

FDA update Editorial 10 09

Hello!

I saw the article pasted below in the FDA Law Blog ([FDA Law Blog](#)). Sadly, some of our clients have also learned first hand that FDA has increased their import inspection activities. This article discusses issues one company had when FDA suspected their materials were contaminated with pesticides. Before importing goods to the US, you must ensure that you comply not only with regulations from Customs and Boarder Protection but also from FDA. It may be worthwhile asking your customs broker if providing a dossier of certificates of analysis and other purity and quality testing would help in a situation like the one described below.

Some of our clients have also been made aware that FDA hired 400 new inspectors last year. Some inspect imports and others are inspecting US facilities. Unfortunately, since they are new and inexperienced, errors have occurred. I am happy to report that we have been able to get some erroneously seized products released very quickly by working with the FDA.

We hope you never experience trouble with your product but we are always ready to assist you in ensuring compliance with FDA regulations.

We send occasional emails like this one to update you on news and events relevant to FDA-regulated products. We hope you find these updates interesting and informative. If you do not wish to receive these messages, please reply with 'Unsubscribe' in the subject line or body of the message.

Take care and enjoy the article below.

[More Evidence of an Increase in FDA Import-Related Enforcement Activities](#)

Posted: 29 Oct 2009 11:13 AM PDT

By [Dara Katcher Levy](#) –

On October 21, 2009, First Fishery Development Services filed suit against FDA seeking declaratory judgment and injunctive relief with regard to its product's placement on [Import Alert 99-08](#) - Detention Without Physical Examination of Processed Foods for Pesticides. According to the [Complaint](#), the Company contends that its bulk Olive Leaf Powder Extract is not adulterated, in violation of section 402(a)(2)(b) of the Federal Food, Drug, and Cosmetic Act ("FDC Act"), because the presence of a pesticide in the product is a result of the presence of the pesticide in an antimicrobial solution used on food contact equipment. The Company contends that this use of the pesticide conforms to an exemption from a pesticide tolerance granted by EPA and is permissible under FDA's threshold of regulation program for substances used in food contact articles that migrate into food.

The Company alleges that FDA first placed the Olive Leaf Powder Extract on Import Alert on July 2, 2009. According to the Complaint, the Company states that the original shipment upon which FDA raised the adulteration charge and that is the basis for placing the Company's product on

Import Alert, has not been the subject of final agency action. The Company maintains that the product is still on “detention status.”

This is where things get interesting. Typically, FDA will “Refuse” a shipment before placing a product or entity on an Import Alert. (See our recent [article](#) in the Food and Drug Law Institute’s Update publication explaining how FDA generally deals with import matters.) Although issuing a Refusal before placing on Import Alert is typical FDA practice, FDA’s procedures for placing products or entities on Import Alert (or Detention Without Physical Examination - DWPE) do not require the issuance of a Refusal and may be based on a finding of one violative sample. See FDA Regulatory Procedures Manual (“RPM”) [Chapter 9](#). This departure in practice is yet another sign of FDA’s increase in enforcement activity against imports.

First Fishery alleges, among other things, that for FDA to recommend DWPE based on one violative sample, FDA must have evidence that at least one sample has been found violative and the violation represents a potentially significant health hazard. This is, in fact, FDA’s stated procedure (RPM Ch 9, 9-21). However, under the authority of the FDC Act, FDA may take action against a shipment without the existence of an actual violation; section 801(a) provides that FDA may refuse admission to articles that “appear” to be violative. The burden is on the importer to overcome the appearance of a violation.

Given the discretion afforded to FDA in the FDC Act over imports, we have no doubt that FDA will present myriad arguments that First Fishery’s case is without merit. We will be watching this case, as well as the [recent case](#) filed against FDA over a tobacco-related product Import Alert.