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

Dear Sir or Madam:

Re: Docket No: 02N-0276: Registration of Food Facilities

The Food and Consumer Products Manufacturers of Canada (FCPMC) is pleased to have the opportunity to provide comment on the above sections of the Bioterrorism Act. We believe it is important to the free flow of trade across our mutual borders that appropriate mechanism are in place to ensure the security of our food supply chain, while taking into account the unique circumstances of traffic across our mutual border.

FCPMC is the industry association representing over 150 Canadian-operated member companies that manufacture and market retailer and national brand food and consumer products that are integral to daily life at home, work and leisure. A list of our members is attached. These companies provide Canadians with safe, nutritious and high quality products sold through retail grocery, drug, convenience, mass merchandise and foodservice distribution channels. Last year, the industry generated over \$24 billion annually in GDP (15% of the Manufacturing Gross Domestic Product), employed 312,000 Canadians directly in every region in Canada, contributed \$33 million to charitable causes and donated over 4.5 million bags of groceries to needy Canadians. The industry has a record of embracing world-class regulatory standards and is governed by 442 federal and provincial pieces of legislation, as well as thousands of regulations and self-imposed standards.

FCPMC recognizes that currently The Food and Drug Administration (FDA) has limited information concerning foreign food facilities. Since all facilities, both domestic and foreign will be required to register this is not viewed as a protectionist or anti-NAFTA act.

FCPMC further recognizes that registration must achieve two primary objectives. First, the registration process must remain as simple as possible for all participants; and, second, FDA must limit its scope of registration to the types of facilities clearly envisioned as part of the legal statute while avoiding the unnecessary overburden associated with unintended registrant.

PAST CHAIR

Michael Rosicki
Parmalat Canada

02N-0276

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Facility Registration and Scope

Given the number of foreign facilities estimated by FDA (200,000) and that the system would not become operational until at least October 12, 2003, FCPMC questions whether or not the December 12, 2003 registration deadline is feasible. There are some companies that have to register more than 60 facilities. FCPMC recommends that a six-month grace period be provided in order to ensure FDA electronic system is in place and companies have adequate time to provide all information required. FCPMC believes that FDA should adapt a graduated approach similar to US Custom's recent introduction to the CSI-24 hour rule, thereby utilizing the 6 month window as a grace period to allow timely registration of importers without being subject to detention or monetary penalties.

FCPMC believes that for companies located in Canada with U.S. corporate parents, the current proposal allows for the authorization of the U.S. corporate parent to register its Canadian facilities. FCPMC is seeking clarification from FDA regarding this issue on behalf of its members.

FCPMC notes that due in part to FDA's inadvertent contradictions of exemptions and definitions within the statute, the estimated number of facilities proposed by FDA that will require registration is vastly under estimated and therefore request that FDA revise proposed regulatory language to avoid the unnecessary overburden of unintended registrants.

Critical examples of this inadvertent imprecision in the statutory language include proposed, 21 CFR 1.227(c)(2), noting that delivery trucks, truck trailers, shipping containers and rail cars all would meet the condition of "a mobile facility traveling to multiple locations" and would therefore fall within the scope as "a facility that manufacturers/processes, packs, or holds food for consumption in the United States." The number of delivery trucks, truck trailers, shipping containers and rail cars that would fall under this category would in itself greatly exceed the estimated number of facilities requiring registrations and place undue burden on FDA's registration system. FCPMC recommends FDA exclude mobile facilities from the definition of facilities.

FCPMC believes FDA intended to exempt farms from the registration process. however, in proposed 21 CFR 1.227 (c)(3), FDA has inadvertently created some conditions to limit the exemptions for farms. Namely these limitations are geared around definitions of "manufacturing/processing" and "packing."

21 CFR 1.227 (c)(6), "manufacturing/processing" includes activities such as cutting, trimming and washing that are traditionally part of farming activities performed immediately after harvest. Examples include threshing of grain (cutting) and washing or cosmetic trimming of harvested fruits and vegetables.

Activities that may include boxing of produce or protective wrappers undertaken at the farm to assist with the transportation off the farm would appear to meet the definition under “packing” in proposed (c)(8). FCPMC does not believe that FDA intended to render farming exemptions invalid due to imprecise statutory language and recommends FDA to review the definitions related to farming activities and applicable exemption thereby specifically excluding cutting, trimming and washing from the definition of manufacturing/processing and boxing/wrapping for the sole purpose of transporting harvest off the farm from packing definitions.

Registration Information

The list of categories in 21 C.F.R. 170.3 is outdated and incomplete. Some categories of marketed foods are not listed, i.e. dietary supplements. The inclusion of product categories will complicate the registration process and cause frequent update requirements as product categories are added or deleted from the marketplace. It is questionable whether the inclusion of category information will be more of a hindrance than a benefit.

FCPMC recommends that for the purposes of registration, the U.S. agent identification be optional and be completed only by facilities electing to authorize a U.S. agent to complete the registration on the behalf of the foreign facility with FDA. Further, the proposed registration form presupposes that a foreign facility may only have one U.S. agent, when in fact it may have several U.S. agents, depending on the nature and business practices of the foreign facility. FCPMC believes that FDA goes beyond the scope intent of the statute in presuming to require changes in business practices, which would unduly constrain international trade.

It is essential to protect the integrity and confidentiality of the registration number and information provided. Therefore, FCPMC recommends FDA investigate using an industry databases such as UCCnet or ECCnet. FDA can improve the process of registering electronically if multi-facility registrants were able to send a single transmission containing all the required data, in lieu of entering data interactively over the Internet. FCPMC further recommends the final rule include an option to submit electronic data files, such as XML documents, Microsoft Excel documents, or standard flat files.

If you have any questions about FCPMC’s submission, please contact Barbara Tordoff, (416) 510-8024 ext. 2243 or barbt@fcpmc.com.

Respectfully Submitted



Laurie Curry, Vice President
Public Policy

attachment



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FCPMC Member List

- 3M Canada Company
A. Lassonde Inc.
Abbott Laboratories Limited
Agropur Cooperative
Alberto-Culver Canada Inc.
Alcan Foil Products
Alcoa Ltd. - Reynolds Consumer Products
Arla Foods Inc.
- Bayer Consumer Care Division
Bernardin Ltd.
Bertolli Canada
Beta Brands Limited
Big 8 Beverages Ltd.
Blue Water Seafoods
Bristol-Myers Squibb Consumer Products
Group – Canada
Buena Vista Home Entertainment Canada
Burnbrae Farms Ltd.
- Cadbury Beverages Canada Inc.
Cadbury Trebor Allan Inc.
Campbell Soup Company Ltd
The Canadian Salt Company Limited
Carlton Cards Limited
Cascades Tissue Group
Cavendish Farms
Charcuterie La Tour Eiffel Inc.
Church & Dwight Canada
The Clorox Company of Canada, Ltd.
CKF Inc.
Clover Leaf Seafoods Inc.
Coca-Cola Bottling Company
Coca-Cola Ltd.
Colgate-Palmolive Canada Inc.
The Coming Home Foods Company
ConAgra Frozen Foods Limited
ConAgra Grocery Products Limited
Concord National Inc
Cott Beverages Canada, a Division of Cott
Corporation
Crown Cork & Seal Canada Inc.
- Dare Foods Limited
Del Maestro Foods Inc.
Dial Canada Inc.
DiverseyLever Canada
Dole Foods of Canada Ltd.
Dover Industries Limited
Duracell Canada Inc
- Effem Inc.
Energizer Canada Inc.
- Ferrero Canada Ltd.
Fishery Products International Limited
Fleischmann's Yeast, Division of Burns Philp
Food Limited
Food Producers Canada Inc.
Frito Lay Canada
Fuji Photo Film Canada Inc.
- Ganong Bros. Limited
Gay Lea Foods Co-operative Limited
General Mills Canada Corporation
George Weston Limited
Georgia-Pacific
Gerber (Canada) Inc.
Gillette Canada Inc.
GlaxoSmithKline Consumer Healthcare
Good Humor – Breyers
Grantham Foods Ltd.
GVMF Canada
- H.J. Heinz Company of Canada Ltd
Hershey Canada Inc.
High Liner Foods Incorporated
Humpty Dumpty Snack Foods Inc.
- Irving Tissue
Italpasta Ltd.
- J.M. Smucker (Canada) Inc.
Janes Family Foods Ltd.
Jergens Canada Inc.
John O. Butler Company
Johnson & Johnson Inc.
Kellogg Canada Inc.
Kimberly-Clark Inc.

Kingsmill Foods Co. Ltd.
Kodak Canada Inc.
Kraft Canada Inc.

Lantic Sugar Limited
Lavo Inc.
Les Aliments Dainty Foods
Lindt & Sprüngli (Canada), Inc.

McCain Foods (Canada) A Division of
McCain Foods Limited
McCormick Canada
Mead Johnson Nutritionals
Melitta Canada Inc.
The Minute Maid Company Canada Inc.
Morrison Lamothe Inc.
Mother Parker's Tea & Coffee Inc.
Mott's Canada
Multifoods Inc.

National Importers Canada Ltd.
Natrel Inc.
Nestlé Canada Inc.
Nestlé FoodServices
Nestlé Ice Cream
Nestlé Nutrition
Nestlé Purina PetCare
Novartis Consumer Health Canada Inc.
Novopharm Limited

Ocean Spray International Services, Inc
oetker ltd
Old Dutch Foods Ltd.

Parke-Davis
Parmalat Canada
The Pepsi Bottling Group (Canada), Co.
Pepsi-Cola Canada Ltd.
The Perrier Group of Canada Limited
Pfizer Canada Inc. Consumer Group
Pharmacia Consumer Healthcare Canada,
Division of Pharmacia Canada Inc.

Pinnacle Foods Canada Corporation
Playtex Limited
Procter & Gamble Inc.
Purity Factories Limited
QTG Canada Inc.

The Reader's Digest Association (Canada)
Ltd.
Reckitt Benckiser (Canada) Inc.
Redpath Sugars, A Division of Tate & Lyle
North American Sugars Ltd.
Reinhart Foods Limited
Robin Hood Multifoods Inc.
Rogers Foods Ltd.
Rogers Publishing Limited
Ronzoni Foods Canada Corporation
Ross Products Division

S.C. Johnson and Son, Limited
Sara Lee Bakery Canada
Schneider Foods
Scotsburn Dairy Group
Scott Paper Limited
Storck Canada Inc.
Sun-Rype Products Ltd.

Tetley Canada Inc.

Ultima Foods Inc.
Unico Inc.
Unifine Richardson B.V.
Unilever Bestfoods Foodservice Canada
Unilever Canada Limited
Unilever Cosmetics International (Canada)

W.T. Hawkins Ltd.
Weston Bakeries Limited
Weston Bakeries/Ready Bake – Quebec
Weston Bakeries/Ready Bake - Atlantic
Weston Bakeries/Ready Bake – Ontario
Weston Bakeries/Ready Bake - Western
William Neilson Ltd./Ltee
Wrigley Canada