



# Truckload Carriers Association

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VIA FIRST-CLASS MAIL

July 1, 2003

Food and Drug Administration  
Docket Management Branch (HFA-305)  
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

Dear Docket Clerk:

The Truckload Carriers Association (TCA) submits the following comments in response to the Notice of Proposed Rulemaking published by the Food and Drug Administrations (FDA) in the above-referenced docket at 68 Fed Reg. 25188 (May 9, 2003). TCA is the national trade association representing the truckload segment of the trucking industry. Truckload carriers account for approximately 97 percent of the for-hire freight tonnage annually transported by motor carriers and many of TCA's members are engaged in the transport of food products that will fall within the scope and requirements of the proposed rule. Matters relating to and affecting the operations and recordkeeping requirements imposed on truckload carriers are of vital interest to our members and we appreciate the opportunity to submit our thoughts and concerns regarding FDA's proposed rule.

TCA supports what FDA is seeking to accomplish through its proposed rules and, in general, we support what FDA has proposed. As a basic principal, however, because of the extent to which motor carriers have long been subject to a number of record keeping and retention requirements of the Federal Motor Carrier Safety Administration (FMCSA) governing essentially the same information being addressed here, it is TCA's recommendation that FDA adopt record keeping and retention requirements for motor carriers that are consistent with the FMCSA's requirements to the maximum extent possible. Furthermore, in promulgating the rules that will apply to motor carriers, FDA should recognize and take into account the specific and limited role and responsibility of a motor carrier in the transportation of food in relation to the greater role and responsibility of the shipper, receiver or other parties that are involved in the shipment of

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food. In submitting the following comments, TCA has taken each of these factors into consideration, as discussed more fully below.

1. The Final Rule Needs to Be More Specific and Much Clearer Regarding What Foods Are Subject to These Regulations and What Are Not: Several provisions of the proposed rule, *e.g.*, §§1.327 and 1.328, attempt to distinguish between those foods which will be subject to the requirements of the regulations and those foods that will not be subject. In doing so, proposed regulations refer to other federal statutes (*e.g.*, the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act), as a means to provide the regulated community with the relevant details as to whether and when their conduct will come within the scope of the regulations being proposed. While statutory references such as these may suffice to inform farms, food manufacturers, restaurants, and other food-related facilities that deal with these statutes on a daily basis whether and when they will be subject to FDA's final rule, that is clearly not the case with motor carriers and FDA should wisely not assume that to be so. Indeed, because of the stiff rate competition among motor carriers, long-term shipper-carrier or receiver-carrier relationships are no longer the norm. It is increasingly unlikely, therefore, that a motor carrier will know – let alone have a need to know – about these other statutes and/or regulations of the USDA that do not have direct application to the transportation of a food shipment that the carrier will transport. It would also be highly detrimental to the eventual success of these rules for FDA to assume that every motor carrier that engages in the transport of food will have such knowledge. Therefore, it is incumbent that FDA explain what food is subject to the final requirements and what is not in layman's language in order to avoid any confusion. It is TCA's further recommendation that FDA attach a list of the applicable or the exempted foods as an appendix to the regulations that it adopts.

2. The term "Responsible Individual" in Proposed §§1.352(a)(1) and (a)(2) Needs to be Clarified and the Scope of the Transporter's Responsibilities Under Both Sections Modified: Currently proposed §§1.352(a)(1) and (a)(2) would require in relevant part that a transporter would have to establish and maintain a record identifying "the name, address, phone number and, if available, e-mail address of the *responsible individual* . . . who had the food" immediately before and after the transporter (emphasis supplied). As set forth in the proposed rule, the term "responsible individual" infers that FDA intends to require the transporter to obtain and maintain a record of the name, etc. of the specific individual at the loading or unloading dock who personally tendered or received the load. However, in response to a question posed during a recent public outreach meeting held at the American Trucking Associations headquarters on June 17, 2003, FDA Regulatory Leader Ms. Leslye Fraser advised that such a literal reading of the proposed rule is not intended by the FDA and that FDA actually contemplates that the "responsible individual" is a manager or other supervisory personnel of the shipper and receiver with sufficient knowledge of the food shipment to be able to provide timely assistance to the FDA should the trace of a specific shipment ever be required. TCA supports this more practical interpretation of the proposed requirements that Ms. Leslye Fraser described and requests FDA to revise the proposed rule, in either §1.352 (with

examples) or as a defined term (with examples) in §1.328, to make it clear that what Ms. Fraser advised is, in fact, what FDA intends.

At the same time, it is also important for FDA to understand that a transporter's customer may be the shipper, the receiver, or a third-party transportation broker<sup>1</sup>, but not all simultaneously. Moreover, the transporter functions merely as a conduit between the shipper and receiver and will not normally have direct dealings with a "responsible individual" of both the shipper and the receiver regarding a specific shipment. Moreover, as explained in footnote #1, in the event a broker arranges the shipment, the carrier may not have direct dealings with either the shipper or receiver. In other words, the transporter may know and be able to provide accurate information regarding the name, etc. of the "responsible individual" at the shipper, receiver, or broker, but not necessarily or customarily about the responsible individual at all three, *i.e.*, the shipper, receiver *and* the broker. This would depend entirely upon whether the shipper or the receiver is the transporter's customer. When communicating with the shipper or receiver that is not the transporter's customer, especially in the case of retail facilities, the transporter will in almost all instances be dealing with a clerical or administrative employee whose job responsibilities would not rise to the level of the "responsible individual" described by Ms. Fraser.

On the other hand, because of the direct dealings between the shipper and receiver, all of the specific information that FDA seeks regarding the "responsible individual" at both the shipper and receiver would routinely be known by each of those entities. Accordingly, TCA recommends that proposed §1.352(a)(1) and (a)(2) be revised by FDA to relieve transporters from being required to provide the name, telephone number, fax number and e-mail address of a "responsible individual" at both the shipper and receiver for every food shipment transported. FDA should only require the transporter to provide such information if it is known by the transporter, *i.e.*, "if available" – which would depend upon whether the shipper, receiver, or broker is the transporter's customer. Such a revision to the proposed responsibilities of transporters is warranted for two reasons. First, it will eliminate an unnecessary burden on the transporter to obtain and maintain information that the transporter may not ordinarily have but which the shipper, receiver and broker will have and can readily provide. Second, such a revision would also lessen the likelihood that information FDA believes is critical to its mission could be inaccurately documented by a transporter simply because the information concerns an individual with whom the transporter does not routinely deal and, therefore, would at best be second-hand and therefore may not be reliable.

3. A Less-Specific Description of the Food Transported Should Be Required From Transporters: Proposed §1.352(a)(3) would require a transporter to obtain and

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<sup>1</sup> A transportation broker is a third-party whose function is to arrange for motor carriers to transport shipments, especially in the area of food transport. The broker may be hired by the shipper, the receiver, or by the carrier. The broker usually negotiates the rate between the parties and acts as a go-between for the parties. The broker informs the carrier where to pick-up and deliver a load as well as what the shipment will consist of. When a broker is involved, a carrier usually has no direct contact with either the shipper or receiver except for the physical action of picking up and delivering the load.

maintain “an adequate description of the type of food, including brand name and specific variety.” As further explained in the proposed section, a generic description of “lettuce” would not suffice and would instead require the transporter’s records to specify “romaine lettuce.” Even though both the shipper and receiver may know the brand and specific type, such details about commodities being transported is not always provided by the transporter’s shipper/receiver customer. To the contrary, unless such information would affect the freight rate for the shipment or would otherwise be germane to the transporter, such details are customarily not provided to a transporter. Accordingly, TCA believes that this level of specificity should not be required from transporters, especially when the information would be readily available to the FDA from both the shipper and receiver.

Similarly, transporters should also not be required to obtain and maintain the code and lot numbers, as proposed §1.352(a)(4) would require. Such information is ordinarily not relevant to a transporter and therefore not ordinarily provided to a transporter by a shipper. To the extent such information were to be needed by FDA it can easily be provided by the relevant shipper and should therefore be required from the shipper, not from the transporter.

4. For the Sake of Accuracy and Regulatory Consistency the Final Rule Should Recognize That Compliance with the Bill of Lading Regulations of the Federal Motor Carrier Administration Will Constitute Compliance with the Transporter’s Obligations Under §1.352: As discussed in the comments filed in this docket by the Distribution & LTL Carriers Association, motor carriers (*i.e.*, transporters) are required under regulations of the Federal Motor Carrier Safety Administration (FMCSA) to issue a bill of lading and a freight/expense bill for each shipment. Those regulations are codified at 49 C.F.R. §§373.101 and 373.103, copies of which are attached to and made a part of TCA’s comments. As will be noted from both the bill of lading and freight/expense bill, the name of the consignor, *i.e.*, the shipper, and the consignee, *i.e.*, the receiver, as well as the destination point(s), date of shipment, number of packages and a description of the freight are required to be set forth. The information required by the FMCSA’s regulations for purposes of ensuring the orderly transport of goods in commerce should be more than “adequate” (as the proposed rule provides) to enable FDA to trace any food shipment in question without need to impose further obligations on transporters; especially when the transporter will not be, or needs to be, the sole source of information upon which FDA will be relying for purposes of conducting a trace.

Accordingly, TCA agrees with the recommendation of the Distribution & LTL Carriers Association in requesting FDA to expressly provide in the final rule that compliance with the FMCSA’s requirements under 49 C.F.R. §§373.101 and 373.103 will constitute compliance with §1.352.<sup>2</sup>

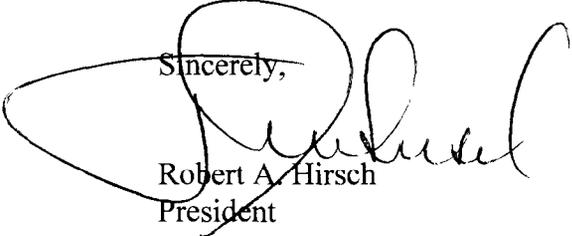
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<sup>2</sup> It is worth noting that identification requirements similar to what FDA has proposed for transporters in this proceeding were proposed by the Department of Transportation’s Research and Special Programs Administration (RSPA). Because of the similar concerns from industry, RSPA subsequently elected not to adopt what it had proposed. See Docket No. RSPA-02-12064: *Security Requirements for Offerors and Transporters of Hazardous Materials*, 68 Fed. Reg. 14509, 14513 (March 25, 2003). TCA hopes that FDA follows the precedent set by RSPA.

5. The Proposed Record-retention Requirements for Transporters Should Also be Made Consistent with FMCSA's Requirements for Bills of Lading: TCA also agrees with the recommendation of the Distribution & LTL Carriers Association that: (1) the record retention requirements under §1.360 should be revised and made the same for both nonperishable and perishable food shipments, rather than the one and two periods, respectively, being proposed, and (2) that the FDA's final rule should adopt the FMCSA's one-year retention period required for bills of lading. As the Distribution & LTL Carriers Association expressed in their comments: "It is difficult to imagine a situation where a food product that has been delivered to a store is not purchased and consumed within a year and therefore it is not necessary to keep these records for a longer period of time."

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TCA thanks FDA for the opportunity to comment in this proceeding.

Sincerely,  
  
Robert A. Hirsch  
President

Attachment

**§ 372.300 Distances and population data.**

In the application of this subpart, distances and population data shall be determined in the same manner as provided in 49 CFR 372.243. See also definitions in 49 CFR 372.239.

[62 FR 15422, Apr 1, 1997]

**§ 372.301 Terminal areas of motor carriers and freight forwarders at municipalities served.**

The terminal area within the meaning of 49 U.S.C. 13503 of any motor carrier of property or freight forwarder subject to 49 U.S.C. subtitle IV, part B at any municipality authorized to be served by such motor carrier of property or motor carrier of passengers in the transportation of express or freight forwarder, within which transportation by motor carrier in the performance of transfer, collection, or delivery services may be performed by, or for, such motor carrier of property or freight forwarder without compliance with the provisions of 49 U.S.C. subtitle IV, part B consists of and includes all points or places which are:

(a) Within the commercial zone, as defined by the Secretary, of that municipality, and

(b) Not beyond the limits of the operating authority of such motor carrier of property or freight forwarder.

[62 FR 15422, Apr. 1, 1997]

**§ 372.303 Terminal areas of motor carriers and household goods freight forwarders at unincorporated communities served.**

The terminal areas within the meaning of 49 U.S.C. 13503 of any motor carrier of property or freight forwarder subject to 49 U.S.C. subtitle IV, part B, at any unincorporated community having a post office of the same name which is authorized to be served by such motor carrier of property or motor carrier of passengers in the transportation of express or freight forwarder, within which transportation by motor vehicle in the performance of transfer, collection, or delivery services may be performed by, or for, such motor carrier of property or freight forwarder without compliance with the

provisions of 49 U.S.C. subtitle IV, part B, consists of:

(a) All points in the United States which are located within the limits of the operating authority of the motor carrier of property or freight forwarder involved, and within 3 miles of the post office at such authorized unincorporated point if it has a population less than 2,500, within 4 miles if it has a population of 2,500 but less than 25,000, or within 6 miles if it has a population of 25,000 or more;

(b) All of any municipality any part of which is included under paragraph (a) of this section; and

(c) Any municipality wholly surrounded by any municipality included under paragraph (b) of this section, or so wholly surrounded except for a water boundary.

[32 FR 20049, Dec. 20, 1967, as amended at 41 FR 56655, Dec. 29, 1976; 51 FR 44297, Dec 9, 1986; 62 FR 15423, Apr. 1, 1997]

**PART 373—RECEIPTS AND BILLS****Subpart A—Motor Carrier Receipts and Bills**

Sec.

- 373.101 Motor Carrier bills of lading.
- 373.103 Expense bills.
- 373.105 Low value packages.

**Subpart B—Freight Forwarders; Bills of Lading**

- 373.201 Bills of lading for freight forwarders.

AUTHORITY: 49 U.S.C. 13301 and 14706; and 49 CFR 1.73

**Subpart A—Motor Carrier Receipts and Bills**

SOURCE: 55 FR 11198, Mar. 27, 1990, unless otherwise noted. Redesignated at 61 FR 54708, Oct. 21, 1996.

**§ 373.101 Motor Carrier bills of lading.**

Every motor common carrier shall issue a receipt or bill of lading for property tendered for transportation in interstate or foreign commerce containing the following information:

- (a) Names of consignor and consignee.
- (b) Origin and destination points.
- (c) Number of packages.
- (d) Description of freight.

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(e) Weight, volume, or measurement of freight (if applicable to the rating of the freight).

The carrier shall keep a record of this information as prescribed in 49 CFR part 379.

[55 FR 11198, Mar. 27, 1990, as amended at 56 FR 30874, July 8, 1991; 62 FR 15423, Apr. 1, 1997]

**§ 373.103 Expense bills.**

(a) *Property.* Every motor common carrier shall issue a freight or expense bill for each shipment transported containing the following information:

(1) Names of consignor and consignee (except on a reconsigned shipment, not the name of the original consignor).

(2) Date of shipment.

(3) Origin and destination points (except on a reconsigned shipment, not the original shipping point unless the final consignee pays the charges from that point).

(4) Number of packages.

(5) Description of freight.

(6) Weight, volume, or measurement of freight (if applicable to the rating of the freight).

(7) Exact rate(s) assessed.

(8) Total charges due, including the nature and amount of any charges for special service and the points at which such service was rendered.

(9) Route of movement and name of each carrier participating in the transportation.

(10) Transfer point(s) through which shipment moved.

(11) Address where remittance must be made or address of bill issuer's principal place of business.

The shipper or receiver owing the charges shall be given the original freight or expense bill and the carrier shall keep a copy as prescribed at 49 CFR part 379. If the bill is electronically transmitted (when agreed to by the carrier and payor), a receipted copy shall be given to the payor upon payment.

(b) *Charter service.* Every motor passenger common carrier providing charter service shall issue an expense bill containing the following information:

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(1) Serial number, consisting of one of a series of consecutive numbers assigned in advance and imprinted on the bill.

(2) Name of carrier.

(3) Names of payor and organization, if any, for which transportation is performed.

(4) Date(s) transportation was performed.

(5) Origin, destination, and general routing of trip.

(6) Identification and seating capacity of each vehicle used.

(7) Number of persons transported.

(8) Mileage upon which charges are based, including any deadhead mileage, separately noted.

(9) Applicable rates per mile, hour, day, or other unit.

(10) Itemized charges for transportation, including special services and fees.

(11) Total charges assessed and collected.

The carrier shall keep a copy of all expense bills issued for the period prescribed at 49 CFR part 379. If any expense bill is spoiled, voided, or unused for any reason, a copy or written record of its disposition shall be retained for a like period.

[55 FR 11198, Mar. 27, 1990, as amended at 59 FR 2303, Jan. 14, 1994; 61 FR 19860, May 3, 1996; 62 FR 15423, Apr. 1, 1997]

**§ 373.105 Low value packages.**

The carrier and shipper may elect to waive the above provisions and use a more streamlined recordkeeping or documentation system for distribution of "low value" packages. This includes the option of shipping such packages under the provisions of 49 U.S.C. 14706(c). The shipper is responsible ultimately for determining which packages should be designated as low value. A useful guideline for this determination is an invoice value less than or equal to the costs of preparing a loss or damage claim.

[55 FR 11198, Mar. 27, 1990, Redesignated at 61 FR 54708, Oct. 21, 1996, as amended at 62 FR 15423, Apr. 1, 1997]

**Subpart B—Freight Forwarders;  
Bills of Lading****§ 373.201 Bills of lading for freight forwarders.**

Every household goods freight forwarder (HHGFF) shall issue the shipper through bills of lading, covering transportation from origin to ultimate destination, on each shipment for which it arranges transportation in interstate commerce. Where a motor common carrier receives freight at the origin and issues a receipt therefor on its form with a notation showing the HHGFF's name, the HHGFF, upon receiving the shipment at the "on line" or consolidating station, shall issue a through bill of lading on its form as of the date the carrier receives the shipment.

[55 FR 11201, Mar. 27, 1990. Redesignated at 61 FR 54708, Oct. 21, 1996.]

**PART 374—PASSENGER CARRIER  
REGULATIONS****Subpart A—Discrimination in Operations of  
Interstate Motor Common Carriers of  
Passengers**

## Sec.

- 374.101 Discrimination prohibited.
- 374.103 Notice to be printed on tickets.
- 374.105 Discrimination in terminal facilities.
- 374.107 Notice to be posted at terminal facilities.
- 374.109 Carriers not relieved of existing obligations.
- 374.111 Reports of interference with regulations.
- 374.113 Definitions.

**Subpart B—Limitation of Smoking on  
Interstate Passenger Carrier Vehicles**

- 374.201 Prohibition against smoking on interstate passenger-carrying motor vehicles.

**Subpart C—Adequacy of Intercity Motor  
Common Carrier Passenger Service**

- 374.301 Applicability.
- 374.303 Definitions.
- 374.305 Ticketing and information.
- 374.307 Baggage service.
- 374.309 Terminal facilities.
- 374.311 Service responsibility.
- 374.313 Equipment.

- 374.315 Transportation of passengers with disabilities.
- 374.317 Identification—bus and driver.
- 374.319 Relief from provisions.

**Subpart D—Notice of and Procedures for  
Baggage Excess Value Declaration**

- 374.401 Minimum permissible limitations for baggage liability.
- 374.403 Notice of passenger's ability to declare excess value on baggage.
- 374.405 Baggage excess value declaration procedures.

**Subpart E—Incidental Charter Rights**

- 374.501 Applicability.
- 374.503 Authority.
- 374.505 Exceptions.

AUTHORITY 49 U.S.C. 13301 and 14101; and 49 CFR 1.73

EDITORIAL NOTE: Nomenclature changes to part 374 appear at 66 FR 49871, Oct. 1, 2001.

**Subpart A—Discrimination in Operations of  
Interstate Motor  
Common Carriers of  
Passengers**

SOURCE: 36 FR 1338, Jan. 28, 1971, unless otherwise noted. Redesignated at 61 FR 54709, Oct. 21, 1996.

**§ 374.101 Discrimination prohibited.**

No motor common carrier of passengers subject to 49 U.S.C. subtitle IV, part B shall operate a motor vehicle in interstate or foreign commerce on which the seating of passengers is based upon race, color, creed, or national origin.

[36 FR 1338, Jan. 28, 1971. Redesignated at 61 FR 54709, Oct. 21, 1996, as amended at 62 FR 15423, Apr. 1, 1997]

**§ 374.103 Notice to be printed on tickets.**

Every motor common carrier of passengers subject to 49 U.S.C. subtitle IV, part B shall cause to be printed on every ticket sold by it for transportation on any vehicle operated in interstate or foreign commerce a plainly legible notice as follows: "Seating aboard vehicles operated in interstate or foreign commerce is without regard to race, color, creed, or national origin."