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July 4, 2003

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



Attention: Docket No. 02N-0276

**Comments of the Canadian Plastics Industry Association with Respect to FDA's Proposed Regulations on Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Docket No. 02N-0276)**

The Canadian Plastics Industry Association (CPIA) is the trade association representing the plastics industry in Canada. Its members embrace the complete plastics industry supply chain, including processors, machinery equipment makers and raw material suppliers. More specifically, some of the members of CPIA manufacture resins and packaging materials that are exported to the United States sometimes to be used in the packaging of food.

The definition of food as used by the FDA in their proposed regulations is the broad definition of "food" found in section 201(f) of the Federal Food, Drug and Cosmetic Act. This definition, in conjunction with the definition of food additive, provides a basis for the FDA to assert regulatory authority over any food contact materials such as packaging. As a result suppliers of empty packaging not yet in contact with food would be required to adhere to the policy of registration as a food facility as specified in the aforementioned act. This is an onerous burden involving increased paperwork and a burden not in keeping with what we believe was the intent of Congress.

Rep. John Shimkus (R-Ill), the bill manager in the house, clarified congressional intent through an entry into the Congressional Record on May 24, 2002:

Mr. Speaker, in addition to my statement for the record on May 22, 2002 during floor consideration of H.R. 3448, let me clarify that language included in the Conference Report regarding Section 307 as it relates to food packaging materials. Section 307 dealing with prior notice of imported food shipments

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should not be construed to apply to food packaging materials or other food contact substances if, at the time of importation, they are not used in food.

It is our understanding that some Canadian companies supplying specific containers for the packaging of food to the United States, for example dairy tubs, are certified by the FDA, listed as an interstate dairy shipper and therefore are subjected to a variety of inspections that ensure compliance with health regulations.

Companies engaged in the packaging of food would normally have two or more sources of supply for their packaging materials and as a result are solely knowledgeable of which supplier's materials are being used to package a particular lot or batch of foodstuff.

Requiring manufacturers of empty plastic packaging to register, as "Food Facilities" is, in our opinion, a nonproductive exercise.

It is our belief that the intent of the statute, namely to be able to trace the source of packaging, would be fulfilled by a simpler regulation requiring food processors to maintain records identifying the immediate suppliers of their finished packaging.

Respectfully submitted on behalf of the Canadian plastics industry.

Yours truly,

A handwritten signature in black ink, appearing to read "S Lavoie". The signature is fluid and cursive, with a large initial "S" and a stylized "Lavoie".

Serge Lavoie  
President & CEO