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**FCPMC · FPACC**

July 8, 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-0277: Establishment and Maintenance of Records

The Food and Consumer Products Manufacturers of Canada (FCPMC) is pleased to have the opportunity to provide comment on the above section of the Bioterrorism Act. We applaud the FDA's commitment to provide a safe and secure food supply. FCPMC believes it is important to the free flow of trade across our mutual borders that appropriate mechanisms 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. 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 supports in principle the objective of the Establishment and Maintenance of Records, where one set of records is required (not two) and where the information required already exists on a standard bill of lading/weigh bill. The following are challenges that would impact the Canadian food and beverage manufacturing:

Lot and Code Numbers:

Under the proposal, food manufacturers and their transporters would have to maintain records of the movement of product that include the lot or code numbers of the food products. This would require the food industry to change the way it currently handles product.

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Tracking lot numbers through the entire chain of food distribution is not possible and would be very costly to introduce. It is now the practice within the industry to track product from production to a warehouse. Once the lot number leaves the warehouse and enters the retail system it is not tracked. For products, which fall into the “direct delivery” category, i.e. snacks, milk, bread, neither the transporter nor the retail store has the technology to track each bag of chips or bag of milk. When a recall is necessary, the food manufacturer would recall the affected product much more broadly than just the potential lot numbers. Retailers will automatically remove all potential products from their shelves.

Responsible Individual:

It is not clear to us whether the responsible individual is the same as the emergency contact for purposes of facility registration. It is recommended that the names of individuals supplied when facilities are registered with the FDA be sufficient. The nontransporter should be able to identify the responsible individual within the transporting company.

Identification of Processing Aids/Specific Ingredients:

FCPMC appreciates that the FDA is altering its position on ingredients that are comingled and recommends that processing aids and incidental additives be treated in the same manner.

Time Periods for Record Retention:

FCPMC recommends that in the case of food products and food for animal consumption, a two-year retention period is acceptable. However, in the case of perishables, which have a very short shelf life, a one-year retention period is excessive. An alternative could be three to six months, since any harmful effect directly related to a perishable would be detected well within the life expectancy of a perishable product.

Protection of Confidential Information:

Although “recipes,” financial information and pricing are excluded from the proposed regulations, ingredients are not. This could lead to exposing highly confidential information such as a “*secret ingredient*” to competitors even though the quantity is not specified. We would be interested in knowing what safeguards will be in place to ensure confidentiality of company “*trade secrets*.”

FCPMC appreciates the opportunity to provide our Canadian perspective and we look forward to the FDA’s evaluation of submitted comments. If you have any questions about FCPMC’s submission, please contact Barbara Tordoff, (416) 510-8024 ex. 2243 or barbt@fcPMC.com

Respectfully submitted



Laurie Curry, Vice President
Public Policy