

# U.S. Food Law Report

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## Lead Story

*FDA opens a new office in China just days after it puts new restrictions on several Chinese food imports*

Page 1

## Legal Update

*Updates on several food-related lawsuits from around the country -- and the world*

Page 2

## Q&A

*An interview with lawyer Ken Odza on melamine contamination, recalls and more*

Page 3

## Innovation

*Thermofisher Scientific patents new method of detecting foreign contaminants in food products*

Page 5

## Briefs

*Slowdown in organic food growth expected due to dismal economic outlook*

Page 6-7

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## FDA limits Chinese imports, opens new safety offices

File under “awkward timing.” Last week, just a few days before FDA was set to open up new food safety offices in three major Chinese cities, the agency announced it would begin detaining shipments of milk products and any food containing milk from China due to the threat of melamine contamination.

In the Nov. 12 import alert, FDA said that “analyses have detected melamine and cyanuric acid in a number of products that contain milk or milk-derived ingredients, including candy and beverages. In addition, information received from government sources in a number of countries indicates a wide range and variety of products from a variety of manufacturers have been manufactured using melamine-contaminated milk or milk-derived ingredients, including: fluid and powdered milk, yogurt, frozen desserts, biscuits, cakes and cookies, taffy-like soft candy products, chocolates, and beverages. These products appear to contain at least one milk-derived ingredient and they are of Chinese origin.

“Reports of contamination have come from more than thirteen countries in Asia, Europe, and Australia, in

addition to the United States,” FDA added. “Additional products from various manufacturers continue to be found to be contaminated with melamine.”

The alert gives inspectors the authority to detain the imports without first physically examining them. In order to get the shipments released, the importer has to either obtain verification that the product is melamine-free through third-party laboratory testing or provide documentation proving the products contain no milk or milk-derived ingredients.

“After months of intense criticism for lack of action by the U.S. Food and Drug Administration on the melamine milk scandal, the agency has finally banned all milk products manufactured in China,” said Wenonah Hauter, executive director of consumer watchdog group Food & Water Watch. She claimed the agency waited too long to take action.

“Unfortunately, FDA is getting into the habit of making these critical decisions too late in the game,” she added. “Although FDA’s action today is a step in the right direction, it does not do enough to ensure consumer safety, especially since melamine contamination in Chinese products continues to broaden.”

A few days later, FDA officially opened satellite offices in Beijing, Guangzhou and Shanghai. HHS Secretary Mike Leavitt and FDA Commissioner Andrew von Eschenbach are scheduled to visit each office this week and meet with officials from the Chinese government to discuss policy and food safety reforms.

“We’re opening up a new era, not just new offices,” Leavitt said. “By having a presence in other parts of the world, we can work more closely with manufacturers and other governments, better share best practices and further ensure that quality and safety are built into food and consumer products at the point of manufacture.”

“A permanent FDA presence in China will help us address the challenges presented by globalization,” von Eschenbach added. “We look forward to working with the Chinese government and manufacturers to ensure that FDA standards for safety and manufacturing quality are met before products ship to the United States.”

FDA’s Chinese offices are just the first phase of a broader international plan. The agency wants to establish a presence in India, Europe, Latin America and the Middle East, as well. Leavitt announced plans last month for an office in Amman, Jordan.

## LEGAL UPDATE

**Here’s a quick roundup of some of the latest food-related legal news in the U.S. and around the world.**

**FLORIDA:** Judge Jon Gordon of the Miami-Dade County Circuit Court earlier this month dismissed a lawsuit filed by three Burger King franchisees against the fast-food giant. The franchisees were irked that Burger King was requiring them to abide by the company’s new extended hours schedule, which meant staying open until 2 a.m. on weekends and opening up at 6 a.m. every day but Sunday. The franchisees said the extended-hour policy violated their agreements with Burger King, but Judge Gordon said the language in their contracts was clear – Burger King had the right to impose any schedule it wanted. Robert Zarco, the franchisees’ lawyer, said his clients aren’t giving up and plan to amend their original lawsuit with additional facts.

**INDIANA:** A Fort Wayne resident is suing ConAgra, claiming she became ill after eating a jar of the company’s tainted peanut butter in November 2006. The lawsuit is the latest fallout from ConAgra’s massive recall of Peter Pan-brand peanut butter in 2007 due to *Salmonella* contamination. Seventy-six-year old Mildred Turner claims she was

hospitalized for several weeks after eating the tainted peanut butter and still hasn’t fully recovered. A spokesperson for ConAgra told a local newspaper that she couldn’t comment on the specifics, but said the company wants to address any concerns related to the 2007 recall.

**CHINA:** Lawyers for families of the children sickened by melamine-tainted milk have decided to go ahead with a class-action lawsuit against a large state-owned dairy company. According to the Associated Press, the lawyers will package the cases of more than 100 families into a single lawsuit against Shijiazhuang Sanlu Group Co. Thus far the government has been slow to respond to calls for compensation for the affected families. However, it’s not clear whether the courts will accept the class action suit.

**DELAWARE:** Assistant managers at more than 2,000 McDonald’s restaurants have filed a collective action complaint against the fast-food giant, claiming that they were required to work in excess of 40 hours a week without being paid overtime. The plaintiffs say that during their assistant manager training periods, they “spent most of their time...doing the work of the other hourly employees at the restaurants where they worked, primarily cooking, serving food and cleaning trash. During the training period, they did not have any management authority or discretion, according to the lawsuit; meaning the employees are entitled to overtime pay for working more than 40 hours a week. However, the collective action lawsuit claims that McDonald’s willfully and systematically fails to pay these employees any overtime pay, despite requiring 45, 50 or even 60 hours of work a week during the training period.”

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# Q&A

## Melamine, Recalls and Crisis Management: A Conversation With Ken Odza

Ken Odza is a partner in the Seattle office of Stoel Rives LLP. A litigator who focuses on food liability law, Ken represents companies responding to foodborne illness claims and counsels clients on how to deal with food recalls and comply with increasingly complex food safety regulations. He maintains a blog on food liability issues at [www.foodliabilitylaw.com](http://www.foodliabilitylaw.com) and is a frequent speaker at industry conferences; he'll be a featured panelist at the upcoming [Food-Borne Illness Litigation conference](#) in Scottsdale, Ariz. Dec. 4-5. He can be reached at [kmodza@stoel.com](mailto:kmodza@stoel.com).

Ken recently wrote a [blog post](#) about the importance of preparing for possible melamine-related contamination, especially given the recent news out of China. We spoke with him about this hot-button issue, and how food companies can better protect themselves from potentially disastrous litigation.



**U.S. FOOD LAW REPORT:** Given the recent spike in melamine contamination cases, you suggest that food companies update their crisis management plans. What specific areas should they consider updating? Does melamine pose challenges that other contaminants don't?

**Ken Odza:** Well, certainly a lot of food and supplement companies are already paying attention to bioterrorism and accidental foodborne illness issues. In my experience, many companies have in place a crisis management plan and regularly rehearse those plans. But I think the melamine issue is a little different. This is driven by fraud. It's not driven by people who are intentionally trying to make people sick or by accidental introduction of contaminants; it's driven by supplier greed. So I think food companies

need to take that into account. For instance, a candy company that drafted its crisis plan a couple of years ago probably didn't anticipate that the proteins or dairy products it received from a supplier would intentionally be tainted with melamine.

Crisis management plans are generally geared toward accidental contamination, bioterror attacks or avian flu. I think companies need to make sure that their supply chain people understand the special issues surrounding melamine contamination, are ready for it, and are identifying suppliers that may potentially pose a problem. For example, how will the company be able to identify a melamine-contaminated source quickly and reliably? How will it assure that a substituted product is not contaminated? How will the company determine what melamine levels require a recall or consumer notice? What will a company do with information that products are contaminated at levels below what FDA considers a safe level, but higher than what other groups believe is a safe amount?

**USFLR:** Within the company, who should be involved in creating a melamine contingency plan?

**Odza:** You can't plan for everything, but you're certainly going to wind up in a better place if you have the right people in the room thinking about the problem.

Aside from your legal team, you want the full array of food safety people in place. That could be your internal staff or outside consultants, or a combination of those folks – food safety experts, epidemiologists, microbiologists. You definitely want some people from accounting to be there too; you need to understand the various costs of the response options. If you deal directly with consumers or other vendors, you'll need to track customer reimbursement.

You definitely want your sales and marketing people involved. They can help coordinate product returns, recalls and the flow of information with customers.

Your quality assurance and supply chain personnel are critical — they're the people who are purchasing and receiving, and who have direct access to suppliers. Supply chain and quality assurance staff can help trace back products and, in the case of melamine, assist food safety ex-

perts to determine sources of contamination.

The public relations staff needs to be involved, too, so they can coordinate internal and external communications. The most important thing a PR team can do is to help a company understand how to manage the information available and develop a strategy to limit negative impact on the brand and the company.

And finally, at the top of the chain, you need to have somebody running the strategic response team – a coordinator. That person should be a senior person at the company and often the CEO. One of many reasons why rehearsing the plan is so important is that the coordinator/leader may not understand their leadership role, and others in the company may not understand how they need to communicate with the leader.

**USFLR: Trust between Asian suppliers and U.S. food manufacturers has taken a severe hit with the melamine revelations. Should U.S. companies be thinking about independently testing the ingredients they source from Asia, or are there drawbacks to such a plan?**

**Odza:** I don't have any inside information on which companies are doing their own additional testing or hiring third parties to do it for them, but I suspect it's happening a lot. Any company testing its products for melamine should consider the following questions: first, what exactly are you testing for, and what's considered a "safe" dosage level; and second, what are you going to do with the information when you get it? What if you discover your product contains melamine at a dosage level that everyone, including the FDA, is telling you is safe? Do you disclose it to your customers and tell them you think it's safe, or do you not disclose it at all? If you ask the questions and do the testing, you've got to be prepared and know what you're going to do with the results. Having product test data but not knowing what to do with it can be very damaging.

Let's take a hypothetical food company that is doing additional testing, and the samples come back with a high level of melamine, but it's within the FDA dosage level threshold. Assuming FDA doesn't require you to disclose it, there's a tension there: "Do we disclose this, or just assure customers our food is safe?" Some people may be nervous about the adverse publicity and possible consumer litigation that could result in releasing this test data. On the other hand, what if someone makes a legal claim in

the future alleging that the level isn't safe and that FDA was wrong in the first place to set the dosage level where it did? In that case, the test data will be revealed in discovery and a company is at jeopardy of being penalized in the court and the press for "suppressing information." It's a double-edged sword.

This goes back to crisis management planning. It's important, to the extent possible, to think through these extremely thorny dilemmas in advance. That way, when something happens, the CEO (or whoever's in charge of crisis management), can say, for example, "We made a decision a long time ago that we're going to disclose everything to our customers, no matter whether we think there's a problem or not." Or the opposite: "It doesn't make any sense to disclose confusing and potentially misleading information to our customers."

Now, if you're a supplier for someone else, you need to look at your contracts and be concerned about your obligations to your vendors. If your vendor contracts can be read to require full disclosure of any test data, then you should generally err towards full disclosure. The melamine issue involves supplier fraud and a supplier not involved with the fraud should avoid even the appearance of impropriety. The last thing any food company wants is to be associated with the fraud and to be thought of as fraudulent itself.

**USFLR: Generally speaking, how well do you think the U.S. food industry has reacted to the melamine situation?**

**Odza:** In the U.S., I'm not sure if we fully understand yet what the impact will be on the U.S. market. There haven't been any significant human health scares from melamine-related contamination. Though the pet food situation opened a lot of peoples' eyes. To date, known contamination in the U.S. appears limited to just a handful of small coffee and candy sellers and no illnesses in the U.S. have yet been reported. But because these proteins are circulating globally, there may be problems with products and animal feed that we still can't appreciate. The scope of the fraud may not be fully known. However, based on my own experience with food companies here in the U.S., I have a positive outlook. I think U.S. companies are generally taking threats seriously and being vigilant.

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# INNOVATION

## Thermofisher wins U.S. patent for food contaminant detector

Thermofisher Scientific (Coon Rapids, MN) was awarded U.S. Patent [7,450,686](#) last week for an x-ray-based invention that detects foreign objects in food.

“Conventional metal detectors often fail when detecting metal contaminants in products that incorporate metal as part of the product or the associated packaging,” the company explained in patent documents, adding: “In the typical x-ray detector there are multiple settings which are optimized for the detection of a certain class of expected contaminant. When the expected contaminant is metal, which has a relatively high x-ray absorption rate in comparison to the surrounding food item, the level of x-ray emission and the corresponding detector sensitivity can be set relatively easily to take advantage of the contrast between the food and any metal that may be present. However, if such a metal optimized setting is used, then the detection of bone or glass, as well as any relatively thin or small metal objects, is much less reliable.”

Existing x-ray devices are also more expensive, the company said, because the emitting device is placed above a moving conveyor and the sensor is placed underneath. “This arrangement necessarily increases the cost of the resulting machine for several reasons. First, an x-ray emitter requires a substantial power source which must be routed to the emitter location. Second, the heat producing x-ray emitter is relatively difficult to cool in an enclosed, elevated location. Third, the x-ray emitter is necessarily spaced relatively far from the object under inspection because it must be well above the aperture through which the conveyor enters and the aperture itself is as large as possible to accommodate larger test items. This mechanical arrangement results in a reduction in the amount of radiation actually entering or impinging upon any item being inspected at fixed flux intensity, thus requiring an increase in the absolute flux density needed to penetrate denser objects. Fourth, the x-ray detectors reside beneath the conveyor where they are subject to additional contamination and are relatively difficult to cool, isolate from vibration and to service.

“Additional problems encountered in a real world food processing assembly line process include the accumulation of contaminants on the test item conveying mechanism,” Thermofisher noted. “These contaminants typically include remnants of the foodstuffs under test as well as lubricants and particulates present in the food processing environment. While the signal processing aspects of existing x-ray detection devices may be quite exotic, the cleanliness and serviceability of the conveyor belt is often primitive and results in downtime that renders the relatively high reliability of the electronics irrelevant to the total real world duty cycle of the machine.”

But the new invention sidesteps these problems, the company says. “In particular, the present invention is a contaminant detector for food inspection that utilizes lateral emission x-ray technology and which includes an integrated conveyor that passes the product under test near the x-ray emitting source. The machine is a conveyor line scan x-ray system that can be produced with different aperture sizes and conveyor speeds and at a relatively low cost. The present contaminant detector uses a wide-angle x-ray emitting source to generate the necessary x-ray radiation for penetrating the object under inspection, thereby permitting detection of a contaminant. Use of a wide transmission angle results in reduced production costs by eliminating the expense associated with a narrow angle radiation source.

“Product learning algorithms automatically determine nominal product characteristics and substantially reduce the need for operator assisted machine initialization activities,” Thermofisher continued. “The operator typically needs only to pass a known nominal product through the machine in order to teach the machine the characteristics of an acceptable product. The controls are thus simplified in comparison to existing metal detectors, thereby eliminating or substantially reducing errors caused by the incorrect setup of operating parameters. The simpler design of the present contaminant detector produces a machine having relatively greater reliability and a longer life expectancy than other x-ray based food inspection machines.

“The primary function of the present invention is to provide for the detection of relatively dense contaminants within food or other products. In an alternate embodiment, quantitative data is identified, permitting identification of the type of contaminant as well as signaling the absence or presence of a particular contaminant. X-ray

scans are used to collect density maps of the Object Under Inspection (OUI) in order to allow discrimination of contaminant presence from both the food and the food package,” Thermofisher explained.

## Nanotech & mad cow: scientists create new testing device

Researchers at Cornell University in New York have used nanotechnology to create a new testing device that they hope will lead to faster and easier ways of detecting mad cow disease prions, according to the U.S. Department of Agriculture (USDA).

With funding from USDA’s Cooperative State Research, Education, and Extension Service (CSREES) National Research Initiative (NRI), the scientists – in collaboration with Innovative Biotechnologies International -- modeled the tool after a device used to find bacterial pathogens, according to CSREES’ Stacy Kish.

The team “developed nanoscale resonators, which are tiny devices that function like tuning forks by changing pitch with increased mass,” Kish explained on the CSREES Web site. “When prions bind to the resonator’s silicon sensor, it changes the vibrational resonant frequency of the device. In experimental trials, the sensor detected prions at concentrations as low as two nanograms per milliliter, the smallest levels measured to date.”

Right now, the resonator is only able to detect BSE prions in a saline solution, but the researchers are working on a way to find them in blood, too.

“The real challenge is going to be to build an automated device that can take blood from a cow in the field and give a rapid response as to whether prions are present,” Cornell’s Harold Craighead said. “At the moment we only test cows when they fall over, but that is a late stage of the disease. It would be ideal to test cows a lot earlier. Resonators could be one path to doing this.”

## BRIEFS

### Organic food growth expected to shrink, thanks to down economy

Organic products may enjoy a reputation for being healthy and natural, but not even those accolades can save the market from a slowing economy, according to research company Mintel.

The market for organic foods and beverages should top \$7 billion this year, a huge leap from the \$3 billion high back in 2003. “But year-over-year, Mintel has seen sales growth slowing,” the company said. “With many Americans now struggling financially, Mintel projects that sales of organic foods and beverages will not rally anytime soon.”

“Rising food and gas prices, the credit crunch and economic uncertainty have deeply affected people’s shopping habits,” said Mintel Senior Analyst Marcia Mogelonsky. “Across the board, Americans are spending less and ‘organic versus traditional’ is a decision many people are thinking about carefully... To cope with higher prices, many shoppers are simply opting not to buy pricey organic or premium brands.”

And when consumers *do* choose to buy organic, more and more of them are choosing private label products over name brands. “Mintel’s Global New Product Database (GNPD) tracked over 540 new private label organic foods in 2007, a massive increase from the 35 new products seen in 2003. Furthermore, when Mintel asked survey respondents about the difference between name brand and private label organics, three in five (60%) said it didn’t matter, that they reached for ‘whatever is available’ when shopping. Private label posts an increasingly large threat to branded organic lines.”

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