



## FCPMC · FPACC

April 2, 2003

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

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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.

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](mailto: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