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Safer Chinese Food

By Eric D. Hargan and Kevin Qian, Contributing Editors

Of the \$80 billion worth of food that is imported into the United States each year (an amount equal to 15% of the country's total food consumption), food and food products from China play an increasingly important role. In the past decade, the value of Chinese processed food and commodity imports has more than tripled, according to USDA, and China has more food facilities registered with FDA than either Canada or Mexico. This inevitably makes FDA approval crucial for China's food product exporters, yet that approval is not a matter of inspection alone.

Over 17 million shipments of imported products of all kinds come into the United States every year, but FDA inspects just over 1% of those shipments. FDA, of course, understands this does not allow for a perfect inspection regime. But, because of the limited number of personnel FDA can deploy, and the limited number of inspections it can make, the agency relies increasingly on risk analysis, assisted by computers.

The FDA may, at any time, reject food based on examination, on a food producer's prior history or even on the appearance of violating FDA standards. The clear implication is that, when food producers based in China, as well as in other countries, export to the United States, their first and most practical line of defense is to meet, as closely as possible, FDA production and safety standards in their own country of origin. An understanding of some of the key issues involved is essential for such compliance efforts.

Inspection standards

FDA may reject any food for import if it appears to be adulterated, misbranded or in violation of the law. The agency may require food that is noncompliant to be relabeled, reconditioned, refused, detained, seized or destroyed. All food manufacturing facilities exporting to the U.S. must conform to FDA's Good Manufacturing Practices (GMP), which cover standards for worker sanitation, plant construction and cleanliness. When FDA conducts surveillance and investigation of a food processing facility for GMP compliance, it may review everything from production history and

firm management to direct observation of "objectionable conditions" and "deficiencies" (to use language commonly used in FDA's Form 483 inspection report). Inspection is carried out by a complex regulatory system that includes:

- FDA Center for Food Safety and Applied Nutrition (CF-SAN), which regulates most food;
- FDA Office of Regulatory Affairs, FDA's field agents, among other things;
- USDA Food Safety and Inspection Service (FSIS), which inspects meat and poultry;
- USDA Animal and Plant Health Inspection Service (APHIS), which regulates animal and plant products.

In making its inspections, FDA has, in some instances, begun to use a standard for food safety ("otherwise unfit for food") that was formerly used for food aesthetics. With ever-greater public expectation of food safety, and with the availability of using new (and perhaps tighter) standards, food producers in China and elsewhere must exercise more collective responsibility throughout the supply chain. They must know where food commodities are from, verify production compliance with all applicable U.S. laws, and supply all required documentation (including their food manufacturer registration number). The combination of limited budgets for inspection personnel and rising shipments means that inspection will increasingly depend upon a shift to computer-assisted risk analysis, focus on high-risk categories, and inspections or other activities carried out by non-FDA agencies (U.S. and non-U.S.) to ensure food-safety compliance. In food imports, this shift will place more emphasis on FDA's Prior Notice System Interface (PNSI), as well as on the Customs and Border Protection agency (CBP) Automated Broker Interface/Automated Commercial System (ABI/ACS), and the anticipated PREDICT system.

Safety considerations

In the past, food safety had been pretty exclusively the

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domain of public health authorities like FDA. However, following the terrorist attacks in 2001, and the subsequent recognition of the vulnerability of the food-safety system, public safety authorities like CBP have become an integral part of the import process for food. This is especially true since FDA, in May 2009, implemented new requirements for advance notice of food importation, and registration of both country of origin and production. These new rules build on FDA's underlying authority to reject any imported food product if it appears to be adulterated, misbranded or in violation of the law, or if it is not in compliance with the minimum prior notice rules for food imports (two hours for land arrival by road, four hours for arrival by air or rail, and eight hours for arrival by water). The regulations are made even more complex by differences between the FDA and CBP rules. One source of confusion arises because the CBP requires identification of the "country of origin" of the food. "Country of production" and "country of origin" are not the same. For example, if beans are grown in the United States, then sent to China to be canned and exported back to the United States, the CBP "country of origin" is the United States, but "country of production" is China, per FDA. This is because FDA, in this case, defines the "article of food" as canned beans.

Greater integration

Although the unique nature of U.S. food safety compliance standards may at times be different than Chinese practices, Chinese food companies must meet U.S. standards for food sanitation and safety if they want to expand their presence in the American market. The International Conference on Harmonization of compliance standards, which today focuses on the U.S., Japan and the European Union, is in the process of outreach to produc-

ers in countries like China, India and Brazil, and this may lead to greater integration of these countries' regulatory standards. In addition, the presence, starting this past year, of FDA food experts in China will also allow progress in transforming the China-U.S. food system into an integrated whole. Further, FDA is pursuing the use of third-party certification for safety and manufacturing standards compliance overseas. This is another area where China could provide certification and allow greater integration of the two countries' inspection regimes. For now, however, Chinese food producers must work to be part of the process as FDA continues to move toward regulating the entire U.S. food supply chain from production through distribution to consumption, both in the U.S. and overseas.

Formerly serving as deputy secretary and regulatory policy officer for the U.S. Department of Health and Human Services, Eric Hargan is currently a partner with McDermott Will & Emery's Chicago office, advising on transactions, healthcare regulations, healthcare policy and government relations. Mr. Hargan also worked with the Ministry of Health of Japan on food safety and importation issues in 2007, and led the Departmental group that responded to the U.S. food safety and importation issues in 2006-2007. Mr. Hargan can be reached at 312/984-0385 or ehargan@mwe.com.

Kevin Qian is a founding partner of MWE China Law Offices, a Shanghai-based joint venture with global law firm McDermott Will & Emery. He has broad multinational experience in food regulatory law and formerly was legal counsel overseeing more than 40 Chinese operations for one of the world's largest beverage and food producers. Mr. Qian can be reached at +86 21 6105 0500 or kqian@mwechinalaw.com .

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