American Bakers Association

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July 8, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
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
68 Federal Register 25187 (May 9, 2003)

Dear Sir/Madam:

These comments are submitted on behalf of the members of the American Bakers Association (ABA), the national trade association representing the wholesale baking industry. ABA membership consists of bakers and bakery suppliers who together are responsible for the manufacture of approximately 80 percent of the baked goods sold in the United States. The purpose of these comments is to voice our strong opposition to the agency's proposal to prescribe "chain-of-custody" recordkeeping requirements essentially for all food/food ingredients under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("Bioterrorism Act"), on the grounds that the proposal cannot be justified to support the public health objectives of the Bioterrorism Act, and to the contrary, appears to be counterproductive, unduly burdensome, and has no proven efficacy in responding to genuine public health emergencies. In addition, ABA proposes an alternative approach for enhancing the existing recordkeeping infrastructure for tracing/recalling food and food ingredients, which has the strong support of ABA members. The ABA proposal would promote the public health objectives of the Bioterrorism Act in the most effective ways, and could be implemented immediately, cost-effectively, and in commercially viable ways across the regulated industry.

While ABA appreciates the substantial effort FDA has put forth in trying to develop a comprehensive and performance-based recordkeeping standard, the agency proposal unfortunately offers no guarantee of enhanced public health protection, is excessively prescriptive, and is economically burdensome. The proposal fails to account for the extensive legal requirements imposed on food companies to maintain recordkeeping systems to support rapid product tracing and recall systems under product liability law and the related body of commercial law. The rigorous food safety standards imposed under this law are already integrated in standard business practices, contractual relationships and are implemented and executed by companies through product recall/crisis management plans. These systems establish performance obligations for companies that supply and transport foods, which commonly encompass the "one step back/one step forward" links in the food/ingredient distribution chain. In addition, the performance obligations imposed by product liability standards are codified in commercial agreements. The massive StarLink® recall, which occurred in the absence of a public health emergency, and the Class I food product recalls undertaken in the ordinary course

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of business to protect public health (e.g., allergens) exposes the strength of the recordkeeping systems in place to trace and recall food products from the market promptly and effectively.

Instead of the prescriptive approach of the FDA proposal, ABA urges the agency to adopt instead a "safeharbor" regulation which would reinforce existing legal and economic incentives for companies to maintain recordkeeping systems that conform with responsible industry practices as these continue to evolve in relationship to product liability standards. ABA proposes specifically that a safeharbor regulation be promulgated which ensures that companies with established tracing/recall systems in place which enable companies to locate articles of food in commerce within a specified time period (e.g., 24 hours), will be deemed to satisfy the recordkeeping requirements of the Bioterrorism Act as a matter of law. The specific time period would be established as a "responsiveness" performance standard reflective of responsible industry practices. The safeharbor approach would function as a public health protective performance standard which would encourage companies to evaluate and enhance existing recordkeeping systems for tracing the sources of ingredients and distribution of products to ensure the "responsiveness" performance standard would be satisfied. Instead of the "cookie-cutter standard" proposed by FDA, which would require companies to track food/ingredients using the same methodology, the ABA approach would enable companies to focus on the endpoint of locating and distinguishing the food/ingredients presenting the risk to public health within the specified timeframe, and to make any improvements in the recordkeeping systems in place necessary to support that level of responsiveness. For the majority of companies who are operating in line with responsible industry practices, existing systems may satisfy the performance standard. ABA proposes that the safeharbor regulation provide for exceptions to ensure that, where the responsiveness of a company's recordkeeping system conforms with responsible industry practices, the company will not be subject to liability under the records provisions of the Bioterrorism Act because the responsiveness deadline (e.g., 24 hours) alone was not satisfied in a particular case. Due diligence in maintaining the recordkeeping system and tracing food/food ingredients should be sufficient for a company to prevent liability under the Bioterrorism Act. Responsible conduct by bakery companies, suppliers and transporters should not be made punishable under the Act.

ABA believes that establishing the proposed safeharbor would encourage companies to maintain and strengthen their existing recordkeeping systems in the specific ways that are best tailored to enhance each company's responsiveness to public health emergencies, given the complex considerations that each company must give to potential hazards, and the dynamic nature of ingredient supplies, distribution networks and transportation systems the company relies upon. ABA believes that the safeharbor would encourage companies to devote resources to those systems that already comprise critically important foundations for the nation's food safety infrastructure, rather than diverting scarce food safety resources to establishing prescribed systems that are unproven and unworkable. No benefit to public health can possibly come from

requirements that have no proven efficacy to protect public health, and divert resources from the maintenance and improvement of established systems that have a well established track record for successful public health protection.

ABA remains unconvinced that the agency's public health justification for prescribing recordkeeping requirements satisfies the public health mandate of the Bioterrorism Act. Most basically, the proposal seems premised on the false and dangerous notion that the government must take charge of food/ingredient tracing during a public health emergency within a particular timeframe. The FDA proposal attempts to define a performance standard and that much is laudable. Yet, the proposed approach fails fundamentally to appreciate, validate and reinforce the legal and economic incentive structure that exists under current law. This existing structure is chiefly responsible for motivating companies to absorb the economic costs necessary to trace and recall product from the market, even when public health risks are merely hypothetical (e.g., StarLink®) or affect a small portion of the population. ABA members must conclude that the potential for adverse public health and commercial implications from the proposal have not been sufficiently evaluated by FDA to justify adopting the FDA proposal.

ABA believes that the strongest protection for public health can only come through recordkeeping systems that support food/ingredient tracing and recalls under the case-specific conditions presented to each company. It is impossible for anyone, let alone a government agency, to possess the seemingly infinite degree of expertise and experience necessary to anticipate and accommodate the diverse range of case-specific circumstances in a regulatory prescription that would effectively address all these circumstances. The safeharbor regulation proposed by ABA builds upon the breadth of experience embodied in the people who are responsible for making safe food, and must make recordkeeping, tracing and recall systems work in the real world. ABA believes that the bakery companies who are engaged in a business whose future depends on delivering safe and secure food to consumers every day, are in the best position to determine how to effectively trace the sources of ingredients and the distribution of articles of food in commerce to support prompt and effective response to public health threats. For this reason, ABA urges the agency to adopt the safeharbor regulation proposed here. The ABA rationale for the safeharbor approach is further supported by the specific issues of serious concern that members have raised with respect to the pending FDA proposal. These are described in more specific detail below.

Commercial Viability and Public Health Protection

When one considers the massive scope of the StarLink® recall, and the need for each affected company to effectively manage economic and legal liability risks to stay in business, one can appreciate the highly sensitive commercial implications of recordkeeping systems that are maintained to trace and recall product from the market. Business risk management decisions that are important to the commercial success of companies influence the specific design of these systems and the manner in which tracing and recall operations are conducted. Cookie-cutter

regulations cannot possibly anticipate or account for all of these important commercial issues, and can produce unnecessary and unintended adverse commercial consequences on companies by failing to accommodate the flexibility necessary for companies to optimize their approach to managing business risks. The specific design of a recordkeeping system a company chooses is influenced by the particularities of the state law systems they are operating under. While it is critically important that companies be equipped to trace and remove food from commerce in response to a genuine public health emergency, it is just as important that the tracing/recall systems function in such times in a manner that makes sense commercially so that food companies, suppliers and transporters can survive such emergencies economically and go on producing safe food. ABA urges FDA to take seriously the potential for commercially infeasible regulatory standards to cause business failures and lead to food shortages which threaten food security and basic access to food. In examining the circumstances surrounding the StarLink® recall and the huge amount of human food that was wasted, ABA is convinced that food security cannot possibly be assured unless regulatory standards can be fully justified on genuine public health grounds. The ABA safeharbor proposal thus offers better and more complete public health protection, and is more commercially viable than the FDA proposal.

Good examples of prompt and massive recall plans include the 1982 Tylenol® cyanide recall and the recall for StarLink® corn ingredients, as discussed above. Current law requires that companies must undertake widespread recalls even when the health risk presented is serious for only a small vulnerable subpopulation present among the general population of unaffected consumers. FDA's proposal does not include discussion of the efficacy of the existing trace back system and further, makes no effort to target the regulations to the extraordinary circumstances of a bioterrorist attack or other food safety emergencies which was the focus of the Bioterrorism Bill.

Within the bakery industry, a substantial degree of expertise and experience has been developed - - "intellectual capital" - - concerning the food safety systems and methods that are most effective in producing safe food, and tracing and recalling product from the market when that is necessary to ensure that only safe food is delivered to consumers. The American Institute of Baking (AIB) offers an industry specific food security audit. The AIB Food Security Audit is based on the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. Audit criteria includes an overview of food security programs including operational risk management, crisis management, recall programs, security inspections, law enforcement contacts, incoming mail, computer backup systems, off-site warehousing and investigation of customer complaint and tampering issues. Included in the detailed audit is an inspection of the outside grounds, employee and visitor programs, material receiving, facility operations and finished goods storage and shipping procedures.

The key elements of effective recall/crisis management plans include systems for tracing the sources of incoming ingredients and the distribution of outgoing food products, with the specific aim of equipping companies to respond quickly to remove product from the market when safety cannot be assured, and to investigate the origin of the safety problem (e.g.,

investigate ingredients/sources of ingredients) so that companies can be sure any safety problem identified can be contained promptly and remedied. These are not "make work" recordkeeping systems developed to support a one-size-fits-all "chain-of-custody" concept for food/ingredient tracking. To the contrary, these systems are designed to be specifically and directly responsive to the public health protection goal presented, removing food from the market and preventing more food presenting the same risk from entering the market.

In establishing and maintaining these highly responsive tracing/recall plans, companies must address a broad range of issues, including the following key elements:

- Efficient system for removing adulterated products from the shelf
- Internal time goals for the rapid removal of products from the shelf and distribution channels
- Organized system to contact FDA, local authorities, and media
- Record of actions taken to effectively and promptly resolve the issue
- System of product labeling that enables company to trace back to its source
- System that can trace where product was shipped
- Names, telephone contacts and dates that product was shipped
- Conduct mock recalls to make sure systems are effective to limit risk

FDA Partnership with Industry

The agency's proposal fails to capitalize on the efficiencies of time and resources available through greater public/private coordination. FDA can count on the full support of the baking industry in its mission to protect the American public and supply them with a safe and wholesome food supply. The livelihood of the baking industry is predicated on the delivery of such products. Currently, issues of product liability and the related body of commercial law drive the industry to manage any public health issue that may arise, therefore the current industry approach to crisis management and control should be utilized as we consider our new mission together with FDA. ABA believes that the safeharbor recordkeeping proposal characterized above would support positive collaboration between food companies and government officials in responding to public health emergencies. Companies would be provided with powerful new incentives and encouragement to direct food safety resources toward maintaining state-of-the-art crisis management/recall plans which include appropriate trace-back/trace-forward food/ingredient tracing features. At the same time, companies with such responsible industry practice systems could be assured of legal compliance under the Bioterrorism Act, and would be relieved of the concern that government officials examining their records during an emergency would be nit-picking and second-guessing the company's recordkeeping system with respect to a cookie-cutter rule, to gain leverage to command the operations of the food company during an emergency. ABA can see no benefit to structuring recordkeeping requirements in a manner that would foster an adversarial relationship between the food industry and government officials during the time of an emergency. In responding to a food safety emergency, ABA believes that the highest level of public health protection can only come from having all the public and private sector experts working in tandem and with a spirit of mutual respect and teamwork to solve the

public health emergency presented. The Bioterrorism Act was enacted to combat threats to the food supply that both government and industry must be effective in addressing. The ABA safeharbor proposal would deter government micromanagement of company recordkeeping systems and crisis response during a food safety emergency, and ABA firmly believes this is essential to provide the highest level of public health protection that is possible to the public.

Statutory Requirements

The cost/benefit justification and feasibility of the chain-of-custody system FDA proposes is unproven and remains doubtful. ABA strongly believes that the agency grossly underestimated the overall economic burden, and specifically the average annual costs of compliance which include education; redesign of current record formats to comply with new rules; preparation for records access within reasonable timeframes (based on FDA' assumption that the proposal would not require substantial deviation from current industry practice), as well as, access procedures. The legal and economic burdens that this proposal places on industry would be huge and cannot be reasonably justified where the need cannot be established and where the effectiveness of the existing industry systems and practices for responding to public health risks from adulterated food already exist. Based on FDA's gross underestimation of great impact and cost to the industry, ABA is doubtful that the Agency is complying with the requirements of the Data Quality Act (P.L.106-554), and requests that the agency's obligations in this regard be considered carefully.

Further, ABA has serious concerns that the agency's proposal to implement the recordkeeping/access provisions of the Bioterrorism Act fail to distinguish inspectional standards and procedures under the basic FD&C provisions, and makes no effort to take an integrated approach which accounts for the additional agency authorities that exist to respond to public health emergencies affecting the food supply under such preexisting laws as:

- The Public Health Threats and Emergencies Act of 2000 amended the Public Health Service Act to enable HHS to address the threat of a bioterrorist attack. (42 U.S.C. § 247d)

- The Federal Anti-Tampering Act (FATA), enacted in response to intentional contamination of consumer products, provides for criminal penalties (including imprisonment for up to life) for any person who recklessly and with extreme indifference "tampers with any consumer product that affects interstate or foreign commerce, or the labeling of, or container for, any such product. The legislation defines "consumer product" to include "food" as defined under the FD&C Act and specifically authorizes FDA to investigate violations involving food products. 18 U.S.C. § 1365.

  Under an older provision of the Public Health Service Act designed to enable the Surgeon General to halt the spread of communicable disease: "The Surgeon General, with the approval of the Secretary is authorized to make and enforce

such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession." 42 U.S.C. § 264(a). This section also authorizes the Surgeon General to "provide for such inspection, fumigation, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary."

- For historical reasons, FDA exercises the Surgeon General's authority under this provision. *See* Reorg. Plan No. 3 of 1966; 21 C.F.R. § 5.10. FDA could use this authority to, by regulation, address the threat of a terrorist attack involving contamination of food products with pathogens.

ABA urges FDA to adopt the proposed safeharbor for recordkeeping systems characterized above, and to establish the safeharbor in regulations that ensure that companies are protected from liability under the Bioterrorism Act, other provisions of the FD&C Act and all other potential statutory authority available to the Secretary, including the above listed statutes.

Congressional Intent

The preamble of the records proposal states that it is FDA's intention "to have as little impact as possible on current recordkeeping practices if those records can meet the requirements of these proposed regulations". This statement of intent is consistent with the ABA recordkeeping safeharbor proposal. Notably, the authority that FDA claims in this proposal for chain-of-custody recordkeeping was not included, nor was it intended, in the Bioterrorism Act; further, it relies on an expansive reading of Section 414 from the Act. FDA's preamble repeatedly emphasizes that the proposed requirements are "intended to provide the necessary information to allow FDA to trace the transportation of all food." As discussed above, the most effective public health protection can only be gained when food companies take responsibility for tracing and recalling product from the market in response to public health threats. The FDA proposal fails to build upon the existing systems in place, and cannot be tailored sufficiently to account for the range of needs and circumstances necessary to be justified on public health grounds.

ABA is quite concerned that the Agency's proposal appears to formulate a recordkeeping system that imposes substantially greater legal and economic burdens on companies than can be justified to promote the public health objectives of the Bioterrorism Act, and the system presents genuine risks to the food safety infrastructure now in place, in our view. For FDA to add further to the present conundrum of regulations that the Bioterrorism Act is calling for creates, in many cases, an unattainable regulatory environment that could be counterproductive to businesses growth and their future vitality. It appears that the agency's proposals are not only beyond the objectives and intent of Congress but would further enhance a very complicated and regulatory mass.

As ABA stated above, the kind of trace back records routinely established and maintained by companies which are necessary for them to do business, maintain and uphold rigorous standards prescribed by product liability law; to investigate potential product defects and to promptly remove defective products from the marketplace to prevent harm are consistent with the terms of the Bioterrorism Bill. Companies need to stay abreast of changing conditions and emerging science and to remain in a constant state of vigilance in responding to new threats to the safety and security of the products for which it is held legally responsible. These standards are not relevant simply in the unusual cases where companies face product liability lawsuits, but instead are codified in the powerful and expansive body of preventive law standards which govern day-to-day business activities, and are enforced through the product quality certifications that exist between suppliers/purchasers, the varied commercial agreements linking companies engaged in food manufacturing and distribution/transporting, and the financial risk sharing arrangements that are made enforceable by such commercial agreements (e.g., indemnity provisions).

Commercial Infeasibility/Workability Issues

Recordkeeping System Infrastructure

ABA is concerned that the detailed distribution phase of recordkeeping that FDA's proposal suggests, is excessively restrictive and would require industry to revamp existing recordkeeping systems that are perfectly adequate to meet the needs of this bill as intended by Congress. The proposed requirements are more burdensome than is necessary to enable food producers to respond quickly and appropriately to a food safety emergency. The proposal also does not take into account the sheer volume that retail grocery stores deal with on a daily basis. On average, retail grocery stores currently have the capability of keeping such records for only approximately one week. For FDA to expect such companies to maintain records in upwards of two years is completely unworkable, and as ABA argues above, it will not serve in the interest of public health in times of crisis.

Definition of Food

Additionally, ABA is concerned that FDA's definition of food includes food contact materials, including food packaging. This expanded definition overreaches the traditional definition for food and expands FDA's authority too broadly and in a manner unjustified by the risks presented by these materials. These items are not intended for consumption and only become components of food incidentally to their primary functions. As a technical matter, it would be nearly impossible to taint such materials with a sustained release mechanism that would contaminate food into which the substance was later placed in contact. Yet, ABA estimates that this additional group of potential products would, at the least, quadruple the number of products that would be captured in the new requirements and would burden companies with an unmanageable database. This significant burden is wholly unfounded given the extremely remote possibility of intentional adulteration of food contact materials, and will not enhance the safety of the United States' food supply.

Definition of Perishable

ABA strongly believes that for the definition FDA uses in its proposal for "perishable" is not reasonable or workable. For this reason, ABA proposes the currently existing NIST Handbook 130 Regulations for Uniform Open Dating Definition for Perishable; Semi-Perishable and Long Term Shelf Life be applied this as the final rule is formulated. These definitions have a history of use and acceptance by industry and government alike. 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"

Record Retention Time Requirements

Based on ABA's recommendation to use the NIST Handbook 130 Regulations for Uniform Open Dating Definition for Perishable; Semi-Perishable and Long Term Shelf Life, ABA further recommends amending the record retention time requirements. Since an infrastructure for long term record retention does not exist to the extent FDA seeks, ABA believes that a more reasonable time requirement should be established. ABA recommends:

- For Perishable - record retention for six months
- For Semi-Perishable - record retention for 12 months
- For Long Shelf-Life - product shelf life plus 12 months or 24 months, whichever is greater

Record Retrieval Time Requirements

ABA strongly recommends that FDA establish a record retrieval time deadline of 24 hours rather than the four hour/8 hours timeframe that was proposed. Based on experience, it can often take 24 hours to retrieve records that are at off site and remote locations. To expect record retrieval within four hours during working hours or eight hours during weekend and holidays is completely unrealistic and in all likelihood cannot be achieved.

Additionally, FDA has also not taken into consideration the fact that companies operate over various time zones. For example, a large company can operate in over five time zones in the U.S. In such cases, records may be stored centrally, and due to the varying time zones, it could take a minimum of five fours just to make contact.

Compliance

To establish the type of recordkeeping system that FDA proposes, the baking industry estimates that it would require no less than several years, and, in any event, far more than the six months proposed by FDA. The workability issues identified above makes it challenging to define a specific timetable where a recordkeeping system of the kind proposed would be fully functional and effective. FDA's proposed six month implementation timetable is grossly inadequate for such a complex task and does not allow individual companies adequate time to institute a system and educate staff on its use. The short, six-month timetable proposed provides further concerning signs that the agency has failed to appreciate the implications of its own proposal.

In contrast, the ABA safeharbor proposal, will encourage innovation to enhance public health protections to existing recordkeeping and product tracing systems immediately upon adoption. ABA anticipates that companies will become interested in modifying systems to trace food products as cost effectively as possible, including by such means as the Universal Product Code (UPC) code system that currently is being updated. Products could be coded to provide much of the information FDA seeks in an organized way. FDA should note that the revision of the current UPC code system had been a lengthy and complicated process which is still not complete. ABA urges FDA to adopt the safeharbor, and by doing so, encourage companies to direct food safety resources toward enhancements, such as UPC linked tracing, through a "responsiveness" performance standard of the kind proposed here. Because the ABA approach requires companies to stay abreast of new technologies, and achieve a defined level of responsiveness on a going forward basis, companies will adopt those technologies that achieve cost effective results, and no further controls or timetables for implementation must be defined by FDA.

Evidentiary Standards and Procedural Safeguards to Protect the Constitutional Right of the Regulated Industry and its Employees

ABA strongly objects to the agency's proposal to prescribe recordkeeping requirements by regulation, but to reserve to nonbinding informal guidance the evidentiary standards and procedural safeguards that are necessary to protect the constitutional rights of the regulated industry and its employees, and to ensure they are enforceable in the ordinary course of business.

ABA members are greatly concerned that the new standards and authorities adopted under the Bioterrorism Act, in the wake of the September 11, 2001 terrorist attacks on our

nation, have the potential to be exploited to address food safety issues of a routine, nonemergency nature, and that unlawful conduct and abuses of discretion by field inspectors and other officials will be impossible to challenge in the ordinary course of business. In contrast to the drug and medical device manufacturing industries, which operate under tightly controlled licensing schemes, the food industry remains largely a private enterprise, which vests full responsibility for ensuring the safety of foods in the food companies themselves. For the most part, foods are not subject to premarket clearance by FDA, and food, food manufacturing facilities, food transporters, and food information (labels, marketing, records) all constitute private property. Under the Fourth Amendment, the owners of this property, as well as the persons who are employed by food companies are entitled to substantial protection from procedural safeguards against unwarranted and unreasonable "search and seizure."

ABA urges the agency to avoid *ad hoc* or novel interpretations of the evidentiary standards triggering agency authority to enter food facilities and inspect records under section 414 of the Bioterrorism Act, and to take care to construe these "public health triggers" for agency jurisdiction in conformance with the evidentiary standards elaborated in Fourth Amendment case law. For example, section 414(a) provides that "if the Secretary 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*" upon certain procedures the food company must allow the government to have *"access to and copy all records related to such article that are needed . . .* in determining *whether the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.*" While this language is broad, it requires the scope of records inspected in a particular case to be confined to those that are "needed" to make the relevant public health determination. Fourth Amendment standards are reinforcing of this "needs" based focus of the Bioterrorism Act, and compel the agency to institute evidentiary standards and procedures to ensure the proper scope of agency authority is not exceeded and unconstitutional "fishing expeditions" are by imprudent field inspectors are deterred and punishable in the ordinary course of business.

FDA must establish procedural safeguards to ensure that search warrants are obtained when necessary, and warrantless administrative searches of private business records are confined, as required by the Fourth Amendment. The Fourth Amendment guarantees that the "right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures shall not be violated, and no Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized." U.S. Const. amend. IV. While warrantless searches may be used in defined circumstances, as a general rule, a warrant, supported by probable cause, must be obtained for a search conducted by the government to be "reasonable" in conformance with Fourth Amendment standards. Warrantless administrative searches of commercial property may satisfy constitutional standards provided that regulatory safeguards are instituted which function effectively as a substitute for a search warrant. *New York v. Burger,*482 U.S. 691 (1987). Warrantless administrative searches do not meet constitutional standards except where the discretion of field inspectors is confined and delineated in a manner

which directs the timing of the search, the selection of companies subject to search, and places appropriate boundaries on the scope of the search. *Donovan v. Dewey,* 452 U.S. 594 (1981).

Because the Bioterrorism Act amendments to the FD&C Act may result in personal criminal liability to corporate officers for legal violations arising within their scope of authority, and such liability may exist without the corporate officer even knowing about the violation (see *United States v. Park,* 421 U.S. 658 (1975)), it is essential that legal violations concerning recordkeeping and records access requirements be defined clearly, so that corporate officers can make responsible decisions and responsible conduct will not be punished unfairly. In addition, since corporate officers who are collaborating with government officials conducting records inspections in response to a public health emergency may be held personally liable for violations identified by the inspector during that process, it is critically important that appropriate Fifth Amendment safeguards be instituted to encourage open dialogue and communication which places the top priority on teamwork in solving the public health problem presented. To err is human - - and everyone - - including the best qualified food safety experts in the government and food industry make mistakes in paperwork from time-to-time. By establishing legal standards and Fifth Amendment safeguards concerning the disclosure of potentially incriminating information, FDA can encourage healthy collaboration by all those involved in responding to a public health emergency and can encourage all participants in the process to stay focused on protecting public health, and avoid the counterproductive distractions of the blame-game that otherwise are inevitable.

We have learned from the unfortunate history of First Amendment infringement by the policies implementing the Nutrition Labeling and Education Act of 1990 (NLEA) that the basic constitutional rights of the regulated industry must be respected and enforceable in the real world. Constitutional rights which exist in word only, – and cannot be enforced except by those who have the resources and time to fight courtroom battles -- for all practical purposes do not exist for the vast majority of people. This cannot continue. The constitutional rights of the regulated industry must be respected uniformly and consistently by all governmental officials.

The agency received well founded comments from the food industry during the NLEA implementation urging FDA to establish standards protecting the First Amendment rights of the regulated industry and public from the beginning. ABA urges FDA to do better this time in implementing the Bioterrorism Act, and to take seriously the agency's legal obligations to ensure that the statutory authority it has been granted is exercised with full respect for the legal rights of the regulated industry.

By taking the steps necessary to establish clear and enforceable constitutional protections during the implementation of the Bioterrorism Act regulations, FDA can help ensure that this new law - - which was so greatly motivated to ensure the nation's effective response to bioterrorist threats on our food supply -- will not unwittingly be turned against the very food companies and food company employees we most count on to stand on the front lines of this battle. To protect the nation's food safety infrastructure, the government must exercise due care

to protect the companies and people who comprise and maintain the effectiveness of our food safety infrastructure. ABA urges FDA to give the highest priority possible to integrating the constitutionally required safeguards into regulations implementing the Bioterrorism Act, and to avoid the mistakes made with respect to omitting to integrate the First Amendment standards into the NLEA implementing regulations. Imprudent regulatory standards and undisciplined discretion by field inspectors which undermine the strength and reputation of food companies and the food company employees we depend on to ensure our food supply is safe and secure cannot be indulged in these times. Strong constitutional protections are essential to advance the public health objectives the Bioterrorism Act was enacted to serve.

ABA appreciates this opportunity to comment on FDA's recordkeeping proposal. The Association is hopeful that the detailed concerns outlined in our comments will assist FDA as the Agency moves forward to finalize policy on this important issue. The technical contact for these comments is Lee Sanders, ABA Vice President, Regulatory and Technical Services, American Bakers Association, 1350 I Street, N.W., Suite 1290, Washington, D.C. 20005-3305 (telephone) 202-789-0300, (fax) 202-898-1164.

Respectfully submitted,

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