



International Dairy Foods Association
 Milk Industry Foundation
 National Cheese Institute
 International Ice Cream Association

July 8, 2003

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

Subject: Docket No. 02N-0277 - Establishment and Maintenance of Records

To the Dockets Management Branch:

The International Dairy Foods Association (IDFA) is the Washington, D.C.-based organization representing the nation's dairy processing and manufacturing industries and their suppliers. IDFA is composed of three constituent organizations: the Milk Industry Foundation (MIF), the National Cheese Institute (NCI) and the International Ice Cream Association (IICA). Its 500-plus members range from large multinational corporations to single-plant operations, and represent more than 85% of the total volume of milk, cultured products, cheese, and ice cream and frozen desserts produced and marketed in the United States - an estimated \$70 billion a year industry.

IDFA strongly supports the concept and provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) and also supports Food and Drug Administration's (FDA) critical role of ensuring the safety and wholesomeness of the American food supply. In addition to support for the Bioterrorism Act's mission, IDFA offers the following comments and suggestions regarding the FDA's proposed regulation on establishment and maintenance of records published in the Federal Register on May 9, 2003.

We will address the following issues in these comments:

1. FDA should focus on the critical purpose of the Bioterrorism Act.
2. Requirements for access to and copying of records need to be consistent with the law.
3. FDA's acquisition of records will not obviate the need for recalls or cooperation.
4. FDA's should eliminate the lot or code number or other identifier requirement
5. Time differences with various compliance deadlines may cause problems.
6. The "perishable food" definition is confusing.
7. FDA should eliminate the need for a "responsible individual."
8. FDA is interpreting the term "food" too broadly.
9. FDA's record retention period is too long.

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Issue #1 - FDA should focus on the critical purpose of the Bioterrorism Act

The critical purpose of the Bioterrorism Act is to enhance the safety of this nation and with respect to FDA's mission, to ensure the safety and security of the food and drug supply. In fulfilling Congressional mandates, FDA should not lose sight of that purpose. IDFA understands that Congressional mandates and global circumstances have placed an enormous burden on FDA and IDFA commends FDA for its efforts thus far and for the openness and cooperation that FDA has shown to the regulated community. While IDFA would be pleased to limit these comments to laudatory remarks, IDFA believes FDA's proposals have gone beyond the core purpose of the Bioterrorism Act.

While understandable under the circumstances, FDA needs to contemplate whether finalized versions of what it has proposed will enhance or detract from food security and safety. FDA should not finalize any regulation, or portion thereof, that undermines safety or security. In assessing whether that occurs, FDA should consider the effect on existing business practices or systems that are effective in providing safety and security in the food industry. If practices or systems are in place that are effective, FDA should focus on efforts on ways to improve matters.

Issue #2 - Access to and copying of records needs to be consistent with the law

The Bioterrorism Act requires that access and copying of company records be done upon written notice. The Bioterrorism Act and the proposed regulation are, however, silent as to who has the authority to issue such a written notice. IDFA believes that FDA's access to records needs to be bounded by appropriate safeguards so that any such action is consistent with Constitutional law and, in particular, the Fourth Amendment. In essence IDFA urges FDA to limit the authority to issue a written notice to the district director of the district in which the facility is located.

IDFA envisions that unless appropriate safeguards are established now, FDA inspectors may at times request access to records when the situation does not warrant such action. By establishing the need for such an order to come from the district director, IDFA is confident that such power will be reasonably exercised and that neither an FDA inspector nor facility personnel will be placed in the uncomfortable position of trying ascertain whether such a request is warranted.

Issue #3- FDA's acquisition of records will not obviate the need for recalls or cooperation

Based on FDA's statements in the May 7, 2003, satellite downlink presentation and subsequently in public meetings, IDFA understands that FDA hopes that requiring precise detailed shipment-specific records for food products including information on brand, size, variety, and lot number will enhance FDA's ability to trace the potential sources of contamination and the identity of all recipients of the potentially tainted food products. IDFA understands FDA's desire to have such information; unfortunately, IDFA believes that the vast majority of companies in the food processing and, in particular, distributing channels cannot currently provide such information. Even if it were technologically feasible this requirement will be quite costly to implement. Inasmuch as it will be costly, one should consider the benefits, which IDFA does not believe are commensurate with the costs.

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While many, if not all, dairy processors currently are able to tell FDA the immediate prior source of ingredients in their products in accordance with the regulation, there is an inability to provide extensive information as to whom the immediate subsequent recipients are if FDA requires that information to include the identification of a lot or code number. As FDA is undoubtedly aware there will be numerous instances when an order is picked from a cooler, or warehouse to fill the needs of a specific customer. In many circumstances that will require the inclusion of the same size, type and brand of product from different production runs with different sell by dates. Please note that it is IDFA's understanding that a sell by date will be deemed to be a "lot or code number or other identifier" which, since it exists on the product package, will become part of the recordkeeping requirements. The complexities of requiring this type of information to be linked throughout a product's life are discussed more thoroughly in Issue #4 below.

Upon reflection, it appears that FDA is seeking to require that businesses provide excessively detailed information so that FDA can acquire, copy and remove those records and independently identify all sources and recipients of food ingredients and products. IDFA is concerned that FDA pursuing such a course of action independently is likely to result in mistakes and will be considerably less efficient than working cooperatively with industry to track foods and ingredients. In addition, and more importantly, even if FDA has that information, it will be of little use considering that FDA will not have access to information about the single most important entity in the chain - the final recipient, that is, the consumer.

If FDA becomes aware that a food presents a risk of serious adverse health consequences or death to humans or animals (SAHCODHA), there is only one way to handle such situation -- by the invocation of a Class I recall. Class I recalls are public and are the only way that a consumer can be protected given a SAHCODHA situation. Class I recalls work and can quickly eliminate problems whereas record keeping, will, at best, get a message to the retail locations where products were placed on sale to consumers.

Over the course of time, IDFA, its members and FDA officials have had numerous opportunities to work closely together. The cooperation and respect that exists today, is in all likelihood, an outgrowth of an understanding that each entity has its own special talents and expertise and that in certain situations, the association, its members and FDA can accomplish things that independently would never be successful. By working together on numerous fronts, we have and will continue to improve the safety and security of the food supply.

As identified above, FDA's promulgation of a regulation that requires the documentation of records to a degree of specificity so that FDA could independently track and trace all potential sources and recipients of a contaminated product probably exceeds the statutory mandates and ignores the cooperative history. Food processors and FDA must continue to work together and not construe Congress' intent to fortify and guarantee FDA's right to have access to meaningful information with a mandate that FDA be able to do everything on its own.

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As stated in the introductory paragraph, IDFA believes little will be gained if FDA requires industry to provide copious amounts of information, and perhaps implement an intricate new product tracking system. Class I recalls will continue to be the appropriate means by which a potential hazard is handled. Requiring the expenditure of significant resources to develop a new system in the absence of a Congressional mandate or a genuine need is questionable. FDA should continue to rely upon the proven capabilities of Class I recalls and cooperation with the food industry.

Issue #4 FDA's should eliminate the lot or code number or other identifier requirement

To understand the issues involved with requirements stemming from any need to link sources and recipients of product with lot or code numbers associated with packaging, ingredients and finished product, IDFA staff recently visited a dairy processing facility. This visit was conducted only after extensive discussions of the proposed regulation and its ramifications with members and underscores our interest in making sure we properly understand the situation. Our conclusion is that is unlikely that dairy processors will be able to meet the requirements of the proposed regulation.

Lot codes are far more prevalent than FDA's proposal assumes. Lot codes are present and associated with cups used for yogurt, sour cream and cottage cheese, pre-made plastic bottles, lids, caps, nearly all ingredients -- virtually everything that goes into a packaged finished product. In many situations, there are also alpha-numeric codes stamped directly onto the packaging.

For example, during a production run of cottage cheese IDFA staff sampled three cottage cheese cups and three lids and found that three unique codes existed on the lids (409F4-3, 409F4-2, 409F4-14) selected and three more unique codes existed on the cups (40924T1-3, 40924T1-9, and 40924T1-6). The codes are on the inside of the lid and are difficult to find. IDFA envisions that any combination of cups and lids could exist so with this limited sample, so in the small subset of a production run, there are nine possible combinations for the same product. IDFA noted that in this instance, cups and lids were being sourced from about twenty different boxes, meaning the reality is that a much higher number, in the realm of 100 or more combinations, is probably more likely. Tracking those combinations is simply impossible given the location and order by which a specific lid is applied to a specific container. Further, the codes references here on the cups and lids are "code numbers." In addition, the cups and lids come from cases that have a "lot #" which can and does vary by case, adding more complexity.

Cottage cheese, sour cream and yogurt are not alone. Milk jugs are problematic as well. Jugs themselves have codes -- multiple codes in most cases. The ubiquitous date code is on milk and many other dairy products is familiar to most consumers and regulators. While some facilities use a date only, others add information they find useful that may include the filler number, the operator's number or alphabetic code, or the time of day the product was filled, or all or some combination. If two or more employees are involved in a production run on the same line, two or more codes will exist for that same run. If the facility adds the time of day or filler number, the volume of codes increases dramatically. This additional information can be extremely useful to a processor in tracing problems and irregularities when they occur, but the schemes and systems were simply not designed to be used to trace forward.

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If tracking a milk jug forward with the above date coding scheme was not difficult enough, consider that the empty jug itself carries variable codes. Typically there is a code on the bottom of each jug that corresponds to the manufacturer of the blow mold. In addition, since blow molding machines usually blow more than one bottle at a time, a designation is molded into each bottle to identify the particular mold from which it came. The facility IDFA staff toured, runs five separate blow molding machines. Each machine blows six jugs simultaneously. Four of the machines blow one gallon jugs and the remaining machine blows half gallon jugs. When the fluid milk fillers are filling gallon jugs most of the blow molding equipment is in operation. Therefore, the gallon jugs will have twenty four precisely different sources and the code numbers on those bottles will precisely identify which of the twenty four molds made it. That precise information is extremely useful in tracing a problem in a blow mold that may be causing leaky milk jugs in the marketplace. But, requiring a processor to identify which of those twenty four variants went to its hundreds or thousands of customers would be an enormous burden.

Further, while the foregoing discussion has focused primarily on being able to track product and packaging during production, when a dairy product is processed and packaged it is ultimately placed in the cooler, traceability with lot numbers and codes at this point becomes even more complex. Multiple lot numbers and codes may exist on the same stock keeping units (SKU) and even the best planned system can suffer as a result of human error. The only way to catch human error that is introduced in the cooler would be to require that each and every unit be checked as it is loaded onto a the truck. As FDA can imagine, an endeavor such as that would be extremely labor intense and costly.

Despite the identified problems with tracing and tracking product with lot or code numbers, the dairy processing industry is able to utilize considerable information in its possession and effectuate Class I recalls in an appropriate and responsive manner. For example, a processor can currently track who processed a product, when, the sources of the raw materials and packaging materials in a matter similar which FDA outline as acceptable for bulk ingredients.

In addition, FDA should be aware that the multitude of coding schemes in use by the industry can provide very helpful and precise information to third parties as well. For example, only last week, federal investigators came to IDFA's offices with evidence they had acquired during a criminal investigation and asked for our assistance in understanding certain elements in that evidence. The evidence was packaging material. Upon examination, IDFA staff were able to identify the precise facility that was source of the unlabelled packaging. Further, IDFA staff did so in 15 minutes using materials and information solely located within IDFA offices.

Finally, the proposed regulation includes an interesting idiosyncrasy in that it only requires a lot or code number or other identifier of the food *to the extent this information exists*. In essence, if a food processor utilizes some form of product coding scheme they will be subjected to a significant additional burden of having to link and trace all shipments of its food products. The failure to do so will be a prohibited act which could result in a criminal prosecution. On the other hand, there is no requirement to have a coding scheme. So, unless a company is doing so due to a state law or other

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requirement, it is possible some processors would abandon their coding schemes in view of the burdens the proposed regulation could impose. While perhaps extreme, it is a logical and legal alternative. In addition, any companies that are or were considering date coding, or other coding scheme, will likely suspend or abandon such consideration immediately.

IDFA believes that the complex coding schemes in use today by dairy processors are extremely useful for the purposes for which they were designed and they should be encouraged. They were not designed, however, to trace forward and requiring a processor to do so would create a great burden. With respect to tracing forward, we believe it is unnecessary as the current practice of initiating a Class I recall is extremely effective. Therefore, IDFA requests that FDA to eliminate tracking with codes or other information.

Issue #5 - Time differences with various compliance deadlines may cause problems

The Bioterrorism Act requires FDA to take into account the size of a business when promulgating a regulation under section 306 of the Bioterrorism Act. FDA has done so and established three separate compliance dates of six, twelve or eighteen months depending on company size, with the smallest companies having the longest time frame. Some IDFA members are concerned that some FDA field personnel may attempt to fill a void in information created by differences in compliance dates for two companies by requiring a company that is subject to the final regulation to fill in gaps that exist where compliance has yet to be required by a smaller company. Expecting a company subject to the regulation to cover for a company where compliance is yet to be required is not appropriate. IDFA would caution FDA to be cognizant of the possibility and take appropriate steps to communicate to field staff that there will be permissible gaps in the information until eighteen months after publication of the final regulation. Further and more importantly, unless FDA dramatically alters this proposed regulation in favor of a simpler and efficient version, even the eighteen month implementation time frame will be unworkable for virtually all facilities.

Issue #6 - The "perishable food" definition is confusing

The proposed regulation defines a perishable food to be a *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 seven days under normal shipping and handling conditions*. The preamble states that fluid milk is considered to be a perishable food, but then states that fluid milk that is ultrapasteurized is not a perishable food. IDFA believes that FDA may be referring to ultrapasteurized milk that has a shelf life of approximately thirty days. IDFA would like to point out, however, that ultrapasteurized milk can have a shelf life of anywhere between thirty and ninety days. IDFA would also like to point out that shelf stable milk is, in essence, ultrapasteurized milk that has been aseptically packaged. While we are not certain, we are aware that it is possible that FDA's statement that ultrapasteurized product is not perishable, may actually be referring to the shelf stable version -- which is a statement with which we would concur. Given the uncertainty, IDFA would like clarification as to which ultrapasteurized product FDA is referring.

If, however, IDFA's correct in believing that FDA is referring to ultrapasteurized milk with a thirty day shelf life, IDFA would disagree and believe that ultrapasteurized milk held for seven days would be

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adversely affected. By definition that would mean it is a perishable food. Holding any product with a short shelf life is adverse to the salability of that product. If a product has a thirty day shelf life and it is held for seven days or longer, almost twenty-five percent of that product's shelf life and salability is eliminated, we believe that is adverse. We are aware that FDA's proposed regulation refers to adversely affected in terms of product quality, our position is that shelf life and salability are inextricably linked to quality and therefore they must be considered together.

That said, many dairy products have relatively short shelf lives and will be adversely affected if held for seven days. Among those products are milk, ultrapasteurized milk that is not aseptically packaged, creamers, cottage cheese, sour cream, dips, yogurt and a host of other dairy products.

In addition, confusion arises in the definition itself, because, the definition begins by stating that perishable foods are foods that are "not heat-treated, not frozen and not otherwise preserved..." Confusion arises because pasteurized milk is heat treated, and FDA's qualification of the three criteria is somewhat awkward and combined with an extensive use of negatives; it will ultimately confuse readers. IDFA believes the definition could be improved if it were restated to read that a *food that has not been treated or otherwise preserved, so as to prevent the quality of the food from being adversely affected if held longer than seven days under normal shipping and handling conditions.*

IDFA would also recommend that FDA flush out the determination of adversely affected through notice and comment rulemaking or through guidance with the food industries cooperation. Given that the determination of adversely affected ultimately establishes the status of *perishable* or *non-perishable* which in turn affects the recordkeeping time frame by an entire year, it is in everyone's best interests to make sure that FDA and the regulated community understand the difference between these two designations.

Issue #7 - FDA should eliminate the need for a "responsible individual"

In several sections of the proposed regulation, FDA is requiring that companies provide the name of responsible individuals. IDFA believes the regulation should clarify the meaning of "responsible," so that companies provide the name of a contact person. Further, it is unclear why FDA would be seeking to establish the identity of individuals in the recordkeeping proposal when FDA's registration system should provide better access to the right individual - the emergency contact. The registration proposal contains a requirement that information be updated and that updates are due within thirty days of a change. Therefore, the names in the registration system will constantly be updated to provide timely access to the appropriate individuals that can facilitate matters in the event of an emergency.

In those circumstances, where a facility is not required to be registered and FDA therefore has no contact information in its database, IDFA would suggest that a having name on a record is similarly less reliable than having the ability to pick up the phone and express that an emergency has occurred and then ask to speak with the appropriate available person. In essence, the phone number is the critical piece of information that is needed, not the name.

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IDFA therefore recommends that FDA delete any requirement for the establishment of a "responsible person" in records keep by a facility.

Issue #8 - FDA is interpreting the term "food" too broadly

For the purposes of the Bioterrorism Act regulations, FDA proposes to define the term "food" as it does in the Federal Food Drug and Cosmetic Act (FFDCA), Section 201(f). Section 201(f) states "*The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.*"

FDA also has proposed to include examples of products that are considered food under 201(f) of the act. These examples include, but are not limited to: fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or components of food, animal feed, including pet food, food and feed ingredients and additives, **including substances that migrate into food from food packaging and other articles that contact food [emphasis added]**. IDFA believe that definition is too broad.

IDFA interprets the current proposed definition of food to include those items that we would traditionally think of as food, but also that it would include virtually all items that come into contact with a food during the processing or packaging. The inclusion of all food contact packaging and other articles that contact food is potentially disastrous. IDFA does not believe that FDA has considered the scope of items that such a broad definition will encompass. For example, theoretically, trace molecular amounts of metals, or metal oxides can migrate, be physically transferred from stainless steel to a food product during food processing. Similarly, miniscule amounts of materials from conveyors, cutting boards, utensils, plastic tubing, gaskets, metal and plastic piping and in all likelihood millions of other items can also be transferred or migrate into a food during processing. Further, it appears that only contact and not migration is necessary to convert a non-food item into a food. Such a broad definition will result in an enormous increase the volume of records that companies will need to maintain, as well as a potentially huge liability for the countless prohibited acts that IDFA expects virtually every company subject to the regulation will commit.

IDFA suggests FDA finalize a regulation which **requires records for those food items that could be used in an attempt to contaminate the foods**. IDFA does not envision that a final definition would include the multitudes of non-food items or food contact surfaces. If we are incorrect in our assumptions and these non-traditional food items do represent a risk, we urge FDA to communicate that fact to the food industry so that appropriate precautionary measures may be undertaken.

Issue #9 -- Record retention period is too long.

FDA has a conflict in record retention times its own regulations. The Pasteurized Milk Ordinance (PMO) requires facilities to keep the pasteurization records for ninety days. This regulation would require information to be maintained for up to two years. The record retention regulations should be consistent with other FDA regulations covering the same product to avoid confusion. FDA has previously determined that ninety days was an acceptable retention time frame for records relating to pasteurized dairy products, we would like to see FDA adopt a similar record retention time frame.

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Conclusion

As stated in the opening remarks of these comments, the critical purpose of the Bioterrorism Act is to enhance food safety and security. Congress, FDA, industry and the consuming public all share in that desire and goal. The reality is that that desire or goal is so important that no matter what FDA ultimately does when it finalizes this and the other Bioterrorism Act regulations, the need to take swift decisive action in times of crisis will cause FDA and industry to act in a responsive manner for the benefit of all. Those actions will be done on a cooperative basis and what is actually written and required in a regulation will be secondary unless it facilitates a speedy resolution to the circumstance at hand.

In the event a food product becomes contaminated, the affected food processors will institute an immediate Class I recalls and will take all necessary steps to ensure that the consuming public is not at risk. FDA will be at those processors sides assisting them and advising them. IDFA urges FDA to consider our comments, especially weighing IDFA's and its members' successful cooperation with FDA in achieving goals similar to those in these proposed regulations, the purpose of the Bioterrorism Act, and promulgate a final regulation that will facilitate and enhance security.

Sincerely,



Clay Detlefsen
Vice President, Regulatory Affairs & Counsel



International Dairy Foods Association
Milk Industry Foundation
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International Ice Cream Association

FAX TRANSMISSION

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Re:	Docket No. 02N-0277	CC:	

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To the Dockets Management Branch:

Please note the attached letter from Clay Detlefsen, Vice President, Regulatory Affairs & Counsel, International Dairy Foods Associations. Re: Docket No. 02N-0277-Establishment and Maintenance of Records.

Please let us know if we can provide further assistance. Clay Detlefsen can be reached at 202-220-3554 or email: cdetlefsen@idfa.org.