

FDA Steps Up Border Enforcement Against Foods Containing Illegal or Undeclared Colors

The United States Food and Drug Administration (“FDA”) is cracking down on food imports with illegal or undeclared color additives and is adding new firms to Import Alert 45-02, "Detention Without Physical Examination and Guidance of Foods Containing Illegal and/or Undeclared Colors" (“IA 45-02”). In April alone FDA added 26 firms to Import Alert 45-02, which accounts for more than 20% of all firms added to any import alert this month. In March FDA added 38 firms, as compared to only adding 23 firms in January and February combined.

In January 2011, FDA began a well publicized evaluation of purported links between artificial food colors and hyperactivity in children. At roughly the same time FDA significantly increased its testing of imported food to look for food colors. This testing was likely intended to identify whether imported foods had a high incidence of undeclared food colors or of unapproved, banned, or unsafe food colors. In late March, the Food Advisory Committee to FDA determined there was an inadequate link between food colors and child hyperactivity. “It looks like on the one hand FDA decided that there is no adequate link between food colors and hyperactivity but on the other found a lot of undeclared or impermissible food colors in imported foods,” says [Benjamin England](#), owner of [FDAImports.com](#), LLC and 17-year FDA veteran. According to FDAImports.com, LLC, that will present a problem for many foreign food manufacturers.

In the U.S., all color additives must be approved by FDA for each specific intended use. If an unapproved color is added to a food, the food is illegal in the U.S. FDA’s color additive approvals do not match the approvals of other countries or regions. Failing to list on a food label the correct name of an FDA-approved color additive is also illegal – such as using “E110” or “Sunset Yellow” for Yellow 6. Finally, failing to declare the presence of any color always results in the food being misbranded and subject to FDA import detention, FDA import refusal and, as seen recently, FDA Import Alert.

FDA frequently checks imported food labels too and then analyzes the food for color additives. If a color additive is declared incorrectly, FDA will detain the food and refuse it unless the manufacturer or importer fixes the problem by relabeling the food. This process results in avoidable time delays and costs.

Foreign manufacturers may face harsh consequences for including an illegal color or failing to declare a color. According to FDA’s *Regulatory Procedures Manual*, a single violation provides the basis for being added to FDA Import Alert 45-02. Once on Import Alert 45-02, FDA will detain all future food entries automatically and the importer or foreign manufacturer must prove the food complies with the law before the shipment will be released. If the violative food contains an illegal or non-permitted color, the importer must hire a private lab to test all future shipments of the imported food to prove the prohibited color is not in the food. “It seems not all foreign food manufacturers on FDA Import Alert know we can usually remove their names from the import alert using a petitioning process,” [Benjamin England](#) stated. Some manufacturers have been on FDA Import Alert for years. England continued, “Hopefully these many foreign food companies that were recently added to FDA Import Alert 45-02 will not wait any longer than they have to.”

Foreign manufacturers can overcome these obstacles by having their formulations and labels reviewed by an expert prior to exporting them to the U.S. First, the formulation must be reviewed to ensure that they only include FDA-permitted color additives for the specific food. Second, they must verify that all of color additives they added to the food are correctly declared, using the names FDA requires in its regulations.

If you are considering exporting foods to the U.S., let FDAImports.com, a Food and Drug consulting firm, evaluate your products to ensure compliance with the color additive requirements and all other food and food labeling regulations. If your firm is already on FDA Import Alert 45-02, FDAImports.com can help you obtain removal from the Alert.