From: Randy Gordon [rgordon@ngfa.org]
Sent: Wednesday, July 09, 2003 5:40 PM
To: fdadockets@oc.fda.gov
Subject: Statement on Docket No. 02N-0277

Dear Sirs:

The National Grain and Feed Association and North American Expor Grain Association tried repeatedly to send the attached statement electronically yesterday using FDA's Internet-based docket submission form, but ran into technical difficulties because of the length of the statement and attachments. As a result, the statement was transmitted only in pieces, and the full copy of the statement was not transmitted.

A hard copy was messengered to the Dockets Management Office today in Rockville, and we are sending this electronic version, as well. The first document is the statement, and the second document is the exhibit referred to in the statement. We respectfully ask that you accept this statement as timely received.

Thank you for your consideration.

Kendell Keith
President
National Grain and Feed Association

Gary Martin
President
North American Export Grain Association

2002N-0277

EMC148

National Grain and Feed Association

North American Export Grain Association, Inc.

NAEGA

1250 I Street, N.W., Suite 1003, Washington, D.C., 20005-3922

July 8, 2003

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

RE: Docket No. 02N-0277
Establishment and Maintenance of Records under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

The National Grain and Feed Association (NGFA) and the North American Export Grain Association (NAEGA) submit this joint statement in response to the Food and Drug Administration's notice of proposed rulemaking that would require the establishment and maintenance of records by domestic and certain foreign facilities that manufacture, process, pack, hold or import food for human or animal consumption in the United States. The FDA-proposed regulations are intended to implement portions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 [Bioterrorism-Prevention Act].

The NGFA, established in 1896, consists of 1,000 member companies from all sectors of the grain, feed, processing and exporting business that operate about 5,000 facilities that handle more than two-thirds of all U.S. grains and oilseeds. The NGFA's membership includes country, terminal and export elevators; feed manufacturers; cash grain and feed merchants; end users of grain and grain products, including processors, flour millers, and livestock and poultry integrators; commodity futures brokers and commission merchants; and allied industries. The NGFA also consists of 36 affiliated state and regional grain and feed associations, as well as two international affiliated associations. The NGFA also has established strategic alliances with the Pet Food Institute and the Grain Elevator and Processing Society.

NAEGA, established in 1912, is comprised of private and publicly owned companies and farmer-owned cooperatives involved in and providing services to the bulk grain and oilseed exporting industry. NAEGA member companies ship practically all of the bulk grains and oilseeds exported each year from the United States. The Association's mission is to promote and sustain the development of commercial export of

grain and oilseed trade from the United States. NAEGA acts to accomplish this mission from its office in Washington D.C., and in markets throughout the world.

The NGFA and NAEGA are committed to enhancing the security of U.S. agricultural facilities and support reasonable, prudent steps that enable FDA to better respond promptly and effectively to a threatened or actual terrorist attack on the U.S. food or feed supply, without imposing undue burdens or costs on the food and feed system. As a demonstration of this commitment, the NGFA on November 16, 2001 published an ***Agribusiness Facility and Operations Security*** guide that outlines security issues and considerations that may need to be addressed at agribusinesses. The guide includes sections on conducting a facility vulnerability assessment; improving the general security of the physical facility and grounds; implementing prudent security operating, shipping and receiving procedures; and a sample emergency action plan. The guide has been distributed widely by the NGFA, and is available at no charge to members and nonmembers alike.

The NGFA and NAEGA join with other sectors of the food and animal feed chain in believing that substantial sections of FDA's proposed recordkeeping requirements exceed the mandate of the Bioterrorism-Prevention Act; transcend what is needed to effectuate an effective and efficient method for identifying the immediate previous source and immediate subsequent recipient of food and feed; and in several respects would be burdensome, costly, and in some respects, unworkable.

For these reasons, the NGFA and NAEGA strongly urge FDA to make major modifications to its proposed rules regarding the establishment and maintenance of records under the Bioterrorism-Prevention Act. Particularly troubling are provisions concerning:

- the quantity and specificity of recordkeeping information FDA proposes be maintained concerning the immediate preceding source and immediate subsequent recipient of food;

- the ambiguity and subjectivity concerning the specificity of information required to be kept for commodities – like raw and processed grains and oilseeds – that customarily are stored, handled and transported on a commingled basis;

- the excessively narrow definition of "retail facilities" exempted under FDA's proposal from maintaining and providing access to records for product sold to consumers.

- the extremely short time frame that FDA proposes that records be made available;

- the lack of clarity concerning when records would be required to be kept (i.e., intra-company versus inter-company transfers);

- the seeming redundancy of records required to be kept by non-transporters and transporters of food and feed; and

- FDA's attempt to exercise regulatory authority over the records maintained by foreign facilities that manufacture, process, pack or hold food for human or animal consumption in the United States. As previously noted in our statement filed in response to FDA's proposed regulations concerning prior notice of imported food, we are concerned that attempting to impose specific recordkeeping requirements on foreign facilities could make the United States vulnerable to challenges under the World Trade Organization and could set a troubling precedent that might be replicated by other countries against firms exporting U.S. agricultural commodities. We cannot stress this latter point enough. FDA's final rules very likely will become the template for practices that could be adopted by foreign countries and applied with equal force and vigor against U.S. exports of bulk and processed agricultural commodities, feed and feed ingredients, meat products and other agricultural exports.

The NGFA and NAEGA offer the following comments concerning specific sections of FDA's proposed rules for registration of domestic and foreign facilities that manufacture, process, pack or hold food for human or animal consumption:

- **Section 1.326 (a) – Scope:** The NGFA and NAEGA urge FDA to clarify in this section of its proposed regulations that the recordkeeping requirements apply only when articles of food change possession between firms. We do not believe that firms should be required to maintain internal records above and beyond what they normally require for their own internal operations, provided that such information is sufficient to identify the immediate preceding source(s) and immediate subsequent recipient once the food or feed changes possession to a different company, firm or person.

  FDA also proposes to require that foreign facilities establish and maintain records as prescribed if they manufacture/process, pack or hold food for human or animal consumption in the United States – the same requirement that would trigger a foreign facility to register with FDA under the agency's previous proposal. The NGFA and NAEGA believe that this is an inappropriate reading of the Bioterrorism-Prevention Act. Section 305 of the statute contains express language requiring foreign facilities to **register** with the agency. But Section 414 of the statute, which governs maintenance and inspection of records, does not mandate recordkeeping by such foreign facilities. Instead, this section of the Bioterrorism-Prevention Act refers to the maintenance and inspection of records related to the "manufacture, processing, packing, distribution, receipt, holding or **importation** of such articles...." *[Emphasis added.]* Thus, the NGFA and NAEGA believe that the statutory intent is to require the agent importing food into the United States to maintain such records, but not the foreign facility itself.

Further, as stated previously, we have real concerns that attempts by FDA to expand requirements on facilities operating within the borders of sovereign states may well encourage or outright trigger an equivalent or more onerous reciprocal move by foreign governments against U.S. firms exporting agricultural commodities and products, thereby disrupting two-way trade. As an alternative, we encourage FDA to examine other mechanisms, such as sharing of information and joint investigations with the foreign governments if and when a foreign country is implicated in a credible bioterrorism threat against the U.S. food supply that meets the statutory threshold – that is, poses a threat of serious adverse health consequences or death to humans or animals.

Further, the NGFA and NAEGA believe that FDA should modify this section of its proposed rules to clarify that domestic grain-handling, feed manufacturing/ingredient or processing facilities dedicated solely to exporting bulk or processed agricultural commodities to other countries should be **exempt** from the recordkeeping requirement unless the commodities, products or byproducts they handle are introduced into U.S. commerce. This clarification would be consistent with the statutory language and FDA's proposed regulations that the recordkeeping requirement applies only to domestic and foreign facilities that manufacture, process, pack or hold food for human or animal consumption in the United States.

- **Section 1.327 – Exemptions:** Consistent with the definition of "food" contained in Section 201(f) of the Federal Food, Drug and Cosmetic Act [which states, in relevant part, *"...articles used for food or drink for man or other animals...,"]* as well as the definition of "food" being proposed by FDA in Section 1.328 of its proposed regulations [which includes *"animal feed, including pet food, food and feed ingredients and additives"*], the NGFA and NAEGA believe **FDA should interpret the exemption from maintaining records for immediate subsequent recipients of food to expressly include retail farm supply and feed stores that sell finished product directly to consumers and final purchasers.** For instance, many small rural feed manufacturers also have a retail outlet in their facilities that sell bagged feed, pet food and feed ingredients/additives over the counter directly to consumers and to final purchasers for use in their own animals. These products are **not resold** by the purchaser-customer. Maintaining records of these sales is not common practice today; would represent a costly burden to such enterprises, many of which are small businesses; and would not demonstrably enhance human or animal protection from bioterrorism-related threats.

  We believe that this concern can be addressed most effectively by amending the definition of "retail facility" in Section 1.328.

- **Section 1.328 – Definitions:**

  - **Definition of Farm:** Under the Bioterrorism-Prevention Act, "farms" are exempt from the recordkeeping requirement. FDA proposes to define farm as a "...facility in one general physical location devoted to the growing of crops for food, the **raising of animals for food** (including seafood), or both...." *[Emphasis added.]* The NGFA and NAEGA believe FDA's definition of the "farm" exemption should be size-neutral, and apply equally to integrated livestock and poultry facilities, so long as the activities engaged in at such locations are limited to "growing or raising" farm animals for human food but do not extend to further processing of food-producing animals into meat, milk or eggs (such as occurs at food processing and packing plants and rendering facilities) for subsequent commercial sale to humans or animals.

  - **Definition of Retail Facility:** For the reasons cited in Section 1.327 (concerning the exemption from the requirement for maintaining records of the immediate subsequent recipients of food) for retail farm supply and feed stores that sell finished product directly to consumers and final purchasers, we urge FDA to amend the definition of "retail facility" to read as follows *[new language boldfaced and underscored; deleted language stricken through]*:

    "Section 1.328. Retail facility means a facility that sells food products directly to consumers ***or final purchasers*** *only,* ***and which is not for further sale****. The term includes, but is not limited to, grocery and convenience stores, vending machine locations,* ~~*and*~~ *commissaries* ***and farm supply and feed stores that manufacture and sell feed, pet food or feed ingredients directly to consumers for use with their own animals, and which are not used in the further manufacture of feed****."*

- **Section 1.330 – Existing Records:** We commend FDA for including this section in its proposed regulations, and for recognizing that existing records maintained by covered firms and persons will suffice if they contain the information required under the final regulations.

- **Section 1.337 – Records Required for Non-Transporters and Transporters Concerning Immediate Previous Source of All Food:** The NGFA and NAEGA believe FDA's proposal would require non-transporters and transporters to collect and maintain records that exceed what is required to meet the statutory requirement of the Bioterrorism-Prevention Act.

  First, we believe that FDA's proposal that records include information that is *"****reasonably available****...to identify the specific source of each ingredient that*

was used to make every lot of finished product [emphasis added]" is unreasonably broad and open to misinterpretation, and is inappropriate for industries like the raw grain handling, processing, animal feed manufacturing and pet food industries that store, handle and transport commodities, ingredients and finished lots on a commingled basis. Our concerns are not allayed – but in fact are reinforced – by the narrative contained in the agency's description of the proposed regulations, in which it states, *"[w]hat is 'reasonably available' may vary from case to case."* FDA goes on to state that its intent is *"not...to require the reconfiguration of each manufacturing plant. These proposed regulations, however, would require you to capture the information available to you to connect finished products with the immediate previous source of each of the food products used to make that finished product. FDA understands that in some multiple sourcing contexts this information only may allow for a reduction in the number of potential sources for a specific food product, but may not necessarily identify one specific source of the food product...."* FDA in its description of the proposed rules cites the example of a bakery that may source flour from five different companies and store the flour "in one common silo" prior to being used in the manufacture of cookies. *"In this scenario," the agency states, "the information is not reasonably available to determine a single source of the flour used in a particular lot of cookies. In this case, the information reasonably available...would be the identity of all of the potential sources of the flour for each finished lot of cookies. Conversely, if the manufacturer did have dedicated silos for each supplier of flour, then the information would be reasonably available to the manufacturer to specify the specific source of the flour for each finished product."*

In this narrative, FDA obviously recognizes that it would be infeasible, unreasonable, burdensome and prohibitively costly for industry sectors – like the grain, feed manufacturing and grain processing industry – that source commodities and ingredients from multiple sources to be required to segregate or identity-preserve such "food" for purposes of this rule. Typical grain-handling facilities and commercial feed mills frequently source raw commodities and ingredients from hundreds of farmers and ingredient suppliers. Thus, this section of the proposed rule is of major concern for entities that store, handle and ship commodities and ingredients on a commingled basis, and we believe additional clarity is needed. Therefore, the NGFA and NAEGA strongly urge FDA to expressly incorporate its stated intent into the regulations, rather than subjecting the regulated industry to case-by-case determinations by FDA district offices of what may or may not constitute "reasonably available" information concerning the specific source of commodities or ingredients used in each and every food product. To effectuate this recommendation, we propose that FDA consider the following revision to this section of its proposed regulations *[new language boldfaced and underscored; deleted language stricken through]*:

"Section 1.337(a) If you are a nontransporter, you must establish and maintain the following records for all food you receive. Your records must include information reasonably available to you to identify the specific source of each ingredient that was used to make every lot of finished product; ***this requirement to identify the specific source of each ingredient shall not apply to nontransporters that originate food from multiple sources and manufacture, process, pack, or hold food as a commingled mass, unless such food is generally segregated or identity-preserved for commercial purposes.*** *"*

Second, FDA's proposed language contained in Section 1.337(a)(2) – by requiring that records identify the "brand name and specific variety" of food – is more appropriate to the finished food and feed industry than to covered facilities that store, handle and/or ship raw agricultural commodities and processed bulk ingredients. We believe this type of descriptive information (e.g., brand name) would be more appropriate if it were relocated to the description section preceding the proposed rule, as well as contained in guidance documents the agency subsequently issues to further amplify the intent of its final regulations. Therefore, we encourage FDA to consider amending this section of its proposed rule to read as follows *[new language boldfaced and underscored; deleted language stricken through]*:

"Section 1.337(a)(2) An adequate description of the ***specific*** *type* ***and variety*** *of food received, ~~to include brand name and specific variety (e.g., brand x and cheddar cheese, not just cheese; or romaine lettuce, not just lettuce.)~~."*

Third, we believe that FDA should limit the scope of information it proposes under Section 1.337(a)(1) to require non-transporters to identify **either** the firm name or individual that represents the immediate previous source of the "food" (e.g., commodity or ingredient), but not both. We also believe it is unreasonable for FDA to require the non-transporter that receives a food to determine the "responsible" individual from the source company, and note that FDA fails to define this term in its proposed rules. Therefore, it is recommended that this section be amended to read as follows *[new language boldfaced and underscored; deleted language stricken through]*:

"Section 1337(a)(1) The name of the firm ~~and responsible~~ ***or*** *individual, address, phone number and, if available, the fax number and e-mail address of the nontransporter immediate preceding source, whether foreign or domestic."*

Fourth, the NGFA and NAEGA wish to note that raw grain, manufactured feed and processed commodities typically are not labeled with a lot or code number that identifies the specific shipment. We note that Section 1.337(a)(4) of FDA's proposed rule recognizes this, by stating that the *"lot or code number or other identifier of the food (to the extent this information exists)."*

- **Section 1.345 – Records Required for Non-Transporters and Transporters Concerning Immediate Subsequent Recipient of All Food:** Consistent with our aforementioned comments with respect to Section 1.337(a)(1), the NGFA and NAEGA recommend that FDA limit the scope of information it proposes under Section 1.345(a)(1) to require non-transporters to identify **either** the firm name or individual that constitutes the immediate subsequent recipient of the "food" (e.g., commodity or ingredient), but not both. We also believe it is unreasonable for FDA to require the non-transporter that receives a food to determine the "responsible" individual from the source company, and note that FDA fails to define this term in its proposed rules. Therefore, it is recommended that this section be amended to read as follows *[new language boldfaced and underscored; deleted language stricken through]*:

  *"Section 1345(a)(1) The name of the firm ~~and responsible~~ **or** individual, address, phone number and, if available, the fax number and e-mail address of the nontransporter immediate preceding source, whether foreign or domestic."*

  Similarly, consistent with our previous comments with respect to the proposed language contained in Section 1.337(a)(2), we encourage FDA to consider amending this section of its proposed rule to read as follows *[new language boldfaced and underscored; deleted language stricken through]*:

  *"Section 1.345(a)(2) An adequate description of the **specific** type **and variety** of food received~~, to include brand name and specific variety (e.g., brand x and cheddar cheese, not just cheese; or romaine lettuce, not just lettuce.)~~."*

- **Sections 1.351 and 1.352 – Transportation Records:** In Section 1.351, FDA proposes to require that domestic transporters of food and feed be required to maintain records containing information on the immediately preceding source and immediate subsequent recipient of food and feed. In Section 1.352, the agency lists the recordkeeping information that transporters would be required to establish and maintain.

  The scope of the records that FDA proposes transporters to keep exceeds the information traditionally provided in truck and rail bills of lading (see attached exhibits), as well as the information necessary to effectuate the purposes of the Bioterrorism-Prevention Act. For example, the bill of lading does not typically list the name of the responsible individual, the phone number, fax number or specific brand name and variety of food being hauled.

  Consistent with our aforementioned comments with respect to Sections 1.337(a)(1) 1345(a)(1), the NGFA and NAEGA recommend that FDA limit the scope of information it proposes under Section 1.352(a)(1) and (a)(2) to

require transporters to identify **either** the firm name or individual that constitutes the immediate previous source and immediate subsequent recipient of the "food" (e.g., commodity or ingredient), but not both. We also believe it is unreasonable for FDA to require the transporter that receives a food to determine the "responsible" individual from the source company, and note that FDA fails to define this term in its proposed rules. In addition, for intra-company shipments, the records reflect a chain of custody that is not necessarily related to the name of a specific individual. Truck drivers, warehouse employees and others engaged in intra-company transfers generally will not have access to the detail needed to require FDA's proposed recordkeeping requirements. For these reasons, it is recommended that these sections be amended to read as follows *[new language boldfaced and underscored; deleted language stricken through]*:

*"Section 1352(a)(1) The name of the firm ~~and responsible~~ **or** individual, address, phone number and, if available, the fax number and e-mail address of the person who had the food immediately before you, and the date you received it from that person;"*

*"Section 1352(a)(2) The name of the firm ~~and responsible~~ **or** individual, address, phone number and, if available, the fax number and e-mail address of the person who had the food immediately after you, and the date you delivered it to that person;"*

Similarly, consistent with our previous comments with respect to the proposed language contained in Sections 1.337(a)(2) and 1.345(a)(2), we encourage FDA to consider amending Section 1.352(a)(3) of its proposed rule to delete the reference to brand name. In addition, for purposes of the records transporters are required to keep, we recommend that reference to the specific variety also be deleted from this subsection, since this information is redundant and already will have been recorded by the immediate previous source and immediate subsequent recipient of the food. Thus, it is suggested that this provision be rewritten as follows *[new language boldfaced and underscored; deleted language stricken through]*:

*"Section 1.352(a)(3) An adequate description of the **specific** type of food received~~, to include brand name and specific variety (e.g., brand x and cheddar cheese, not just cheese; or romaine lettuce, not just lettuce.)~~."*

- **Section 1.360 – Record-Retention Requirements:** We commend FDA for proposing to adopt the existing one-year record-retention requirement that applies to medicated feed under the agency's Current Good Manufacturing Practices to pet food, all other animal feed, and perishable foods not intended for further processing into non-perishable foods. For simplicity's sake, we encourage FDA to consider imposing an identical one-year record-retention requirement on raw grains, oilseeds and all other foods.

- **Section 1.361 – Record-Availability Requirements:** The NGFA and NAEGA believe FDA's proposed rule contains inappropriate, unrealistic and unworkable deadlines for making records available. Reflecting Section 404(a) of the Bioterrorism-Prevention Act, FDA proposes that records be made available if it 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" and that access to records be limited to those "relating to the manufacture, processing, packaging, distribution, receipt, holding or importation of such articles...."

  But we believe FDA then departs from congressional intent by proposing hard-and-fast deadlines by which time records are to be provided. Specifically, the agency proposes that such records "and other information" be made available within four hours if FDA requests it between 8 a.m. and 6 p.m. on weekdays, and within eight hours if the request is made "at any other time." This, we believe, is not consistent with the tenor of the statute itself, which states that facilities and persons covered by the recordkeeping requirements are to **grant access** to such records to FDA *"upon presentation of appropriate credentials and a written notice..., **at reasonable times and within reasonable limits and in a reasonable manner**,...." [Emphasis added.]* The statute contains no deadlines by which time all such records are to be provided, and we believe it is inappropriate and unwise for FDA to propose arbitrary deadlines in regulation given that the scope, volume and complexity of the products and associated records to which the agency may seek access may vary dramatically from one instance to the next. The infeasibility of FDA's proposed deadlines is further exacerbated the fact that records may be stored offsite from the location where FDA seeks access.

  For these reasons, we believe that FDA should revise this section to reflect that covered non-transporters and transporters are to make good-faith efforts at providing FDA access to such records within a specified time frame. As such, we recommend that Section 1.361 be revised as follows *[new language boldfaced and underscored; deleted language stricken through.]*

  *"Section1.361 When FDA 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, any records and other information accessible to FDA under section 414**(a)** or 704(a) of the act must be readily available for inspection and photocopying ~~or other means of reproduction~~. **Access to s**~~S~~uch records and other information must be ~~made~~ provided within ~~4~~ **8** hours of a request if the request is made between 8 a.m. and 6 p.m., Monday through Friday, or within ~~8~~ **24** hours of a request if made at any other time, by an officer or employee duly designated by the Secretary who presents appropriate credentials and a written notice. If records and other information are stored offsite, the records must be retrieved and provided onsite within the*

specified time period. Electronic records are considered to be onsite if they are accessible from an onsite location."

- **Section 1.363 – Penalties for Non-Compliance:** Under the Bioterrorism-Prevention Act and this section of FDA's proposed regulations, failure to establish and maintain records is a prohibited act and subjects the offending party to civil and criminal penalties, as well as debarment. We encourage FDA not to use incidental infractions of its final recordkeeping regulations to as a pretext for bringing additional enforcement for alleged violations of other agency regulations that are outside the scope of the Bioterrorism-Prevention Act.

Conclusion

The NGFA and NAEGA appreciate this opportunity to provide our collective input on FDA's proposed regulations to implement the recordkeeping requirements of the Bioterrorism-Prevention Act. We believe our proposed changes will contribute to implementing the law in the most efficient manner possible, while minimizing the regulatory burdens and costs that could disrupt efficient business operations by companies engaged in providing an abundant and affordable food supply to U.S. and world consumers.

In summary, the following are the major concerns that we believe FDA should rectify in its recordkeeping proposal:

1. FDA should amend the proposed rules to explicitly exempt facilities that handle commodities on a commingled basis from the requirement to identify the specific source of each ingredient, unless such commodities are stored, handled and shipped as a segregated or identity-preserved lot for commercial purposes. *[See pages 5-6]*

2. FDA should amend the definition of "retail facility" to include feed and farm supply stores that sell finished product (feed, pet food and feed ingredients) directly to consumers and final purchasers for use with their own animals. *[See pages 4-5]*

3. FDA should not attempt to expand recordkeeping requirements imposed on foreign facilities, and be cognizant of the backlash and reciprocity that such actions may well trigger from foreign governments against U.S. firms exporting agricultural products. *[See pages 3-4]*

4. FDA should clarify that its recordkeeping requirements apply only when food articles change possession between firms, not to intra-company records. *[See page 3]*

5. FDA should revamp its proposed deadlines by which time access to records is to be provided to reflect that companies would be deemed to be in compliance if they have made good-faith efforts to begin the process of providing FDA with access to such records within 8 hours on weekdays, and within 24 hours at any other time. *[See pages 10-11]*

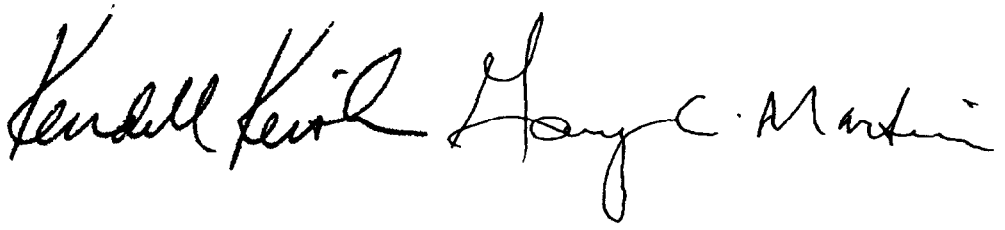
6. FDA should eliminate its proposed requirement that records identify the "responsible" individual from the companies that constitute the "immediate preceding source" and "immediate subsequent recipient" of a commodity, food or feed. *[See pages 7, 8 and 9]*

7. FDA should eliminate its proposed requirement that records identify the "brand name" of a food, since that is inappropriate for the breadth of commodities the agency is proposing to regulate under the recordkeeping requirement. *[See pages 7, 8 and 9]*

8. Records should be required to be kept for only one year for all food, consistent with FDA's proposal to require that records for animal feed, pet food and perishable commodities be kept for only one year. *[See page 9]*

We pledge our continued proactive efforts to work with our industry sectors and with government to further enhance the safety and security of the nation's food and feed supply.

Sincerely,



Kendell W. Keith
President
National Grain and Feed Association

Gary C. Martin
President
North American Export Grain Association

[Code of Federal Regulations]
[Title 49, Volume 6]
[Revised as of October 1, 2002]
From the U.S. Government Printing Office via GPO Access
[CITE: 49CFR1035.2]

TITLE 49—TRANSPORTATION

CHAPTER X—SURFACE TRANSPORTATION BOARD, DEPARTMENT OF TRANSPORTATION

PART 1035—BILLS OF LADING—Table of Contents

Notwithstanding any other provision of Sec. 1035.1(a), with respect to the information called for, the front portion only (appendix A to this part) of a bill of lading may deviate from the language prescribed in this part so long as the deviation conforms with approved national standards for the electronic data interchange or other commercial requirements for bill of lading information; provided that no such deviation in the language shall affect the obligations of any shipper to provide information absent the consent of such shipper nor shall such deviation be deemed to alter any rights or obligations conferred by statute or regulation on either carriers or shippers with respect to the preparation or issuance of bills of lading.

Appendix A to Part 1035—Uniform Straight Bill of Lading

Uniform Straight Bill of Lading

Original—Not Negotiable

Shipper's No_____

Agent's No_____

Company_____

Received, subject to the classifications and tariffs in effect on the date of this Bill of Lading:

at————————, 19—

from_____ the property described below, in apparent good order, except as noted (contents and condition of contents of packages unknown), marked, consigned, and destined as indicated below, which said company (the word company being understood throughout this contract as meaning any person or corporation in possession of the property under the contract) agrees to carry to its usual place of delivery at said destination, if on its own road or its own water line, otherwise to deliver to another carrier on the route to said destination. It is mutually agreed, as to each carrier of all or any of said property over all or any portion of said route to destination, and as to each party at any time interested in all or any of said property, that every service to be performed hereunder shall be subject to all the conditions not prohibited by law, whether printed or written, herein contained, including the conditions on back hereof, which are hereby agreed to by the shipper and accepted for himself and his assigns. [Mail or street address of consignee—For purposes of notification only.]

Consigned to_____

Destination_____

State of_____

County of_____

Route_____

Delivering Carrier_____

Car Initial_____

Car No_____

Trailer Initials/Number_____

Length_____

Plan_____

Length_____

Plan_____

Container Initials/Number_____

Length_____

Plan_____

Length_____

Plan_____

[[Page 74]]

_____

_____

No. packages	Description of articles, special marks, and exceptions	*Weight (subject to correction)	Class or rate	Check column	
.....	.....	.....	.....	.....	Subject to Section 7 of conditions, if this shipment is to be delivered to the consignee without recourse on the consignor, the consignor shall sign the following statement:
.....	.....	.....	.....	.....	.....
.....	.....	.....	.....	.....	The carrier shall not make delivery of this shipment

without payment of freight
and all other lawful
charges.

.....

(Signature of consignor)

If charges are to be prepaid,
write or stamp here,
"To be Prepaid."

Received $—— to apply in
prepayment of the charges on
the property described
hereon.

.....

Agent or Cashier

Per————

(The signature here
acknowledges only the amount
prepaid.)

.....

---

*If the shipment moves between two ports by a carrier by water, the law requires that the bill of lading shall state whether it is "carrier's or shipper's weight." Note. --Where the rate is dependent on value, shippers are required to state specifically in writing the agreed or declared value of the property. The agreed or declared value of the property is hereby specifically stated by the shipper to be not exceeding-- ———————————— per————————————

Charges advanced: ----------

Shipper

Agent

Per

Per

Permanent post office address of shipper

Appendix B to Part 1035--Contract Terms and Conditions

Contract Terms and Conditions

Sec. 1. (a) The carrier or party in possession of any of the property herein described shall be liable as at common law for any loss thereof or damage thereto, except as hereinafter provided.

(b) No carrier or party in possession of all or any of the property herein described shall be liable for any loss thereof or damage thereto or delay caused by the act of God, the public enemy, the authority of law, or the act or default of the shipper or owner, or for natural shrinkage. The carrier's liability shall be that of warehouseman, only, for loss, damage, or delay caused by fire occurring after the expiration of the free time allowed by tariffs lawfully on file (such free time to be computed as therein provided) after notice of the arrival of the property at destination or at the port of export (if intended for export) has been duly sent or given, and after placement of the property for delivery at destination, or tender of delivery of the property to the party entitled to receive it, has been made. Except in case of negligence of the carrier or party in possession (and the burden to prove freedom from such negligence shall be on the carrier or party in possession), the carrier or party in possession shall not be liable for loss, damage, or delay occurring while the property is stopped and held in transit upon the request of the shipper, owner, or party entitled to make such request, or resulting from a defect or vice in the property, or for country damage to cotton, or from riots or strikes.

(c) In case of quarantine the property may be discharged at risk and expense of owners [[Page 75]] into quarantine depot or elsewhere, as required by quarantine regulations or authorities, or for the carrier's dispatch at nearest available point in carrier's judgment, and in any such case carrier's responsibility shall cease when property is so discharged, or property may be returned by carrier at owner's expense to shipping point, earning freight both ways. Quarantine

expenses of whatever nature or kind upon or in respect to property shall be borne by the owners of the property or be a lien thereon. The carrier shall not be liable for loss or damage occasioned by fumigation or disinfection or other acts required or done by quarantine regulations or authorities even though the same may have been done by carrier's officers, agents, or employees, nor for detention, loss, or damage of any kind occasioned by quarantine or the enforcement thereof. No carrier shall be liable, except in case of negligence, for any mistake or inaccuracy in any information furnished by the carrier, its agents, or officers, as to quarantine laws or regulations. The shipper shall hold the carriers harmless from any expense they may incur, or damages they may be required to pay, by reason of the introduction of the property covered by this contract into any place against the quarantine laws or regulations in effect at such place.

Sec. 2. (a) No carrier is bound to transport said property by any particular train or vessel, or in time for any particular market or otherwise than with reasonable dispatch. Every carrier shall have the right in case of physical necessity to forward said property by any carrier or route between the point of shipment and the point of destination. In all cases not prohibited by law, where a lower value than actual value has been represented in writing by the shipper or has been agreed upon in writing as the released value of the property as determined by the classification or tariffs upon which the rate is based, such lower value plus freight charges if paid shall be the maximum amount to be recovered, whether or not such loss or damage occurs from negligence.

(b) As a condition precedent to recovery, claims must be filed in writing with the receiving or delivering carrier, or carrier issuing this bill of lading, or carrier on whose line the loss, damage, injury or delay occurred, within nine months after delivery of the property (or, in case of export traffic, within nine months after delivery at port of export) or, in case of failure to make delivery, then within nine months after a reasonable time for delivery has elapsed; and suits shall be instituted against any carrier only within two years and one day from the day when notice in writing is given by the carrier to the claimant that the carrier has disallowed the claim or any part or parts thereof specified in the notice. Where claims are not filed or suits are not instituted thereon in accordance with the foregoing provisions, no carrier hereunder shall be liable, and such claims will not be paid.

(c) Any carrier or party liable on account of loss of or damage to any of said property shall have the full benefit of any insurance that may have been effected upon or on account of said property, so far as this shall not avoid the policies or contracts of insurance: Provided, That the carrier reimburse the claimant for the premium paid thereon.

Sec. 3. Except where such service is required as the result of carrier's negligence, all property shall be subject to necessary cooperage and baling at owner's cost. Each carrier over whose route cotton or cotton linters is to be transported hereunder shall have the privilege, at its own cost and risk, of compressing the same for greater convenience in handling or forwarding, and

shall not be held responsible for deviation or unavoidable delays in procuring such compression. Grain in bulk consigned to a point where there is a railroad, public or licensed elevator, may (unless otherwise expressly noted herein, and then if it is not promptly unloaded) be there delivered and placed with other grain of the same kind and grade without respect to ownership (and prompt notice thereof shall be given to the consignor), and if so delivered shall be subject to a lien for elevator charges in addition to all other charges hereunder.

4. (a) Property not removed by the party entitled to receive it within the free time allowed by tariffs, lawfully on file (such free time to be computed as therein provided), after notice of the arrival of the property at destination or at the port of export (if intended for export) has been duly sent or given, and after placement of the property for delivery at destination has been made, may be kept in vessel, car, depot, warehouse or place of delivery of the carrier, subject to the tariff charge for storage and to carrier's responsibility as warehouseman, only, or at the option of the carrier, may be removed to and stored in a public or licensed warehouse at the place of delivery or other available place, at the cost of the owner, and there held without liability on the part of the carrier, and subject to a lien for all freight and other lawful charges, including a reasonable charge for storage.

(b) Where nonperishable property which has been transported to destination hereunder is refused by consignee or the party entitled to receive it, or said consignee or party entitled to receive it fails to receive it within 15 days after notice of arrival shall have been duly sent or given, the carrier may sell the same at public auction to the highest bidder, at such place as may be designated by the carrier: Provided, That the carrier shall have first mailed, sent, or given to the consignor notice that the property has been refused or remains unclaimed, as the [[Page 76]] case may be, and that it will be subject to sale under the terms of the bill of lading if disposition be not arranged for, and shall have published notice containing a description of the property, the name of the party to whom consigned, or, if shipped order notify, the name of the party to be notified, and the time and place of sale, once a week for two successive weeks, in a newspaper of general circulation at the place of sale or nearest place where such newspaper is published: Provided, That 30 days shall have elapsed before publication of notice of sale after said notice that the property was refused or remains unclaimed was mailed, sent, or given.

(c) Where perishable property which has been transported hereunder to destination is refused by consignee or party entitled to receive it, or said consignee or party entitled to receive it shall fail to receive it promptly, the carrier, may, in its discretion, to prevent deterioration or further deterioration, sell the same to the best advantage at private or public sale: Provided, That if time serves for notification to the consignor or owner of the refusal of the property or the failure to receive it, and request for disposition of the property, such notification shall be given, in such manner as the exercise of due diligence requires, before the property is sold.

(d) Where the procedure provided for in the two paragraphs last preceding is not possible, it is agreed that nothing contained in said paragraphs shall be construed to abridge the right of the carrier at its option to sell the property under such circumstances and in such manner as may be authorized by law.

(e) The proceeds of any sale made under this section shall be applied by the carrier to the payment of freight, demurrage, storage, and any other lawful charges and the expense of notice, advertisement, sale, and other necessary expense and of caring for and maintaining the property, if proper care of the same requires special expense, and should there be a balance it shall be paid to the owner of the property sold hereunder.

(f) Property destined to or taken from a station, wharf, or landing at which there is no regularly appointed freight agent shall be entirely at risk of owner after unloaded from cars or vessels or until loaded into cars or vessels, and except in case of carrier's negligence, when received from or delivered to such stations, wharves, or landings shall be at owner's risk until the cars are attached to and after they are detached from locomotive or train or until loaded into and after unloaded from vessels.

Sec. 5. No carrier hereunder will carry or be liable in any way for any documents, specie, or for any articles of extraordinary value not specifically rated in the published classifications or tariffs unless a special agreement to do so and a stipulated value of the articles are indorsed hereon.

Sec. 6. Every party, whether principal or agent, shipping explosives or dangerous goods, without previous full written disclosure to the carrier of their nature, shall be liable for and indemnify the carrier against all loss or damage caused by such goods, and such goods may be warehoused at owner's risk and expense or destroyed without compensation.

Sec. 7. The owner or consignee shall pay the freight and average, if any, and all other lawful charges accruing on said property; but, except in those instances where it may lawfully be authorized to do so, no carrier by railroad shall deliver or relinquish possession at destination of the property covered by this bill of lading until all tariff rates and charges thereon have been paid. The consignor shall be liable for the freight and all other lawful charges, except that if the consignor stipulates, by signature, in the space provided for that purpose on the face of this bill of lading that the carrier shall not make delivery without requiring payment of such charges and the carrier, contrary to such stipulation, shall make delivery without requiring such payment, the consignor (except as hereinafter provided) shall not be liable for such charges. Provided, that, where the carrier has been instructed by the shipper or consignor to deliver said property to a consignee other than the shipper or consignor, such consignee shall not be legally liable for transportation charges in respect of the transportation of said property (beyond those billed against him at the time of delivery for which he is otherwise liable) which may be found to be due after the property has been delivered to him, if the consignee

(a) is an agent only and has no beneficial title in said property, and

(b) prior to delivery of said property has notified the delivering carrier in writing of the fact of such agency and absence of beneficial title, and, in the case of a shipment reconsigned or diverted to a point other than that specified in the original bill of lading, has also notified the delivering carrier in writing of the name and address of the beneficial owner of said property; and, in such cases the shipper or consignor, or, in the case of a shipment so reconsigned or diverted, the beneficial owner, shall be liable for such additional charges. If the consignee has given to the carrier erroneous information as to who the beneficial owner is, such consignee shall himself be liable for such additional charges. On shipments reconsigned or diverted by an agent who has furnished the carrier in the reconsignment or diversion order with a notice of agency and the proper name and address of the beneficial owner, and where such shipments are refused or abandoned at ultimate destination, the said beneficial owner shall be liable for all legally applicable charges in connection therewith. If the reconsignor or diverter has given to the carrier [[Page 77]] erroneous information as to who the beneficial owner is, such reconsignor or diverter shall himself be liable for all such charges. If a shipper or consignor of a shipment of property (other than a prepaid shipment) is also the consignee named in the bill of lading and, prior to the time of delivery, notifies, in writing, a delivering carrier by railroad (a) to deliver such property at destination to another party, (b) that such party is the beneficial owner of such property, and (c) that delivery is to be made to such party only upon payment of all transportation charges in respect of the transportation of such property, and delivery is made by the carrier to such party without such payment, such shipper or consignor shall not be liable (as shipper, consignor, consignee, or otherwise) for such transportation charges but the party to whom delivery is so made shall in any event be liable for transportation charges billed against the property at the time of such delivery, and also for any additional charges which may be found to be due after delivery of the property, except that if such party prior to such delivery has notified in writing the delivering carrier that he is not the beneficial owner of the property, and has given in writing to such delivering carrier the name and address of such beneficial owner, such party shall not be liable for any additional charges which may be found to be due after delivery of the property; but if the party to whom delivery is made has given to the carrier erroneous information as to the beneficial owner, such party shall nevertheless be liable for such additional charges. If the shipper or consignor has given to the delivering carrier erroneous information as to who the beneficial owner is, such shipper or consignor shall himself be liable for such transportation charges, notwithstanding the foregoing provisions of this paragraph and irrespective of any provisions to the contrary in the bill of lading or in the contract of transportation under which the shipment was made. The term ``delivering carrier'' means the line-haul carrier making ultimate delivery.

Nothing herein shall limit the right of the carrier to require at time of shipment the prepayment or guarantee of the charges. If upon inspection it is ascertained that the articles shipped are not

those described in this bill of lading, the freight charges must be paid upon the articles actually shipped.

Where delivery is made by a common carrier by water the foregoing provisions of this section shall apply, except as may be inconsistent with part III of the Interstate Commerce Act.

Sec. 8. If this bill of lading is issued on the order of the shipper, or his agent, in exchange or in substitution for another bill of lading, the shipper's signature to the prior bill of lading as to the statement of value or otherwise, or election of common law or bill of lading liability, in or in connection with such prior bill of lading, shall be considered a part of this bill of lading as fully as if the same were written or made in or in connection with this bill of lading.

Sec. 9. (a) If all or any part of said property is carried by water over any part of said route, and loss, damage or injury to said property occurs while the same is in the custody of a carrier by water the liability of such carrier shall be determined by the bill of lading of the carrier by water (this bill of lading being such bill of lading if the property is transported by such water carrier thereunder) and by and under the laws and regulations applicable to transportation by water. Such water carriage shall be performed subject to all the terms and provisions of, and all the exemptions from liability contained in the Act of Congress of the United States, approved on February 13, 1893, and entitled ``An act relating to the navigation of vessels, etc.'' and of other statutes of the United States according carriers by water the protection of limited liability as well as the following subdivisions of this section: and to the conditions contained in this bill of lading not inconsistent with this section, when this bill of lading becomes the bill of lading of the carrier by water.

(b) No such carrier by water shall be liable for any loss or damage resulting from any fire happening to or on board the vessel, or from explosion, bursting of boilers or breakage of shafts, unless caused by the design or neglect of such carrier.

(c) If the owner shall have exercised due diligence in making the vessel in all respects seaworthy and properly manned, equipped and supplied, no such carrier shall be liable for any loss or damage resulting from the perils of the lakes, seas, or other waters, or from latent defects in hull, machinery, or appurtenances whether existing prior to, at the time of, or after sailing, or from collision, stranding, or other accidents of navigation, or from prolongation of the voyage. And, when for any reason it is necessary, any vessel carrying any or all of the property herein described shall be at liberty to call at any port or ports, in or out of the customary route, to tow and be towed, to transfer, trans-ship, or lighter, to load and discharge goods at any time, to assist vessels in distress, to deviate for the purpose of saving life or property, and for docking and repairs. Except in case of negligence such carrier shall not be responsible for any loss or damage to property if it be necessary or is usual to carry the same upon deck.

(d) General Average shall be payable according to the York-Antwerp Rules of 1924, sections 1 to 15, inclusive, and sections 17 to 22, inclusive, and as to matters not covered thereby according

to the laws and usages of the Port of New York. If the owners shall have exercised due diligence to make the [[Page 78]] vessel in all respects seaworthy and properly manned, equipped and supplied, it is hereby agreed that in case of danger, damage or disaster resulting from faults or errors in navigation, or in the management of the vessel, or from any latent or other defects in the vessel, her machinery or appurtenance, or from unseaworthiness, whether existing at the time of shipment or at the beginning of the voyage (provided the latent or other defects or the unseaworthiness was not discoverable by the exercise of due diligence), the shippers, consignees and/or owners of the cargo shall nevertheless pay salvage and any special charges incurred in respect of the cargo, and shall contribute with the shipowner in general average to the payment of any sacrifices, losses or expenses of a general average nature that may be made or incurred for the common benefit or to relieve the adventure from any common peril.

(e) If the property is being carried under a tariff which provides that any carrier or carriers party thereto shall be liable for loss from perils of the sea, then as to such carrier or carriers the provisions of this section shall be modified in accordance with the tariff provisions, which shall be regarded as incorporated into the conditions of this bill of lading.

(f) The term ``water carriage'' in this section shall not be construed as including lighterage in or across rivers, harbors, or lakes, when performed by or on behalf of rail carriers.

Sec. 10. Any alteration, addition, or erasure in this bill of lading which shall be made without the special notation hereon of the agent of the carrier issuing this bill of lading, shall be without effect, and this bill of lading shall be enforceable according to its original tenor.