



Headquarters: 400 N. Tampa Street/P. O. Box 1531/Tampa, Florida 33601/813-273-6572 Fax: 813-273-4396

1015 13 JUL-7 2003
July 3, 2003

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

**Re: Docket No. 02N-0277 – Establishment and Maintenance of Records
Under the Public Health Security and Bioterrorism Preparedness and
Response Act of 2002**

Ladies and Gentlemen:

By notice published in the *Federal Register* for May 9, 2003 (68 FR 25188), the Food and Drug Administration ("FDA") published a proposed rule that would require, among other things, the establishment and maintenance of records by certain domestic persons and foreign facilities who or which conduct certain activities with respect to food intended for human or animal consumption in the United States (the "Records Rule").

The following comments on the Records Rule are submitted on behalf of National Juice Products Association ("NJPA"), a trade association whose regular membership is comprised of 57 processors of fruit and vegetable juices and juice beverages. Those located in the United States ship and receive juices and juice beverages (in interstate, intrastate and foreign commerce), as well as ingredients used in the production of such food products. Many of NJPA's regular members located in the United States are both importers and exporters of these products, and members located in foreign countries export juices, juice concentrates and other juice beverage ingredients to destinations in the United States. Many of the Association's 51 associate members provide equipment, packaging, supplies and ingredients to juice processors in the United States, and also import juices and juice beverage ingredients into the United States. NJPA's member companies are located primarily throughout the United States, Canada and Central and South America, and represent a majority of the juice and juice beverage processors in the United States. Most, if not all, of the Association's member companies will be affected by FDA's adoption of the proposed Records Rule.

General Comments

While NJPA submitted no comments to the Office of Management and Budget on the "information collection provisions" of the proposed rule, virtually all of the proposed rule's substantive requirements relate either to the information required to be maintained by persons subject to the rule's requirements, or to FDA's access to such

02N-0277

C46

Ansley Watson, Jr., Executive Director
Direct Line (813) 273-4321

Kristen C. Gunter, General Counsel
Direct Line (941) 680-9908

Tammy G. Andis, Executive Secretary
Direct Line (813) 273-4330

information. Thus, the "substantive" and "information collection" aspects of the Records Rule are virtually indistinguishable.

NJPA agrees that FDA needs the ability to address credible threats of serious adverse health consequences or death to humans or animals, and that certain information is necessary to accomplish this objective. This does not mean, however, that FDA actually needs to inspect records in order to trace a food product or its ingredients in order to remove the product from the market to prevent serious adverse health consequences to humans or animals. In fact, Section 414(b) of the Act,¹ as added by Section 306 of the Bioterrorism Act,² arguably does not mandate that the recordkeeping requirements of the proposed Records Rule be established by FDA; that is, it can be argued that the authority granted is permissive.

Virtually all companies in the juice industry have long maintained their own information on the products they manufacture and distribute, and the ingredients used in their production, in order to have the ability to track and remove from the market any products which are adulterated, particularly those which may pose a serious health risk to consumers. These companies have developed and maintained these information systems to assure the safety of the foods they distribute, for which they are responsible regardless of any regulatory requirements imposed by state legislatures, the Congress, FDA or other state or federal regulatory bodies (e.g., they have duties to the consuming public under product liability and other legal concepts unrelated to food industry regulatory requirements).

NJPA recognizes that the state and federal governments, as well as agencies such as FDA, have an interest in promoting and maintaining the public health. Nevertheless, the "bottom line" is that it is the companies comprising the food industry (including NJPA's member companies) that must ultimately ensure the safety of the products they produce and distribute to consumers, regardless of whatever regulatory requirements the government may impose on the products or the companies responsible for their production.

In view of the information already maintained by NJPA's member companies, which permits them to trace product for purposes of removing it from the market, NJPA questions whether FDA has demonstrated in the proposal that it "needs," as required by Section 414, the records identified in the proposed rule. Further, even if the proposed rule is to be adopted with its current focus, NJPA believes that certain portions can be

¹ Federal Food, Drug and Cosmetic Act, as amended.

² Public Health Security and Bioterrorism Preparedness and Response Act of 2002, P.L. 107-188, June 12, 2002.

modified and/or clarified without detriment to the food safety objectives of the proposal as set forth in the Bioterrorism Act.

Definition of "Food"

Section 1.328 of the proposed rule would define "food" as such term is defined in Section 201 of the Act, but includes as examples of "food" items which may or may not come within the Act's definition. NJPA agrees that substances that migrate into food from food packaging constitute food, but does not agree that "articles that contact food" also constitute "food" under all circumstances. FDA should clarify that the mere contact by an article with food does not render such article "food."

Packaging

Section 306 of the Bioterrorism Act states that FDA has the authority to require certain recordkeeping as to "food, including its packaging." NJPA does not believe that food packaging other than immediate food-contact packaging defined as "food" in the Act should be included within the scope of the Records Rule. This appears to be consistent with FDA's intent in that the term "packaging" is neither defined nor used in the proposed rules.

"Perishable" Food

The Records Rule proposes to define "perishable food" (which is not defined in the Bioterrorism Act) as food that is "not heat treated, not frozen, and not otherwise preserved in a manner so as to prevent the quality of the food from being adversely affected if held longer than 7 days under normal shipping and storage conditions."³ This definition's only importance for purposes of the Records Rule is to set the time for retention of records required by the rule to be established and maintained.

NJPA agrees with FDA's decision to divide the food products subject to the record maintenance requirement into perishable and non-perishable groupings, but disagrees with the seven-day aspect of the proposed rule's definition of perishable. In addition, NJPA does not believe that whether a food has been subjected to heat treatment or thermal processing should be a factor in differentiating between perishable and non-perishable food. NJPA members consider as "perishable" those juice products which have a shelf-life of 90 days or less. If 90 days was substituted for seven days in the definition of "perishable," this would result in retention of records for perishable

³ This is the same definition contained in the proposed rule relating to Administrative Detention of Food in Docket No. 02N-0275 (see Footnote 5, *infra*). NJPA will submit similar comments in response to that proposal.

products for at least four times their shelf life.⁴ While the 90-day versus seven-day distinction between perishable and non-perishable foods may not have that much significance for purposes of the proposed Records Rule, the distinction assumes greater importance in the context of the currently proposed rule on administrative detention of foods,⁵ to which NJPA also intends to submit comments.

NJPA would support the following revised definition of the term "perishable food":

Perishable food means food that ~~is not heat treated, not frozen, and not may have been thermally processed~~ or otherwise preserved in a manner so as to prevent the quality of the food from being adversely affected if held ~~longer than 7~~ for 90 days or less under normal shipping and storage conditions.

Records to Be Established and Maintained

As added to the Act by Section 306 of the Bioterrorism Act, Section 414(b) specifies the "records" that FDA is given authority to require to be established and maintained as those

. . . needed by the Secretary for inspection to allow the Secretary 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. (emphasis supplied)

Records Required. The records required by the proposed rule to be established and maintained, however, exceed those which are "needed by the Secretary" to "identify" the immediate previous sources and immediate subsequent recipients of food. As discussed at the outset of these comments, NJPA seriously questions whether, in view of the extensive records already maintained by its member companies, FDA has met the statutory burden to demonstrate that the proposed recordkeeping requirements

⁴ The Food Marketing Institute's comments filed in this docket on August 30, 2002, suggested that "perishable" products should be defined as those having a shelf life of six months or less, and that this approach would be consistent with FDA's current records maintenance requirements under the seafood and juice HACCP regulations. See 21 CFR §123.9(b) (records for refrigerated seafood products must be retained for one year, while records for frozen, preserved or shelf-stable products must be retained for two years); 21 CFR §120.12(d) (required records must be maintained for one year for refrigerated or perishable juices and two-years for frozen, preserved or shelf-stable products).

⁵ Docket No. 02N-0275, *Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, 68 FR 25242 (May 9, 2003).

are "needed" as required by Section 414 of the Act. That is, the information "needed" by FDA to trace products and their ingredients to address credible serious health threats are already maintained by companies comprising the food industry. Whether FDA itself would ever "need" the records required by the proposed rule is also suspect, in that many if not most threats to public health will likely be dealt with directly by the responsible company without any need for FDA's access to the records required by the proposed rule. What FDA may want (and what the responsible company would likely want to provide to FDA) is the information contained in the company's records regarding the suspect product or ingredient. The specific records detailed in the proposed rule may not be needed for this purpose. NJPA suggests that the requirements (if any) of the proposed rule should be made far less specific, and simply require that companies maintain such information as may be required to effect collection from commercial distribution channels, of food as to which there is credible evidence that it poses a threat of serious adverse health consequences or death for humans or animals. Each company would then become the best judge (as it is ultimately responsible anyway for the products it distributes) of the information needed to accomplish that objective, and the best way to collect and maintain the information. This approach to the recordkeeping requirements authority added by Section 306 of the Bioterrorism Act would also permit affected companies to focus on improving, to the extent necessary and possible, the quality and retrieval time associated with their existing recordkeeping systems, which have been shown in the past to be effective, rather than on creating new systems of recordkeeping to provide FDA access to the same information.

The proposed rule would require nontransporters to keep records regarding the immediate previous nontransporter sources of food and ingredients, as well as the immediate subsequent nontransporter recipients of food they ship. Nontransporters must also keep records of the transporter from which they receive food and ingredients, and the transporters via which they send food and ingredients to other nontransporters. FDA has requested comments on whether an approach different from the proposed rule that would require or create incentives for nontransporters to obtain and keep records on all the transporters that transport food between the nontransporters, by obtaining records from the transporters, would be a reasonable interpretation of the statute. NJPA believes such an interpretation would be unreasonable because of the burden it would create for nontransporters. Aside from the added burden on nontransporters, the currently proposed rule permits both transporters and nontransporters to create the records contemporaneously with their individual contact with a shipment of food or ingredients and the persons from or to which the shipment moves. They can better handle the recordkeeping for these portions of a product's movement than they can for portions of its movement with which they have no contact. It also reduces the numbers of records any person in the chain of a product's movement must maintain and search in the event a particular article of food is affected by an event of bioterrorism.

"Responsible Individual". Proposed §1.337(a)(1) requires not only the name of the entity constituting the nontransporter immediate previous source from which food was received, but also the name of the "responsible individual." While FDA has sought comments on whether the "responsible individual" required by proposed §1.352(a)(1) to be identified by a transporter immediate previous source should be the operator of the conveyance or someone else within the transportation company who has overall responsibility for the vehicle and the food being transported, the preamble to the proposal gives no guidance with respect to FDA's intent on this item in the case of a nontransporter immediate previous source.

The name, address and phone number of the entity constituting the nontransporter immediate previous source should provide information sufficient for FDA to trace the food back to such immediate previous source, and the requirement to record the "responsible individual" at such entity should be deleted from the information required by this section, as well as from proposed §§1.337(a)(6), 1.345(a)(1) and (6), and 1.352(a)(1), (2) and (6). To the extent information akin to "responsible individual" is needed at all, NJPA submits that such information should be described as "contact information" or "emergency contact information," which will have already been provided under FDA's facility registration requirements.⁶ This would provide FDA, if necessary, with the information needed in each of these instances to contact the appropriate sources of information at the immediate previous or subsequent transporter or nontransporter, without the necessity for the recordkeeper's having to make a judgmental determination with respect to the "responsibility"⁷ of some named individual. If FDA determines there is a need to determine a particular person is "responsible" for purposes of these sections of the proposed rule, then it needs to define or clarify its intended meaning of the term "responsible" in the final regulation, and discuss the concept of "responsibility" in the preamble thereto. Otherwise, affected recordkeepers (transporters and nontransporters alike) will be required to guess FDA's intent in this regard, at the risk of committing a prohibited act under Section 301 of the Act.

Access to Records

Records Access Authority. As added to the Act by Section 306 of the Bioterrorism Act, Section 414(a) grants FDA authority to access and copy only certain records relating to food and only if the Secretary has a "reasonable belief" that the food is adulterated and presents a threat of serious adverse health consequences or death to

⁶ Docket No. 02N-0276, *Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, 68 FR 5377 (February 3, 2003).

⁷ Neither the term "responsible" nor the concept of "responsibility" is defined or discussed in the Bioterrorism Act or the preamble to the proposed rule.

humans or animals.⁸ If the "reasonable belief" standard of the statute is satisfied, Section 414(a) authorizes the Secretary to inspect and copy those records "relating to such article that are needed to assist the Secretary in determining" whether the food is, in fact, adulterated. This would consist only of those records "relating to" the article(s) of food as to which the Secretary had developed the previously mentioned "reasonable belief." Thus, FDA's records access under Section 414(a) is subject to a public health limitation (in addition to the limitations imposed by the Fourth Amendment to the U.S. Constitution, which will not be discussed in these comments), and is granted only to permit inspection of those records that are necessary to address serious adverse health consequences or death to humans or animals. Under the circumstances, NJPA believes that Section 414(a) requires FDA to make a determination (*i.e.*, hold a "reasonable belief") that a particular food is adulterated to the extent it presents a threat of serious adverse health consequences or death *prior to* the agency's seeking access to the records of a nontransporter or transporter of such food. Although this interpretation of the records access authority granted by Section 414(a) is not set forth in the preamble to the proposed Records Rule, NJPA urges that it be acknowledged by FDA. The records access provided by Section 414 may not be used by FDA to conduct fishing expeditions, but only to access the records related to those *specific* articles of food as to which the agency has developed the reasonable belief specified in the statute and which the agency *needs* to address the threat. The amendment to Section 704(a) of the Act is subject to the same limitations.⁹

Written Notice. While both Section 414(a), as added to the Act by the Bioterrorism Act, and proposed §1.361 make reference to a requirement that a person permit FDA access to the referenced records relating to certain food "upon presentation of . . . a written notice to such person," the proposed rule should be clarified to require that the written notice set forth (1) the specific article(s) of food as to which records are being requested and (2) the basis upon which FDA has arrived at its "reasonable belief" that the article(s) is or are adulterated and presents or present a threat of serious adverse health consequences to humans or animals. Requiring the written notice to contain these items of information would serve a two-fold purpose. First, it would permit the affected company, from which the records were being requested, to know which records were actually being sought. Second, it would provide the legal basis for the request.

⁸ NJPA believes this is a two-pronged standard in that the "reasonable belief" must be *both* that the food is adulterated *and* that it poses a threat of serious adverse health consequences or death. A reasonable belief only that a food is adulterated would not satisfy the statutory standard for records access with respect to the food involved.

⁹ It is NJPA's position that only a *prior* reasonable belief by the Secretary that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals will trigger the applicability of the records inspection authority granted by Section 414.

Because of the need to ensure that the authority to request records covered by the proposed rule is exercised only in the circumstances permitted by new Section 414 of the Act, NJPA also suggests that FDA give serious consideration to requiring prior approval of any such request by the FDA District Director in whose district the implicated food is located, or by an FDA official senior to such District Director.

Protection of Sensitive Information. Section 414(d)(4) of the Act, as added by the Bioterrorism Act, provides that the record establishment and maintenance and records access provisions of Section 414 shall not be construed to extend to "recipes for food, financial data, pricing data, personnel data, research data, or sales data (other than shipment data regarding sales)." In addition, Section 414(c) provides that the Secretary "shall take appropriate measures to ensure that there are in effect effective procedures to prevent the unauthorized disclosure of any trade secret or confidential information that is obtained by the Secretary" pursuant to Section 414.

While proposed §1.362 recognizes the records excluded by Section 414(d)(4), it is still possible that FDA may obtain certain of this information via documents provided by a person pursuant to records request. It may be possible to limit the occasions on which FDA receives such data (or other trade secret or confidential information) by permitting a person subject to the requirements of Section 414 either to redact such information from records properly sought by FDA pursuant to that section, or to create a separate document containing only that information FDA is entitled to inspect. This concept will be mentioned further in connection with NJPA's comments on the record availability requirements of proposed §1.361. With respect to the occasions on which FDA does receive information entitled to protection from disclosure, the Records Rule contains nothing acknowledging the provisions of Section 414(c).

Availability of Records. Section 414(a) contains no specific requirements with respect to the time within which, following a request by FDA, a person is required to provide access to the records enumerated in the section. All the statute states is that a person must permit access to the records, "upon presentation of appropriate credentials and a written notice . . . , at reasonable times and within reasonable limits and in a reasonable manner."

Notwithstanding the purpose of Section 414, NJPA submits that the four-hour and eight-hour time periods following a request for access set forth in proposed §1.361 are unreasonable. Further, many (if not most) of NJPA's member companies would not likely be able to comply with these requirements as to the records (or all of the records) sought. In the preamble to the proposal, FDA itself recognizes that

[t]he most common problem encountered by the FDA in a tracing investigation has been a lack of ready access to records. . . . In FDA's

experience, rarely do firms make records available within 24 hours. The usual timeline is 2 to 3 days. . . .

68 FR 25199.

Particularly in view of the fact that the Bioterrorism Act (and proposed §1.363) makes the failure or refusal to make the required records available a prohibited act under Section 301 of the Act, NJPA submits that the second sentence of proposed §1.363 should be amended to read:

Such records and other information must be made available as soon as reasonably possible, and within a period not exceeding 4 24 hours of a request ~~if the request is made between 8 a.m. and 6 p.m., Monday through Friday, or within 8 hours of a request at any other time~~, by an officer or employee duly designated by the Secretary who presents appropriate credentials and a written notice.

The changes suggested above will permit a more reasonable time period within which an affected firm may respond (without being deemed in violation of Section 301 of the Act) to a request by FDA for access to records needed to assist in determining whether a specific food is adulterated and presents a threat of serious adverse health consequences or death. The 24-hour time period will permit sufficient time for the affected firm to insure that the information provided to FDA is accurate, and can be reconciled in terms of inventory received or produced, inventory on hand, and product shipped, etc. In such a case, the affected firm would likely make every effort (and would likely have already undertaken) to gather the records needed by FDA (or the firm itself) to conduct a tracing investigation, but would not be required by the rule to do so. These suggested more reasonable time frames for providing access to the required records would be more in line with FDA's "rare" experience, and still enable FDA to effectively and efficiently perform a tracing investigation.

More importantly, the changes suggested would not preclude the affected company from providing the *information* contained in the records requested as soon as it could be retrieved, notwithstanding the actual records might not be made available until later. As discussed previously in these comments, FDA's focus should be on the information contained in the records, rather than the records themselves. The changes suggested would also permit the affected company, in consultation with FDA, to prioritize the information (or records containing the same) in terms of that which is deemed most time-critical for purposes of addressing the potential threat to public health.

In addition, in a case where FDA actually needed to view the records themselves, to the extent the information required to be maintained by the affected firm

Dockets Management Branch
Docket No. 02-0277
July 3, 2003
Page 10

under proposed §§1.337 and 1.345, or proposed §§1.351 and 1.352, contain information excluded from FDA's access authority under the Bioterrorism Act and proposed §1.362, or which is otherwise confidential, the affected firm may have time to either redact such information from the source records (purchase orders, bills of lading, etc.) or create separate records containing the information required by Section 414 but not including the §1.362 or other confidential information. The suggestion is to permit the food and transportation industries to create separate records containing only the *information* required by the proposed rule when the standards set forth in Section 306 of the Bioterrorism Act create the need for FDA to have access to such information, thereby avoiding the need to protect sensitive information not required by the act to be disclosed.

NJPA fully supports the purpose and intent of the Bioterrorism Act, but believes the proposed Records Rule would require the food industry to create and maintain records which are in duplication of other records containing much, if not all, of the required information. It also believes that the purpose and intent of the act can be satisfied while permitting nontransporters and transporters alike more time within which to respond to a request by FDA for access to records containing information required by the rule to be maintained.

NJPA hopes FDA will find the foregoing comments useful as the proposed rule is finalized later this year. If we can provide any additional information in this regard, or be of assistance in any other way, please do not hesitate to contact me at 813-273-4321 or aw@macfar.com.

Respectfully,



Ansley Watson, Jr.
Executive Director

AWjr/a