

KELLER AND HECKMAN LLP

Serving Business through Law and Science®

1001 G STREET, N.W.
SUITE 500 WEST
WASHINGTON, D.C. 20001
TELEPHONE 202.434.4100
FACSIMILE 202.434.4646
WWW.KHLAW.COM

July 9, 2003

Ralph A. Simmons
(202) 434-4120
simmons@khlaw.com

Electronic Submission and Federal Express

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: SPI Comments on Proposed Regulation on Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 [Docket No. 02N-0275]

Dear Madam or Sir:

The Society of the Plastics Industry, Inc., (SPI)¹ by its attorneys and through its Food, Drug, and Cosmetic Packaging Materials Committee (FDCPMC), hereby respectfully submits these comments with regard to the regulation proposed by the Food and Drug Administration (FDA) entitled “Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002,” which was published in the *Federal Register* on May 9, 2003 (68 *Fed. Reg.* 25241). This notice requested public comment on the proposed regulation that would establish procedures for the detention of an “article of food” if FDA has “credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals. . . .” 68 *Fed. Reg.* 25242. The statutory provision underlying the proposed regulation is contained in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the “Bioterrorism Act”). Section 303, Pub. L. 107-188 *amending* Federal Food, Drug, and Cosmetic Act (FFDCA) (codified at 21 U.S.C. 334 *et seq.* (2002)).

¹ Founded in 1937, The Society of the Plastics Industry, Inc. is the trade association representing the fourth-largest manufacturing industry in the United States. SPI’s 1,500 members represent the entire plastics industry supply chain, including processors, machinery and equipment manufacturers, and raw material suppliers. The U.S. plastics industry employs 1.5 million workers and provides \$330 billion in annual shipments. The Food, Drug, and Cosmetic Packaging Materials Committee is composed of SPI members with particular interest and expertise in packaging for food and other FDA-related products. The Committee has a long history of working cooperatively with FDA on regulatory issues relating to packaging.

SPI and its members fully support Congress and FDA in implementing measures to protect the U.S. food supply from terrorist acts. Because the administrative detention provision does not propose a continued, unreasonable burden on the food packaging industry, and the industry recognizes the need for FDA to have the authority to detain food that presents a threat of serious adverse health consequences or death to humans or animals, SPI does not oppose the applicability of the proposal to food-contact materials. However, it is unclear which materials FDA intends to be subject to the provision, and the rule will need to be clarified on this point.

As is the case with the other proposed bioterrorism regulations, suppliers of food packaging and other food-contact materials are brought within the reach of the proposed regulation by virtue of the proposal's definition of "food," which is coextensive with the definition of "food" in the Federal Food, Drug, and Cosmetic Act (FFDCA). As we have discussed in comments on the previous proposed bioterrorism regulations, the definition of "food" under Section 201(f) of the FFDCA includes both articles used for food by man or animals and **components** (emphasis added) of such articles. A "food additive" is defined in Section 201(s) of the FFDCA as any substance "that is reasonably expected to become a **component** of food" (emphasis added). Therefore, any food-contact substance that meets the definition of a "food additive" also comes within the definition of "food," which FDA has incorporated by reference in the proposed regulation on administrative detention and the other proposed bioterrorism regulations. In fact, court decisions indicate that a food-contact article or material comes within FDA's authority over "food" even if it is exempt from the need for premarket clearance as a "food additive" (by being a "houseware," for example).

In the language of the proposed regulation itself, FDA indicates that the Agency intends "food" to be interpreted as extending to the full breadth of the term's definition under the FFDCA, offering as an example of "food" "substances that migrate into food from food packaging and other articles that contact food." 68 *Fed. Reg.* 25268. This language, then, indicates that the regulation would apply, at a minimum, to all food-contact substances that meet the definition of "food additive," and, possibly, to literally all food-contact articles and materials. On the other hand, as with the other proposed bioterrorism regulations, the Agency has expressed an intent to limit administrative detention to finished packaging that is in immediate contact with food by including the following language in the preamble to the proposed regulation:

"substances that migrate into food from food packaging" include immediate food packaging or components of immediate food packaging that are intended for food use. Outer food packaging is not considered a substance that migrates into food.

68 *Fed. Reg.* 25245. If FDA wishes to limit the regulation to this extent, the rule itself will need to be clarified on this point.

In this regard, we recommend that the Agency remove the phrase "including substances that migrate into food from food packaging and other articles that contact food" from the

discussion of the definition of food in Section 1.377 of the proposed rule. The following language should then be inserted into this Section: "FDA does not intend for all packaging materials to be subject to this provision. Only "finished" food packaging intended for direct contact with food, which is in its final form and requires no further processing before food can be added, is intended to be subject to this provision. "Further processing" does not include minor alterations to the exterior of the packaging, such as the application of labels or inks." SPI also recommends that the language in the preamble be revised in the same way, clarifying the meaning of "immediate food packaging," and removing the reference to "components of immediate food packaging," which could include all of the materials of construction of the "immediate packaging."

SPI's FDCPMC appreciates this opportunity to comment on FDA's proposed regulation concerning administrative detention of food. SPI hopes that these comments demonstrate fully the commitment of the plastics industry to cooperate with FDA on initiatives that offer real protection of the public against terrorist attacks.

Sincerely,

Handwritten signature of Ralph A. Simmons in blue ink, with a circled initial 'RS' at the end.

Ralph A. Simmons
Legal Counsel for
The Society of the Plastics Industry, Inc.