that their fresh vacuum packaged seafood products have been held under continuous temperature controls to prevent *clostridium botulinum* formation. Importers must provide FDA with "proof" that their product has been maintained at or below 38°F (3.3°C) from the time of packaging through the time of importation in order for a product covered under this Alert to "overcome" the "appearance" of adulteration.[74]

In *Syncor International Corporation v. Shalala,* the D.C. Circuit ruled that an FDA rule was not within the exceptions to the APA's notice-and-comment procedures.[75] Rather, the "interpretative rule," as FDA had characterized it, was in reality a substantive rule. The case involved a manufacturer's challenge to FDA's decision that radiopharmaceutical drugs should be regulated under the FDCA. The manufacturer argued that FDA had violated the APA's requirement of public notice prior to rulemaking.[76] The court primarily focused on whether, in the absence of the rule, there would be an adequate legislative basis for enforcement action. Because the rule did not interpret any language in a statute or regulation, the rule was not interpretative. The court thus vacated the rule as not in accordance with the APA.

Current Alerts mirror the lack of interpretation addressed in the *Syncor* case—they do not purport to interpret any language in a statute or regulation. For example, Alert #99-14 instructs field personnel to "Automatically detain without analysis any … products where countrywide detention has been initiated … if the shipper or grower fails to provide a valid certificate of analysis showing the product does not contain illegal residues … of pesticide(s)."[77] There is no statutory requirement for an importer to provide a certificate of analysis at the time of importation. The only reference to an *actual* statutory requirement is the statement that "The article is subject to refusal of admission pursuant to Section 381(a)(3) in that it appears to contain a pesticide chemical … in violation of section 402(a)(2)(B)." While the Alert references an *actual* statutory violation, it fails to interpret the language of "appearance," which is the exact language that FDA must "interpret" to find the authority to DWPE.

Only by interpreting "appearance" in the Alert ("guidance") itself, could FDA extend its regulatory authority to DWPE. The reason for this is simple. A product not accompanied by a certificate of analysis, as in this example, cannot "appear" to contain a pesticide because there is no such requirement in a statute or regulation. The *only* actual statutory requirement is that product, if it "appears" to be in violation of the FDCA, shall be refused. Until FDA "interprets" "appearance" under section 801, an Alert cannot be an interpretative document excepted from notice and comment. In the absence of the Alert, there would be no adequate legislative basis for refusing the product, unless FDA Alerts interpret "appearance." Even if Alerts did interpret "appearance," the Alerts would be binding. As the next case demonstrates, binding rules are not exempt from the APA's notice provisions.

In *Community Nutrition Institute v. Young*, a public interest group sued FDA for issuing "action levels" without conducting informal rulemaking under the APA.[78] CNI challenged FDA's action level for aflatoxins in corn because the agency did not follow the APA's notice-and-comment provisions prior to enforcement of the action level. FDA argued that the action level was an interpretative rule, or in the alternative, a general

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[74] *Id*.

[75] 127 F.3d 90, 93-94 (D.C. Cir. 1997).

[76] *See id*. at 5-6; 5 U.S.C. § 553(b).

[77] *See* Food and Drug Admin., Import Alert #99-14, Countrywide Automatic Detention of Raw Agricultural Products for Pesticides (July 11, 1994, last updated Oct. 16, 2003), *available at* http://www.fda.gov/ora/fiars/ora_import_ia9914.html (last visited Oct. 20, 2003).

[78] Community Nutrition Inst. v. Young, 818 F.2d 943, 947-48 (D.C. Cir. 1987).

statement of policy. The court considered three criteria in order to determine whether the action level was an interpretative rule, a general statement of policy, or a substantive rule.

First, the court looked at the language used by FDA to describe action levels. FDA's regulation, 21 C.F.R. § 109.4, states that an action level may *prohibit any detectable amount of substance in food and as such, the* food *will be deemed to be adulterated.* The court found that the language reflected an interpretation of action levels as presently binding norms.[79]

Second, the court considered FDA's requirement for food manufacturers to secure *exceptions* to the action levels. According to the court, the need to secure an "exception" implies that in the absence of an exemption, all food containing aflatoxin over the action level would be considered adulterated.[80] The court found that the action level was a binding norm because the adulteration determination was derived from the action limit itself. If action levels did not bind FDA or the manufacturers, it was not necessary to require "exceptions."

Third, the court looked at FDA's previous characterizations of its aflatoxin action level. In a formal notice published in the *Federal Register*, FDA wrote that "Any food that contains aflatoxin in excess of 20 ppb … *is considered by FDA to be adulterated* under section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 342(a)(1)), and *therefore may not be shipped in interstate commerce*."[81] FDA's own language suggested the action levels that the agency deemed permissible. Therefore, the court held that the action levels were substantive rules and, therefore, invalid because FDA had not engaged in notice-and-comment rulemaking.

Current Alerts that impose country-wide (geographic) DWPEs have legal effects similar to the action level at issue in *CNI*. For example, Alert #24-01 provides for detention without physical examination of all bean curd from Hong Kong and the Peoples Republic of China, "except" shipments from firms listed that are "exempt" from DWPE.[82] Alert #16-02 provides for DWPE of all dried shark fins, dried fish maws, and dried shark cartilage powder derived from shark fins/maws from all countries—except those "exempted."[83] Like the action level in *CNI*, these types of Alerts imply that in the absence of an exemption, all products identified by the Alerts are adulterated. Therefore, like the actions in *CNI*, these Alerts are legislative rules and are vulnerable to legal challenge under the APA.

V. THE EFFECT OF AN ALERT

The following illustration highlights the binding effect that an Alert has on subsequent importers.

A. *Salmonella in Lobster Tails*

Suppose FDA collects a physical sample of lobster tails that a U.S. company, Importer A, imports. Those lobster tails originate from a French company, Producer F.

[79] *Id.* at 946.

[80] *Id.* at 947.

[81] 46 Fed. Reg. 747 (1981) (emphasis added).

[82] *See* Food and Drug Admin., Import Alert #24-01, Detention Without Physical Examination of Bean Curd From Hong Kong and the Peoples Republic of China (Apr. 13, 2000), *available at* http://www.fda.gov/ora/fiars/ora_import_ia2401.html (last visited Oct.20, 2003).

[83] *See* Food and Drug Admin., Import Alert #16-02, Detention of All Dried Shark Fins, Dried Fish Maws and Shark Cartilage Powder Without Physical Examination (May 21, 1996, revised Aug. 14, 2003), *available at* http://www.fda.gov/ora/fiars/ora_import_ia1602.html (last visited Oct. 20, 2003).