

Customs Law Advisory

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US Agreements with China May Mean More Scrutiny for Importers of Food, Drugs and Medical Devices

In December 2007, the US Department of Health and Human Services (“HHS”) signed two memoranda of agreement (“MOAs”) with the Chinese government to increase cooperation on the safety of (1) food and feed and (2) drugs and medical devices. The MOAs outline measures to help China build greater quality assurance into its products. They appear in the context of the current debate in the US over legislative initiatives and other action to address broader concerns about the safety of Chinese imports. The terms of these MOAs suggest that US importers should expect greater scrutiny of food, feed, drug, and medical device imports from China. Importers should act now to strengthen their collaboration with Chinese and other overseas suppliers and consider potential responses to shipment interruptions or product safety issues. For the complete text of both MOAs, visit <http://globalhealth.gov/news/agreements/>.

The general purpose of the two agreements is to establish methods of cooperation regarding the safety of food, feed, drugs and medical devices and ensure that products made in one country meet the quality requirements of the other. These agreements represent China’s follow-through on its previously-stated intentions to change its procedures by requiring closer inspection of export shipments and working internally and with the US government to ensure that safety standards are met. Both agreements provide for the exchange of information on national regulatory frameworks, including standards and procedures. Notably, the food accord establishes a mandatory registration system for exporters and sets up an export certification program for four product categories. It also expands the role of HHS’ Food and Drug Administration (“FDA”) in certifying and inspecting Chinese food products. The drugs and medical devices MOA also expands the US role in the inspection of Chinese manufacturing firms.

The two agreements come in the wake of months of US recalls of Chinese-made consumer goods and fears of contaminated food products. Consequently, import safety continues to be the focus of media attention and increased legislative and administrative activity. In this climate, the agreements themselves already have come under attack from some groups. Criticism has centered on the limited scope of the food and feed agreement. Questions have been raised about whether the FDA has the legal authority to fulfill the information-sharing requirements and China’s ability to carry out its obligations. There is also concern that the food safety MOA could eventually result in less scrutiny of Chinese-made food products because registered or certified manufacturers might become lax or escape periodic review. Some members of Congress reportedly have suggested hearings to explore these concerns. Such efforts could lead to attempts to further broaden the scope of the MOAs and the introduction of legislation, among other measures.

In light of the criticism, officials in both countries may attempt to use the tools of the MOAs to demonstrate improvements in product safety. Importers into the United States may notice heightened scrutiny of suppliers and shipments that can delay or derail commercial schedules. In the current climate, importers should take concrete initial steps with their Chinese suppliers to check and recheck the quality of their products and their compliance with the MOAs and the latest regulatory standards and programs. For example, importers of the products subject to the food MOA should ensure that their suppliers are registered with the Chinese agency responsible for exported food safety. Importers also should consider whether additional manufacturing or quality control steps can be phased-in at a reasonable pace now, to maximize the likelihood that products consistently meet or exceed commercial specifications and US regulatory requirements, rather than be driven by an agency demand or an actual product safety issue. If you have any questions related to import product safety, please contact Greg McCue at 202.429.6421 or gmccue@step toe.com.

“Careful Contracts Reduce Risk: A contract with watertight provisions can save retailers, distributors, and importers expenses that result from recalls of defective Chinese products”

by Grace Parke Fremlin

In the January/February issue of The China Business Review, Steptoe & Johnson's Grace Parke Fremlin presents “Careful Contracts Reduce Risk.” This article provides practical guidance on how to minimize import product safety risks using careful supply contract terms. US retailers, distributors and importers can substantially reduce risks using contract provisions, such as explicit language dealing with recalls and products liability and the requirement of product recall insurance from a reputable carrier. For the complete article, go to: <http://www.step toe.com/assets/attachments/3288.pdf>.

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