

U.S. FDA Removes Many Chinese Candies From Import Alert 99-30 Based on Insufficient Evidence, According to FDAImports.com, LLC

Benjamin L. England, founder of FDAImports.com, LLC has been in an ongoing, and sometimes heated debate, with FDA on behalf of inappropriately detained shipments under Import Alert 99-30, which authorized FDA to detain any milk-based products due to the potential of the presence melamine. On May 3, 2010, all of the efforts of those who challenged FDA on the issue produced fruit. FDA quietly updated Import Alert 99-30 removing all FDA Product Codes in Industry 33 – or Candy Products without Chocolate – from the alert altogether.

On May 3, 2010, in response to legal pressure and a dearth of evidence, FDA finally narrowed the scope of its automatic detentions of milk-based food products from China that could potentially be affected with melamine. Benjamin L. England, founder of FDAImports.com, LLC has been in an ongoing, and sometimes heated debate, with FDA on behalf of his clients arguing that many manufacturers and importers of products that do not contain milk are severely and adversely affected by the overly broad import data screening criteria built into FDA's electronic import screening system used to implement the alert. "This alert represented a drastic level of FDA over reaching [in late 2008] when it was first issued," said England. He continued, "I said so then and it has proven to be true. Many products, which do not and which were not likely to even contain milk were automatically detained by FDA; being delayed by weeks and adding thousands of dollars in actual costs and expenses onto every shipment." England queried, "Who do you think paid for those costs and expenses? The consumer!"

FDA [Import Alert](#) #99-30 (IA 99-30) authorized FDA inspectors to automatically detain all shipments from China of products containing any form of milk-derived ingredients or finished food products containing milk because of the potential presence of melamine. Mr. England filed petitions and appeals obtaining release after release of detained shipments, and he eventually sought an exemption from the alert for one Chinese candy manufacturer who, according the England, "had demonstrated complete control over its products and processing. That company was not shipping tainted product. I guarantee it." Yet, every shipment was affected. "These candy products were the poster child of FDA's overbroad detention criteria problem," said England, "and FDA cannot show one instance where candy that did not contain milk was ever contaminated with melamine"

On May 3, 2010, all of the efforts of those who challenged FDA on the issue produced fruit. FDA quietly updated Import Alert 99-30 removing all FDA Product Codes in Industry 33 – or Candy Products without Chocolate – from the alert altogether. FDA had already intimated this change in response to various FDAImports.com, LLC's challenges that FDA was developing mechanisms to better target information and make informed entry decisions in relation to Product Codes.

FDA originally published Import Alert #99-30, "Detention Without Physical Examination of All Milk Products, Milk Derived Ingredients and Finished Food Products Containing Milk from China Due to the Presence of Melamine and/or Melamine Analogs" in late 2008. Due to the highly-publicized melamine contamination scare affecting infants in China, FDA created an overly broad import alert, which included many foods that did not even contain milk or milk-derived ingredients (including the candies in FDA Product Code category 33), "Whether or not a product actually contained a melamine risk, FDA was routinely detaining it automatically because of the way the FDA's OASIS Product Code System is designed," says [Benjamin England](#), Food and Drug Law specialist and founder of [FDAImports.com](#),

LLC. “As a result FDA detained thousands of imported shipments based upon guidance that was wholly inapplicable.”

Under the Food, Drug, and Cosmetic Act (FDCA) §801(a)(3), FDA may detain without physical examination (DWPE), any product that may “appear” to “bear or contain” melamine (in the case of IA 99-30). Melamine is an unsafe food additive, causing any product that contains it to be adulterated. However, for a product to “appear” to be in violation, the FDA must submit to initial examination of either the products’ food label or of the product itself.

FDA’s unsustainable automatic detention of products that did not meet the IA 99-30 criteria was largely caused by significant weaknesses in FDA's Operational and Administrative System for Import Support (OASIS) system. OASIS is an electronic screening system that uses preset criteria to stop all imported shipments that contain products declared to be within certain FDA set "Product Codes". These codes are assigned based upon the products, the level of processing, and other elements related to the imported product. "It’s a badly antiquated system," says England. "FDA has not performed a major overhaul of its product codes for decades in many industries." Therefore, according to FDA import experts, the system is weak and incapable of managing the diversity in today's international trade environment. Because OASIS and the import alerts rely on the product coding system, “OASIS, which is not a very smart system, has been deciding which products (based on Product Codes alone) should bear the cost of detention and delay,” says England.

FDAImports.com, LLC filed challenges against FDA arguing that many products that fell under FDA Product Code 33 – Candy Products without chocolate – did not and could not reasonably be thought to contain milk ingredients. “We are talking about fruit candies, gummie candies, products that no one would think contained dairy ingredients, but which were being stopped over and over again by FDA only because of this overly broad Import Alert," reported England. In response, FDA admitted to "limitations in their product code system, and foretold of a more advanced mechanism that is expected to limit the number of firms that will encounter situations where products not intended to be subject to DWPE are held by FDA. England responded, "Well, now we know what this great 'advanced mechanism' is: Just remove the product codes that should never have been on the alert in the first place. It sounds like 'on' or 'off' to me. Not very 'advanced'."

[FDAImports.com, LLC](#) works with FDA on a daily basis helping importers comply with Federal rules and regulations. If you have a product that is being detained on IA 99-30, and want to know if the violations are truly applicable, call FDAImports.com today. FDAImports.com, LLC is a consulting firm that specializes in working with the FDA on all subject matters. When exporting a product to the US, don’t allow your products to be detained because of a ‘system limitation’. We can show you ‘the way through’ the system as well as the way off of an Import Alert you may already be inappropriately placed on. Don’t pay any more storage and testing fees to the FDA. Instead, contact FDAImports.com, LLC for advice on your particular situation.