Key

ACROSS

2 ISAP
6 Fifteen
8 Liver
9 Older Adults

DOWN

1 FPP
2 Irradiation
3 BT Act
4 China
5 Infection
7 FFDCA
10 USDA