

Pueblo International, LLC
PO Box 363288
San Juan, PR 00936-3288
tel: (787) 757-3131
fax: (787) 768-5775
e-mail: fbonilla@pueblo.net

Fernando J. Bonilla
Vice-President
General Counsel
Secretary

1130 '03 JUL -9 10:08

July 8, 2003

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

Re: Establishment and Maintenance of Records under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Docket No. 02N-0277)
Puerto Rico and the U.S. Virgin Islands should be excluded from the proposed rules.

Dear Sir or Madam,

On behalf of Pueblo International, LLC, and its subsidiary FLBN Corporation ("Pueblo"), I am pleased to respond to the Food and Drug Administration's (FDA) request for comments on the proposed regulations to require the establishment and maintenance of records by domestic persons who handle food intended for human and animal consumption in the United States. For your information, Pueblo International operates 42 combo supermarkets in the Commonwealth of Puerto Rico, and FLBN Corporation operates 6 traditional supermarkets in the U.S. Virgin Islands. In Puerto Rico, Pueblo operates a 350,000 square foot Distribution Center for its stores and a 10,000 square foot Reclamation Center to process unsaleable merchandise from its stores.

Pueblo appreciates the threat that bioterrorism may pose to the United States and therefore strongly supports the goals of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the "Bioterrorism Act"). However, we believe that some aspects of the FDA's proposed regulations exceed the Agency's authority and will not further the cause of food security.

Pueblo believe that extending the applicability of the Bioterrorism Act and the proposed regulation to the Commonwealth of Puerto Rico and the U.S. Virgin Islands (hereinafter the "Caribbean Jurisdictions"): (i) is not warranted, (ii) will be an overreaching application of the proposed regulation, (iii) will not deterred unwanted bioterrorism threats, and (iv) will only jeopardize the island economy of the Caribbean Jurisdictions by increasing unnecessary the cost of food retailing activities which are already more expensive than in the continental United States, by adding, among other things, the maritime transportation cost to the goods.

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Pueblo also wants to states that should the Bioterrorism Act and the proposed regulation be applicable to the Caribbean Jurisdictions as discussed more fully below, we strenuously object to the FDA's proposal to require retailers to maintain and track food products by lot code. Lot code tracking will not enhance food security but will significantly impede the efficiency of the overall food distribution system, which is currently capable of identifying and removing adulterated product from our shelves at an extremely rapid pace. Furthermore, FDA should consider food banks and reclamation centers as "consumers" for purposes of the recordkeeping regulations. Reclamation centers are the single largest source of food for food banks. If it becomes necessary to track food products that are routed to consumers through these sources, Pueblo will not be able to donate nearly as much food to charitable organizations. Our full comments follow.

A. The Proposed Regulation Should not be Applicable to the Commonwealth of Puerto Rico and the U.S. Virgin Islands

1. The Application of the Proposed Regulation is not warranted and will not deterred unwanted bioterrorism threats. The people of Puerto Rico paid dearly for the consequences of the terrorist acts of September 11. Over 100 Puerto Ricans (or descendants of Puerto Ricans) were killed by the horrendous acts of September 11. We felt that disaster with our own blood and soul. Puerto Ricans were also sent in significant numbers to Afghanistan and Iraq to defend the nation against terrorism. However, notwithstanding the suffering by our own people, we believe that the overreaching requirements on grocery operators like Pueblo (in the Caribbean Jurisdiction territory) will not be a deterring element against bioterrorism acts in the continental United States or in the Caribbean Jurisdictions. To be effective with their "game plans," known terrorism elements strike against symbolic icons in the continental United States, rather than in islands more than 3,000 miles away from the main territory. Retailers like Pueblo (in the Caribbean Jurisdictions) do not export merchandise to the north; on the contrary, it is the other way around. Therefore, if the proposed regulations were to be effective in the territory of the Caribbean Jurisdictions, then it would be because of compliance by companies in the continental United States, rather than compliance by companies doing business in Puerto Rico or the Virgin Islands.

2. The Application of the Proposed Regulation will be an overreaching application of the proposed regulation. We have review the Bioterrorism Act and we haven found no specific language to make the Act applicable to the Caribbean Jurisdiction or legislative intent in that regard. As explained above, to prevent bioterrorism attacks in the continental United States or in the territory of the Caribbean Jurisdictions the applicability of the Act is not necessary in the Caribbean Jurisdictions.

3. The Application of the Proposed Regulation will only jeopardize the island economy of the Caribbean Jurisdictions by increasing unnecessary expenses to the food retailing activity which already is more expensive than in the continental United States by just adding, among other, the maritime transportation cost to the goods. As indicated above, the application of the Bioterrorism Act will not have an effect on achieving its goals. The only consequence will be unnecessarily increasing the cost of operations of retailers like Pueblo in the Caribbean Jurisdictions. The islands in the Caribbean depend significantly on suppliers in the continental United States for their source of consumable items. The scarce agricultural activity in the islands is not a reliable source of produce for the islands' economies.¹ Therefore, merchandise for grocery retailing comes from the continental United States. As islands, merchandise transported exclusively by airplanes or water common carriers, adding a significant cost to the same merchandise that is sold in the continental United States. The record retention requirements, in particular, add cost to the goods to be sold. The increased cost of selling these goods will be an unnecessary cost to merchandise that is already more expensive than in the continental United States.

B. Requirement To Retain Lot Code Information Will Not Enhance, But Impede, Food Security

Section 414 of the Federal Food, Drug, and Cosmetic Act, as amended by the Bioterrorism Act, grants FDA the limited authority to require the food industry to maintain records sufficient to allow FDA to "identify the immediate previous sources and the immediate subsequent recipients of food, including its packaging" to the extent that such information is necessary to address credible threats of serious adverse health consequences or death. From this limited grant of authority, FDA has proposed to require the food industry to maintain an exorbitant amount of information, including detailed information on the transporter and the lot code for each food product. Such information, which is well beyond FDA's authority to require and the food distribution industry's ability to deliver, is entirely unnecessary to respond to a situation where the Agency has a "reasonable belief that an article of food is adulterated and presents a serious threat of adverse health consequences to humans or animals" – the only situation in which FDA is entitled to access this information.

Under these circumstances – equivalent to a class I recall scenario – the food industry has repeatedly and reliably demonstrated the ability to identify and remove product from grocery store shelves with unprecedented speed and efficiency. The diversion of substantial resources that would be necessary to implement the Agency's

¹ The Secretary of Agriculture of Puerto Rico recently stated that the local agriculture activity only generate 10% of the produces sold at retail.

proposed regulations would not further food security but instead would diminish the overall efficiency of the food distribution system, which is necessary to serve food safety and security needs, as well as commercial purposes.

Currently, lot code information is not available to distribution centers and retailers on any sort of reliable or meaningful basis. The case boxes for some food products may bear some identifying information, such as a production date, but the information is not provided on all boxes and is far from uniform. We do not currently capture or have the ability to capture and retain lot code information on the tens of thousands of different food products that are delivered through distribution centers to retail stores on a daily basis short of hand writing the information to create some sort of record, which would be an inordinately time-consuming and inefficient way for us to conduct our business and would not enhance food security in the least.

Furthermore, we estimate that some 40% of the foods that we offer to consumers at our retail locations are distributed to the stores via direct store delivery or DSD. DSD means that the vendor provides the food directly to the store, sometimes stocking the shelves, rather than sending the product to the distribution center from which we would route the product to the stores. Most baked goods, breads, soda, snack foods, beer and wine, ice, and milk are distributed to our stores via DSD. Currently, there are no systems in place to log or track the type of information that FDA has proposed to require – particularly lot code numbers – in the DSD context.

Given the significant difficulties that developing and implementing systems to track lot code numbers would cause and the fact that adulterated foods can quickly and efficiently be removed from the marketplace with the systems currently in place, tracking lot code numbers will not enhance food security and, therefore, we respectfully urge FDA to remove the requirement from the final regulations that the food industry track products by lot code.

C. Unreasonable and Unnecessary To Require Retailers To Produce Records in Four Hours When Food Itself Can Be Retrieved In Comparable Time

FDA's proposed regulations would require us to produce complete records on the immediate previous source and immediate subsequent non-consumer recipient, including transporters, of food within four hours if the request was made between 8:00 a.m. and 6:00 p.m. and within eight hours if the request was made at any other time. FDA is only authorized to exercise its authority in this regard if the Agency has "a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals." See 21 USC § 414(a).

We believe that the Agency is applying the wrong standard to this situation. If the circumstances for a class I recall are presented, retailers and distributors can identify and

retrieve product from their systems far faster than they can produce documents identifying where the products are. We respectfully submit that, if the Agency has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to consumers, that it is far more important to remove the product from the system than it is to document its location. FDA should not impose a specific time frame within which records must be produced; rather, if a food safety or security situation of the urgency described above presents itself, the Agency should enable the food distribution industry to retrieve the food products and provide FDA with any necessary documentation once the situation has been secured.

D. Immediate Subsequent Recipient Exclusion

FDA's proposed regulations exclude retail facilities from the requirement to keep records documenting the immediate subsequent recipient of food products, but limits that exclusion "only to food sold directly to consumers." 68 Fed. Reg. at 25195. The preamble adds that a facility that sells food to wholesalers and/or other retailers in addition to consumers would have to keep records of the immediate subsequent recipients because wholesalers and retailers are not considered consumers for purposes of this regulation. *Id.* We have the following concerns regarding this standard.

1. FDA Should Consider Reclamation Centers and Food Banks To Be Consumers for Purposes of the Recordkeeping Regulations

Although we make every effort to provide food to our customers in a timely and efficient manner, a small percentage of the food that is in a grocery store is sent to a reclamation center from which it is either returned to the manufacturer or sent to food banks. *Reclamation centers are currently the largest single source of food donations for food banks.* Food may be sent to reclamation centers if its packaging is damaged or if it is past the "best if used by" date. The system for sending food to reclamation centers is simple: the unsaleable products are collected in banana cartons and then shipped to the center where the food is sorted and either donated to charitable organizations, such as food banks, or returned to the manufacturers. No records are kept by the store of the foods shipped to the reclamation center. FDA's regulations should consider reclamation centers and food banks to be "consumers" for purposes of the recordkeeping regulations.

Specifically, food retailers do not currently track the foods that are sent to reclamation centers, nor is there a mechanism available to do so. The requirement to develop and implement new recordkeeping systems would be a serious disincentive to corporate food donations and, again, would serve no purpose with respect to food security. If it is not necessary to track product to individual consumers to enhance food security, no purpose is served by monitoring those products that are sent through reclamation centers to consumers. Any products that are returned to the manufacturer are removed from the food distribution system so they will not reach consumers and their whereabouts need not be accounted for. Accordingly, FDA should broaden the exclusion

for retailers to include food products that are routed to consumers through reclamation centers.

2. Recordkeeping Exclusion Should Apply To All Foods Sold Through Retail Facilities

As noted above, the preamble states that, although retailers will not be required to keep track of foods sold to consumers, retailers will be required to keep records on those immediate subsequent recipients who are wholesalers or other retailers. We respectfully submit that, unless the recordkeeping exclusion applies to all foods that are sold from the store, it is essentially meaningless.

Food retailers do not know whether a person who comes into our store and buys food will be using the food for personal consumption or for a business purpose. To cover the possibility that a purchase was intended for business purposes would essentially require us to record all consumer transactions. We do not believe that this would advance the purposes of food security or increase consumer confidence if they felt that retailers and the federal government were monitoring their grocery store purchases. The trust of our consumers is of tantamount importance to Pueblo. Requiring us to document all consumer transactions will diminish that trust without furthering the goal of food security.

E. Six Month Effective Date Is Unrealistic for Food Distribution Industry, Particularly Given Delayed Implementation for Small and Very Small Businesses

The Bioterrorism Act directs FDA to consider the size of impacted businesses when developing the recordkeeping regulations. Toward this end, FDA has proposed to grant small businesses an additional six months to comply with the regulations and very small businesses an additional twelve months to comply with the regulations. Although we recognize the unique needs of small businesses, we are also concerned about the impact that the time discrepancy will have on Pueblo's ability to comply with the regulations six months after promulgation.

The food distribution chain is comprised of multiple components, some of which will qualify as small or very small businesses, such as independent truck operators or some direct store delivery operations. For example, some large, national baked goods companies deliver products directly to our stores through individuals who function as independent businesses, e.g., they own their own trucks, purchase the food from the vendor and sell it to the store, and hold licenses to the particular delivery routes.

If these businesses are eligible for the small business exemption, they will not be required to provide the information that we will be required to retain. We recommend that FDA either extend the exemption through all subsequent links in the distribution

chain or else recognize the interconnectedness of the systems and impose a single, more realistic effective date with which all in the food distribution chain will be able to comply, e.g., establish a universal effective date for the regulations of 18 months after Federal Register publication.

F. FDA Should Clearly Exempt Food Offered To Consumers Through In-Store Food Service Operations from Recordkeeping Requirements

The Bioterrorism Act specifically precludes FDA from requiring farms and restaurants to maintain records. FDA's proposal defines a restaurant as follows:

[A] facility that prepares and sells food directly to consumers for immediate consumption. Restaurants include but are not limited to cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens.

68 Fed. Reg. at 25238. In the preamble, FDA states that those facilities that meet the "restaurant" definition, but are engaged in other activities would be required to keep records as to those activities covered by the rules that do not meet the restaurant definition. 68 Fed. Reg. at 25195.

Today's retail food stores offer a variety of services and conveniences to consumers, including foods that are prepared in-store and ready for immediate consumption. Except for one store, Pueblo operates deli-cafeteria in all its stores, where customer can have hot prepared meals to be eaten at the store. To the extent that retail food stores operate restaurant-type facilities in the store, these should be excluded from the recordkeeping requirements, just as FDA is proposing to require restaurants to keep records of the non-restaurant activities that they conduct. Whether a coffee shop is operated by a national chain outside the four walls of our store or inside our store or whether Pueblo operates the coffee shop is irrelevant: all of these activities are properly considered restaurant functions and should be exempt from the recordkeeping regulations, regardless of their physical location.

G. Retail Store Is Not Subsequent Recipient To Distribution Center under Common Ownership

Section 414 allows FDA to require the food industry to maintain records on the immediate previous source and the immediate subsequent recipient of food products. FDA's proposed regulations define "transporters" and "nontransporters" and would require information to be maintained on both. A "nontransporter" is a person who owns food or who holds, processes, packs, imports, receives or distributes food for purposes other than transportation. 68 Fed. Reg. at 25238. A "transporter" is a person who has

possession custody or control of an article of food solely to transport the food, but does not own or hold the food for purposes other than transportation. Id.

For its operations, Pueblo operates one 350,000sq.ft. distribution center and one 10,000sq.ft. Reclaim Center. Under these circumstances where the entire distribution chain – from warehouse to retail store – is owned by a single corporate entity, once the food is received at the warehouse, we should not be required to keep records of its movement within our structure because the ownership, possession, custody and control of the food does not change. That is, once Pueblo obtains ownership of the food at the warehouse receiving dock, there is no subsequent transporter or nontransporter recipient until the food reaches the consumer. Accordingly, as the statute only permits FDA to require records on the immediate subsequent recipient and Pueblo does not have an immediate subsequent recipient until the food reaches the consumer, FDA's regulations should recognize that retailer/wholesalers under common ownership need only maintain records on the immediate previous source and are not required to track the food products from the distribution center to the retail store.

Pueblo recognizes the importance of ensuring the safety and security of our food supply and appreciates the opportunity to provide you with our comments on FDA's proposed recordkeeping regulations. We urge you to fully consider and incorporate the recommendations we have made in the final rules, particularly the one related to the inapplicability of the proposed rules to the Caribbean Jurisdictions, as recommended in Part A of this letter.

Sincerely,



CC: Hon. Aníbal Acevedo-Vilá,
Commonwealth of Puerto Rico Delegate to U.S. House of Representatives
Hon. Donna M. Christian-Christensen,
U.S. Virgin Islands Delegate to U.S. House of Representatives