From: Paula [paula@purcell-intl.com]
Sent: Thursday, May 13, 2004 7:36 PM
To: 'fdadockets@oc.fda.gov'
Subject: Prior Notice Comments

Importance: High

To whom it may concern,
Please note and receive the attachment as my comments with regard to "Prior Notice".
Thank you,
Paula Routh
Traffic
Purcell International

EMC183

PURCELL INTERNATIONAL

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May 13, 2004

Dockets Management Branch
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Michael S. Craig
PGA Coordinator
Bureau of Customs and Border Protection
1300 Pennsylvania Avenue, N.W.
Room 52C
Washington, D.C. 20229

Re: Docket No. 02N-0278 – Comments On Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 -- Reopening Comment Period

PURCELL INTERNATIONAL has been importing food products for 50 years and is pleased to submit comments to the Food and Drug Administration (FDA) on the Interim Final Rule, Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), 69 Fed. Reg. 19763 (April 14, 2004) (Prior Notice Interim Final Rule).

Exemptions For Trade Samples

Companies in the food industry routinely receive samples from customers, suppliers and affiliates for qualitative testing, organoleptic analysis, research and evaluation. Filing prior notices for these pre-purchase and trade samples imposes significant burdens without improving food security.

Samples for the uses above are of very small quantity and are not intended for commercial distribution. The lack of risk to public health that justifies exempting personal use and homemade foods from prior notice requirements applies, indeed even more persuasively, to pre-purchase and trade samples.

Communication of Rejections of Prior Notice Filings and Refusals of Articles of Food

The Prior Notice Interim Final Rule provides that the carrier is the point of contact if an article of food is refused. The problem with this requirement is that the carrier is not in a position to resolve

the problem. Burdening truck drivers, railway operators, airlines and other cargo shippers with a duty to report a product refusal to the importer or other concerned party is likely to lead to delays, confusion and ports clogged with refused food.

In the case of a rejected notice, the importer or ultimate consignee, if different, and the filer, if different, are the persons in the best position to address the agency's concerns regarding the refused articles and to correct any prior notice deficiencies or other problems. The importer, the ultimate consignee and the filer are also in the best position to export or destroy the refused food if the prior notice defects cannot be corrected. Delaying the notification to the importer, ultimate consignee and filer unduly hinders resolution and increases the likelihood of crowding ports of entry with refused food. Effecting this change will not cause any additional burden since FDA knows from the prior notice filing the importer's identity and contact information. Thus, the agency has the ability to swiftly communicate with the importer via email.

Communication to the Trade

Currently, a filer is receiving only the FDA/CBP confirmation that a transmission was received and that the fields have data. No error message is sent if data is incomplete or inaccurate. As a consequence, we are looking with concern toward the future when FDA begins enforcing prior notice requirements because we do not yet know what errors are being made and may not know until FDA refuses an article of food.

We urge that before full enforcement of the prior notice provision, FDA establish a notification system that alerts the submitter of a prior notice of precisely what problems are encountered with that prior notice. Additionally, we request that FDA publish deficiency information on its website that lists the most common problems seen in submitted prior notices. This should be done both before and after full enforcement is in place.

Additional Comment Period Needed

FDA should reopen the prior notice rule comment period for an additional 60 days after full enforcement has been in place for at least six months. Both the government and industry need the benefit of experience with active and full enforcement before fine-tuning the prior notice regulations for the final time.

I thank FDA for its efforts to create a workable prior notice system.

Sincerely,
William E. Purcell
President