



United Fresh Fruit &
Vegetable Association

July 8, 2003

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

Re: Docket No. 02N-0277. Proposed Regulation for the Establishment and Maintenance of Records under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. (68 Federal Register 25166; May 9, 2003); Submission of comments.

Dear Sir or Madam:

The United Fresh Fruit & Vegetable Association (United) is pleased to provide comments on the proposed rule for the contained in Docket Number 02N-0277. This proposed rule was developed by the Food and Drug Administration (FDA) to fulfill their obligation set forth by the provisions of Title III, Subtitle A, Section 306 (Establishment and Maintenance of Records) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("Bioterrorism Act"). The summary of the Bioterrorism Act legislation is as follows:

- Amends Chapter IV to authorize the Secretary to have access to certain records when there is 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. It applies to all records relating to the manufacture, processing, packing, distribution, receipt, holding, or importation of the food. It excludes farms and restaurants. It also excludes information such as recipes, financial data, personnel data, research data, and sales data (other than shipment data regarding sales).
- Requires the Secretary to promulgate proposed and final regulations within 18 months of enactment to establish requirements for the establishment and maintenance of records needed to determine the immediate previous sources and the immediate subsequent recipients of food.
- Directs the Secretary to consider the size of a business in promulgating the regulations.
- Directs the Secretary to take appropriate measures to ensure protection from disclosure of sensitive information.

Introduction

United is a national trade association representing member growers, shippers, packers, processors, marketers and distributors of fresh produce in the United States. United members provide the leadership to shape business, trade and public policies that drive our industry. Working with thousands of industry members, United provides a fair and balanced forum to promote business solutions; helps build strong partnerships among all segments of the industry,

promotes increased produce consumption; and provides scientific and technical expertise essential to competing effectively in today's marketplace.

The dramatic impact of the terrorism attacks of September 11, 2001 has led to a new focus in public policy aimed at promoting greater safety and security and preventing terrorist action. As our members provide over 1,000 different fresh fruits and vegetables to American consumers from both domestic growers and around the world, we take seriously our responsibility for prevention, detection, and all necessary actions to protect consumers from intentional contamination of our products.

We encourage FDA to issue final regulations that allow flexibility and take into account the produce industry's diversity of products and complexity of global production and distribution. Flexibility is critical in that many prescriptive recommendations would be inappropriate or not applicable to our diverse industry. Thus, the agency's goal in promulgating regulations should be to work with the food industry as efficiently and effectively as possible to address credible threats without imposing undue burdens.

We commend the U.S. Food and Drug Administration (FDA) for its leadership in working with the private sector, including our industry, to ensure that appropriate steps are in place to minimize the potential of terrorist action to contaminate foods. However, let us keep in mind the American food supply continues to be the safest in the world. Continuing to ensure the safety and security of fresh fruits and vegetables whether produced domestically or abroad is a top priority of the entire produce industry. With this in mind, we have serious reservations about certain provisions of the proposed rule for Establishment and Maintenance of Records.

Background

The proposed rule would require the establishment and maintenance of records by certain domestic persons who manufacture, process, pack, transport, distribute, receive, hold, or import food intended for human and animal consumption in the United States. In addition, these requirements apply to certain foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States. Such records are to allow for the identification of the immediate previous sources and the immediate subsequent recipients of food. The FDA expects that the requirements the agency is proposing in these regulations, if finalized as proposed would result in a significant improvement in FDA's ability to respond to and help contain threats of serious adverse health consequences or death to humans or animals from accidental or deliberate contamination of food.

The Act is widely comprehensive, and affects the food industry in many ways. The general purpose throughout the Act is to determine if credible evidence exists that the food presents a threat of serious adverse health consequences or death to humans or animals. Access to certain records when there is a reasonable belief by the Secretary that a food is adulterated or presents a serious adverse health threat is a necessary component for a regulatory agency. However, the government's most important investment in either food safety or food security is in *prevention*, not tracking records after the fact. This is particularly important with highly

perishable products that move rapidly through distribution systems and are quickly consumed. Unlike many processed food products, a certain lot of fresh produce is likely gone from the food distribution pipeline before public health authorities even learn of a threat or contamination event.

The proposed rule indicates that the purpose of records maintenance and access is to allow FDA to improve their ability to respond to threats which could cause serious health consequences to humans or from contamination of food deliberately or accidental. The information required by FDA is too specific and does not consider what may already be available and sufficient for the agency to respond quickly to an incident. By not considering what is already available, the proposed regulation is seeking tracking details that will not be cost effective, but more so unnecessary to achieve to meet the purpose of the regulation.

Procedures for record access authority

The proposal fails to include adequate procedures for the exercise by FDA of its record access authority. For example, although the proposal states that the records access will be triggered by the presentation of “appropriate credentials and a written notice,” there is no indication that the written notice will describe the basis on which FDA has concluded that the high statutory hurdle for records access has been met. Further, there is no indication that FDA will require that a supervisory person approve the request for records access so that individual inspectors could not legitimately request access on their own initiative.

FDA interstate commerce authority

Under FDA’s interpretation of the Bioterrorism Act, the scope of the records maintenance provision is not limited to persons engaged in interstate commerce. FDA is proposing to assert jurisdiction over food, whether or not it enters interstate commerce. This federal government’s assertion of power to regulate food in intrastate commerce may be unconstitutional. FDA’s interpretation that the Bioterrorism Act extends the agency’s jurisdiction over food that does not enter interstate commerce is inconsistent with limitations imposed by the Commerce Clause of the U.S. Constitution. FDA asserts that Congress in the Act intended to give the agency authority over detention of food in purely intrastate commerce as well. The Commerce Clause generally restricts Congress’ power to regulate purely intrastate commerce. Congress cannot delegate power to FDA that which it does not possess. In fact, FDA should have assumed that Congress did not intend to violate the Constitution, and should amend the proposed rule accordingly.

Timeframe to make records available

Under the proposal, FDA states that upon request, records must be “readily available for inspection and photocopying or other means of reproduction.” Specifically, FDA proposes to require that records be made available within 4 hours for requests made between 8 a.m. and 6 p.m. (local standard time), Monday through Friday and within 8 hours for requests made at all other times. In the discussion in the preamble to the proposal, FDA suggests that: (1) these time

periods are necessary for it to effectively conduct “trace back” investigations; and (2) the time periods are considerably shorter than FDA’s experience with records requests in the past.

Four hours is too short of time to legally require turnaround of complete documentation of records for a food item. The availability of knowledgeable personnel to access specific records, the verification of completeness and accuracy of the records, and the transmission of data to appropriate authorities may require additional time. Clearly, providing only a four hour requirement regardless of whether it is during normal business hours will result in confusion impede the process further.

While it is likely that four hours will be sufficient in many cases, as all responsible parties will quickly respond to an emergency, there may be some circumstances when more time will be needed. United proposes that twenty-four hours should serve as the maximum amount of time for response with complete and accurate data. Twenty-four hours should serve as the single standard, regardless of what time of day the FDA request is made. As stated in the proposed rule, FDA’s experience in receiving records to a request is “2 to 3 days.” In fact, FDA admits that “rarely do firms make records available within 24 hours.” Thus, a mandatory twenty-four hour turnaround time would improve current conditions. This timeframe is much more reasonable and manageable for a legal limit of time when violations and penalties can be assessed for those exceeding the limit.

The Agency should focus on obtaining information expeditiously manner and not the timeframe to obtain them. With millions of foods transported annually, many firms utilize various data systems and have implemented records maintenance procedures to meet their specific company needs. Compliance with this new rule would require establishing new protocols and developing new database systems, which would require a substantial capital investment.

Confidential information

The potential disclosure of confidential corporate information to FDA is worrisome: FDA has failed to set forth in any detail the procedures that it will use to maintain the confidentiality of trade secret and other confidential commercial information that it may obtain through its new records access authority. The Agency should in the final regulation, clearly detail these procedures to ensure protection of this type of information.

“Perishable” food definition

“Perishable food” would be defined as “food that it 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.” The proposed definition is modeled after the definition of “perishable commodity” in FDA’s Regulatory Procedures Manual.

However, the U.S. Department of Commerce's NIST Handbook 130 Regulations for Uniform Open Dating Definition of Perishable Food These definitions have thirty years of regulatory history (thus avoiding conflict with state and local regulations currently on the books) and industry-wide acceptance. These definitions are:

- "Perishable Food means any food for which a significant risk of spoilage, loss of value, or loss of palatability within 60 days of the date of packaging"
- "Semi-Perishable means any food for which a significant risk for spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 minimum of 60 days, but within 6 months, after the date of packaging"
- "Long Shelf-Life means any food for which a significant risk of spoilage, loss of value, or loss of palatability does not occur sooner than six months after the date of packaging, including foods preserved by freezing, dehydrating, or being placed in a hermetically sealed container"

We recommend the Agency consider revising the current definition to reflect this existing federal definition for perishable products. In keeping with the suggested use of the Department of Commerce definition for perishables, why should records be maintained for an additional 22 months after a product has been consumed? Six months is more than sufficient time to maintain records necessary for any traceback investigation related to food safety or security risks in the produce industry.

“Farm” Definition

We commend FDA for putting forth such an exemption; however, the definition of a “farm” outlined by FDA in the proposed rule is far too narrow in scope to cover all the parameters of farming operations in the produce industry. Historically, farming has played an important role in our development and identity as a nation. The official definition of a farm in the United States is determined by the U.S. Department of Commerce and as might be expected, this definition has a commercial orientation. Variations of this official definition have been around since 1850 when the first census of agriculture was taken. According to U. S. Department of Agriculture’s National Agricultural Statistics Service, since 1974, a farm has been defined as "any establishment from which \$1,000 or more of agricultural products were sold or would normally be sold during the year." Generally, FDA has defined exemptions, related to the produce industry, in the Food, Drug, and Cosmetics Act (FD&C Act) based on the definition of a "raw agricultural commodity." According to the FD&C Act, the term "raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing. To assist in defining a farm for the purpose of the Bioterrorism Act, we again recommend FDA use a definition for agricultural operations similar to that set forth in the California Food and Agriculture Code:

“For purposes of this section, the term "agricultural activity, operation, or facility, or appurtenances thereof" shall include, but not be limited to, the cultivation and tillage of the soil, dairying, the production, cultivation, growing, and harvesting of any agricultural

commodity including timber, viticulture, apiculture, or horticulture, the raising of livestock, fur bearing animals, fish, or poultry, and any practices performed by a farmer or on a farm as incident to or in conjunction with those farming operations, including preparation for market, delivery to storage or to market, or delivery to carriers for transportation to market.”

The definition of “farm” should also include typical post-harvest operations, such as packing/packaging, washing, grading, waxing, sizing, cooling, conventional storage, controlled-atmosphere storage, transportation to and from the fields or farm, transportation to storage or processing facilities, and packing or holding activities that are incidental to farming. The definition in the proposed regulation also includes “facilities that pack or hold food, provided that all of the food used in such activities is grown or raised on that farm or is consumed on that farm.” By including these facilities under the “farm” exemption, FDA accurately recognizes activities that are “incidental to farming” in which “most farms engage in (e.g. holding and packing of harvested crops).” The holding and packing of harvested crops are traditional farming practices, and such activities should continue to be included in the “farm” definition in the final rule. We request that FDA further provide clarification to the “farm” definition by acknowledging that post-harvest activities, if all food is grown on the farm, also fall under the scope of “activities incidental to farming.”

“Food” Definition

The definition of “food” in the proposed regulation is far encompassing. FDA defines “food” in proposed §1.328 as “substances that migrate into food from food packaging,” which include “immediate food packaging or components of immediate food packaging that are intended for food use.” The proposed rule also explains that “food contact substances” are included in the definition of “food.” For many products in the produce industry, conventional interpretation of FDA’s ambiguous definition of “food” would mean that the plastic wrapping inside the corrugated boxes and product brand label (sticker with PLU information) would be considered as “food” and, therefore, subject to the recordkeeping requirements. The establishment and maintenance of detailed records associated with the manufacture and distribution of plastic wrapping and brand labels would be a burdensome and challenging task for the produce supply chain. Thus the regulation should limit the definition of “food” to food, not its packaging.

“Outer” packaging

FDA is seeking comment “on whether the level of risk to human and animal health from potential contamination of outer packaging is high enough to warrant inclusion of outer packaging in the final regulations.” United agrees with FDA’s conclusion that “the risk to human and animal health from contamination of outer food packaging is relatively small compared to the risk from contamination of the immediate packaging that comes in direct contact with food.” Therefore, outer packaging should not be included in the final regulations.

“Holding” of food

Similar to United's comments filed with FDA in consideration for the final rulemaking on section 305 of the Bioterrorism Act (Food Facility Registration), United believes that there are certain areas in the supply chain that provide temporary space for the food during transit and that these areas should not be considered as "holding" or "storing" food and subject to either the food facility registration and recordkeeping requirements. Sites that serve as transitory staging areas where produce is momentarily held prior to transportation should be exempted from the definition of "holding" in the proposed regulation. Given the perishable nature of the product and the desire to rapidly transport the fresh commodity, produce moves from these staging areas as quickly as possible.

"Responsible individual"

It is not necessary for FDA to have the "responsible individual" by name, but rather the emergency contact information needed to meet the intent of the records regulation. The information FDA is requiring is too specific and would need updated due to the frequent changes in the "responsible individual" during operations. We believe the necessary information provided during the registration process the information can be retrieved readily and will suffice during an investigation

Product coding

In many cases computer programs have abbreviated the name of the food, variety, style, package size, and package type. The FDA proposal requires all of this information to be spelled out which could result in a change in computer programs and working forms used for record keeping. The abbreviated format used traditionally by many food companies should be sufficient for FDA to identify foods under question in a timely manner.

Lot code tracking

The proposal states if lot codes are available they shall be tracked forward in each step of the produce distribution system. The failure to do this or to error in transfer of a piece of the code is a prohibited act and subjects a firm to civil and criminal penalties. Therefore, it discourages the development of lot coding systems on food containers. Lot code information should therefore be removed from the final regulation. Due to the impractical burden that would be placed on the distribution chain, we encourage FDA to not focus on lot-level tracking, but rather on the company's ability to provide source information on products. United believes that current systems in place to recall products through written notification are the most practical way to identify and remove products from the distribution system.

Effective date of implementation

It is impossible to imagine that the entire food industry under FDA jurisdiction will be able to implement this proposed rule to capture the necessary information requested by the Agency in the 6 to 18 month phase-in period. While we commend the Agency for the phase-in

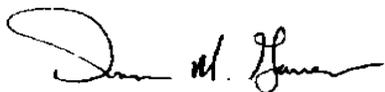
consideration based on business size, we anticipate that the collective food industry could reasonably take 5 to 7 years to develop and implement programs necessary for the records requirement.

Conclusion

In conclusion, the produce industry has grave concerns regarding the economical impact the proposed regulations would incur as currently written. Regulations should not impose unnecessary and burdensome requirements on produce companies. While farms may appear exempt once they sell a product for food the record keeping requirements begins at that point. This regulation has major economic impact for the food industry and has not been properly reflected in the FDA economic justifications. The FDA has not considered several factors influencing current international trade when developing the proposed regulation. Many companies as previously mentioned do not currently have the technology, manpower, or capital to accommodate the additional records establishment and maintenance requirement. The recordkeeping and maintenance process needs to be as simple as possible and not unnecessarily disrupt the flow of commerce. If even a small percentage of produce are delayed or removed from the marketplace, the cost implications could be immediate and dramatic.

The produce industry is committed to ensuring the security of its products. The industry is proud of the contribution it makes to the health of Americans by providing wholesome foods essential for good health. It is important to always consider that increasing the consumption of fresh fruits and vegetables is a critical component of public health, and that risk management steps are properly weighed with the public health impact on the cost and availability of fresh produce. Thank you for the opportunity to comment. We look forward to continuing to work together with the FDA on these important matters.

Sincerely,

A handwritten signature in black ink, appearing to read "Donna M. Garren". The signature is fluid and cursive, with a large initial "D" and "G".

Donna M. Garren, Ph.D.
Vice President, Scientific and Technical Affairs