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United States Senate

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COMMITTEE ON THE JUDICIARY
COMMITTEE ON FOREIGN RELATIONS
COMMITTEE ON THE BUDGET
SPECIAL COMMITTEE ON AGING
DEMOCRATIC POLICY COMMITTEE

September 4, 2003

Mr. Amit K. Sachdev
Associate Commissioner for Legislative Affairs
Food and Drug Administration
Parklawn Building
5600 Fishers Lane, Room 15-47
Rockville, MD 20857-0002

Dear Mr. Sachdev,

One of my constituents has contacted me regarding the Bioterrorism Act of 2002 and food packaging regulations.

I have enclosed a copy of my constituent's letter which outlines these concerns. I would appreciate it if you would forward any information you may have concerning this matter to the attention of Matthew Steiner in my Washington office so that I may forward that information to my constituent.

Thank you for your assistance.

Sincerely,

Russell D. Feingold
United States Senator

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Domtar Industries Inc.
Nekoosa and Port Edwards Mills
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Domtar

The Honorable Russell Feingold
506 Hart Senate Office Building
Washington, DC 20510-4904

August 8, 2003

Dear Senator Feingold:

I am writing to express the concern of Domtar Industries to the manner in which the United States Food and Drug Administration (FDA) is interpreting and proposing to implement certain provisions of the Bioterrorism Act of 2002.

The Bioterrorism Act of 2002 was legislation passed by Congress with the intent of providing adequate safeguards to the nation's food supply. The Act calls on food processors and food suppliers to apply appropriate safeguards to protect the nations food supply from contamination at the hands of terrorists.

Earlier this year, the FDA issued two proposals to implement portions of the Act. One proposal calls for facility registration and the other for import notification for "food." At issue is the fact that the FDA has expanded the definition of food to include not only what we would commonly think of as edible material, but also "substances that migrate into food from food packaging and other articles that contact food." By proposing to adopt this definition, the FDA would include food processing facilities, as well as manufacturers and suppliers of food packaging materials.

We believe neither the statutory language nor the legislative intent provide for the FDA to include packaging materials to the definition of food. Further, we are convinced the FDA does not grasp the magnitude of complying with their proposal. The negative financial impact to Domtar will be substantial, and our industry estimates compliance with the FDA proposals will add tens of millions of dollars to the nation's food bill each year.

I am sending you a series of "bullet points" that highlight our specific concerns as addressed to the Office of Management and Budget (OMB). We ask that you please review these points and encourage you to seek answers from the FDA as to why the agency has proposed such an overly broad definition of food.

Please let me know what action you intend to take to address our concerns.

Sincerely,

Ross Stairs, General Manager
Nekoosa and Port Edwards Mills

Enclosure
1. Concerns with FDA's proposed implementation of the Bioterrorism Act of 2002

DOMTAR'S CONCERNS WITH FDA PROPOSALS
TO IMPLEMENT THE BIOTERRORISM ACT

AUGUST 8, 2003

1. **The extension of the provisions of the Bioterrorism Rules to the food packaging industry is not mandated by statute and provides no benefit to food safety.**

- FDA's proposed rules would apply equally to conventional food and food packaging materials (even before they contain food). The imposition of this burden is not mandated or supported by the statutory language and legislative history of the Bioterrorism Act. (See appendix.) Moreover, applying these requirements to food packaging not yet containing food confers no benefit of increased security for the United States food supply.

- To understand possible costs of food-borne illness, FDA presents examples of five contamination outbreaks. The "vehicles" for these five outbreaks are all conventional foods, and have nothing to do with packaging or food contact articles. If FDA thinks that food contact materials pose a potential threat from any intentional attack on the food supply, FDA should have estimated the cost of such an attack and should have shown that these provisions will minimize that risk, in an attempt to justify the immense burden being placed on the industry. FDA has provided no such cost minimization justification.

- As a technical matter, there is no reasonable expectation that a terrorist would attempt to contaminate food indirectly by tampering with empty packaging. We are not aware of any adverse health incidents attributed to adulterated food packaging. FDA provides no reason to believe that packaging could pose a threat.

- FDA indicates that a benefit of facility registration would be aiding the agency in understanding what facilities might be included in possible future regulations. Thus, we are left to wonder what future regulatory burdens the agency may seek to impose on the food and food packaging industries.

2. **FDA vastly underestimates the scope and burden of the proposed regulations.**

- There is a wide range of "upstream" manufacturers that make ingredients and components that go into food packaging and other food contact articles. The potential list of food contact articles is tremendous. For example, the broad array of material FDA regulates in its food additive regulations, 21 C.F.R. Parts 170 through 189, are "food" under the statute.

Articles typically referred to as "housewares"—which are food contact articles such as plates, utensils, and cookware used in the home or retail establishments—have traditionally been considered outside the scope of FDA's food additive authority, but are still "food" under the FD&C Act. Under FDA's proposed regulations, all facilities manufacturing, processing, packing, or holding these articles would be covered. Thus, all firms engaged in any of the following industries would be subject to the regulations--paper, paperboard, plastics, most industrial chemicals, metals, glass, pottery and china, rubber products, lubricants, food processing equipment, and utensils. Applying the regulations to this broad variety of products will overwhelm both industry and FDA resources, with no benefit of increased security for the United States food supply.

- The immense burden posed by the proposed regulations will not fall only on large packaging and chemical suppliers. In fact, FDA estimates that 99% of impacted facilities are small businesses.

- The recycling industry will also be affected, because many food contact articles make use of recycled input. This would include all curbside recycling programs, which are clearly sources of raw materials for food packaging. The paperwork burden imposed by the proposed recordkeeping requirements would overwhelm many of these small facilities. Applying these rules to the recycling industry is simply bad public policy, for it would lead many establishments to leave the business of turning recycled materials into food contact materials because they would not be able to keep up with the recordkeeping requirements.

- Many facilities connected with packaging produce both food and non-food use products. Because the registration requirement is for the entire facility, any facility that produces (or stores) any food contact material would be required to register. As the registration requirement is proposed, virtually every facility connected in any way with food packaging or packaging materials, and the facilities of the suppliers to those facilities, will be required to register, as well as maintain records.

- FDA's proposed requirement for updating the registration within 30 days of any change in the information on the registration, coupled with the extensive list of information required for the registration, creates essentially a monthly registration requirement. It is entirely foreseeable that at least one element of the information on the registration could change each month, thereby necessitating an update to the registration. Also, given the requirement to update within 30 days, all companies must review their registration at least once every 30 days to ensure the information remains accurate. This will impose an immense burden in personnel-hours, and one that was not accurately captured in the proposal.

- FDA is also not considering the burden of having these records prepared, verified, and provided up and down the supply chain. Customers at every stage will require verification all the way back up the supply chain that all required registrations are in place. Even though FDA has stated that each facility is only liable for its own registration, this ignores the reality in the marketplace, which is that the entire supply chain must be verified at each stage.

- FDA's analysis underestimates the impact that FDA's proposed definition of "article of food" will have on imports, and thus the cost of the prior notice proposal. The categories in the OASIS system do not cover the imports of bulk chemicals, polymers, bulk papers, and other precursor materials that are used in food packaging and other food contact articles. Under FDA's proposed regulation, importers of these materials will be required to submit a prior notification if they are aware that the materials may be used with food. Because it is difficult to know for certain every possible use of a bulk chemical, the prudent importer will be forced to submit a notification to ensure that, if the product is to be used in contact with food, it is legal to do so. This creates an unnecessary burden on several levels. For industry, notifications will be required for a vast quantity of material that will not contact food. For FDA, unnecessary resources will be spent processing notifications for materials that may never contact food.

- FDA further underestimates the burden of the prior notice proposal by not considering the upstream component manufacturers. Because FDA's proposed definition of food would apply to all ingredients of food packaging and other food contact articles, notification must be submitted for the import of all these items. This extends FDA's notification requirement far beyond the food categories FDA considered to include all the inputs used to manufacture food contact articles. And because these items and the ingredients used to manufacture them are all primarily shipped in bulk, with no way to distinguish the food use from non-food use material, notification will be required for all of it. Thus, the number of notifications required will be much larger than FDA estimates, with an enormous cost to industry and FDA. Also, given that none of these articles will be allowed to cross the United States border without proper notification, there will be a tremendous impact on commerce.

- FDA's cost estimate also fails to adequately account for additional costs that will be imposed on industry by the prior notice requirements. Currently, industry has been able to minimize storage costs by taking advantage of "just-in-time" shipping. This means that orders are placed and raw materials arrive just as the factory needs them. This minimizes storage and warehouse costs. Because of the timing requirements of the prior notification, there will be no way to utilize a just-in-time system if it

involves a cross-border shipment. There are many instances where a facility may not know by noon of the previous calendar day that it will need a particular input. If this deadline is missed, an additional 24-hour wait must be built in, as there is no way to submit a notification for an earlier shipment. This will require facilities to maintain additional inventories to cover for any shortfall in supply that may result.

- Companies have adapted to the changing environment since the passage of the North American Free Trade Agreement (NAFTA) and have located facilities on either side of the border. Currently, if one facility requires an input that the other facility has, it is simply shipped over to where it is needed. As this often involves a border crossing, under FDA's proposed prior notice regulation, this practice will no longer be possible. This will once again force the facilities to maintain larger inventories, and will disrupt efficient methods of business. The cost of this disruption is difficult to quantify, as it will require an entirely new model of operation to accommodate the time periods and paperwork burden of the proposed regulation.

- Regarding recordkeeping requirements, many packaging producers and their suppliers produce both food and non-food use products. Because a facility may not know at the time it ships a substance or material whether it is destined for food use, the facility will establish records in an abundance of caution to insure compliance with regulatory requirements in the event that the substance is in fact used for food at some point down the chain of commerce. This cautious approach will result in a tremendous waste of resources, perhaps leading to the establishment of records for every shipment of every chemical substance that might possibly have a food contact use.

- FDA's recordkeeping requirements for transporters fail to consider transporters of food contact substances. These transporters are unlikely to be aware that the materials they are transporting—for example, chemical precursors to these substances or aluminum sheeting—are considered "food" by FDA. They will have no way of knowing that they are obligated to establish and maintain records regarding the shipment of these materials. If FDA assumes that the facility from which the materials are being sent should advise the shipper of the recordkeeping requirement, then the agency would be imposing an additional notification requirement on the food contact industry that goes beyond what is required of the conventional food industry. There is no justification for this disparate treatment, particularly given the fact that any security risk to the food supply is likely to be posed by a direct attack on conventional food and <u>not</u> on packaging or its components not yet in contact with food.

3. **FDA did not employ the least burdensome option with practical utility.**

FDA failed to evaluate the option of excluding food packaging and food contact materials from any of its proposals. The burden of its proposed rules does not account for the broad range of "upstream" manufacturers that make ingredients and components that go into food packaging. Under the agency's proposals, the requirements would extend to food packaging facilities and all of the distributors and suppliers of raw materials for the constituents of food packaging.

Conclusion

In order to effectively further the purposes of the Bioterrorism Act, FDA need only apply its proposed rules to conventional food facilities. All conceivable threats to the safety of the food supply could be addressed and contained in this manner.

APPENDIX

EXPRESSIONS OF CONGRESSIONAL INTENT TO EXCLUDE PACKAGING FROM THE REQUIREMENTS OF THE BIOTERRORISM ACT

I. Facility Registration

The statutory language addressing the facility registration requirement refers to "food for consumption." Plainly, food packaging is not "for consumption," and therefore was not intended to be covered by the registration requirements. Moreover, while the definition of "food" in the Federal Food, Drug and Cosmetic Act ("FD&C Act") would encompass food contact substances that may migrate into and become components of food, the qualification "for consumption" in the Bioterrorism Act is clearly intended to indicate that only conventional foods, and not food packaging or food contact materials, are within the ambit of the registration requirement.

II. Prior Notice

While the provision on prior notice of imports refers only to "articles of food," the legislative history clearly expresses the congressional intent to exclude food packaging and food contact substances, unless used for or in contact with food at the time of importation. The Conference Report explains that "[t]he Managers intend that the requirements of this section [307] should not be construed to apply to packaging materials if, at the time of importation, such materials will not be used for, or in contact with, food as defined under section 201 of the [FD&C Act]." H. R. Rept. No. 107-481, 107th Cong., 2d Sess. 137 (May 21, 2002). Congressman Shimkus, one of the Managers of the Bioterrorism Act, provided further clarification on the House floor: "Section 307 dealing with prior notice of imported food shipments 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." 148 Cong. Rec. E916, (daily ed. May 24, 2002).

III. Recordkeeping

The statutory language of the recordkeeping provision authorizes FDA to require recordkeeping by persons "who manufacture, process, pack, transport, distribute, receive, hold, or import food," which records are needed by FDA "to identify the immediate previous sources and the immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequences or death to humans or animals." Sec. 414(b). FDA has interpreted this provision to allow the agency to require recordkeeping by those who handle packaging materials. However, the language of the provision appears to require merely recordkeeping by food handlers sufficient to identify the immediate previous sources and subsequent recipients of food packaging. This will be accomplished by having conventional food facilities document the sources of packaging for their food products and the subsequent recipients of the packaged food. The purpose of this provision – to address credible threats of serious adverse health consequences – is not furthered by imposing recordkeeping requirements on the food packaging industry; particularly given the highly remote chance that packaging by itself could pose a health risk.