



Summary & User Guide:
FDA's Safe Transportation of Food Final Rule
Advancing the Sanitary Transportation of Human and Animal Food

Published by the
International Refrigerated Transportation Association



A Core Partner of



Version 2.0 – Updated April 2017

Acknowledgements

The International Refrigerated Transportation Association (IRTA), a Core Partner of the Global Cold Chain Alliance (GCCA), would like to thank all the members who were instrumental in the development of this valuable publication. In particular, GCCA would like to recognize:

Authors:

Patrick Brecht, Ph.D. – President, PEB Commodities, Inc.

Don Durm – Vice President – Customer Solutions, PLM Trailer Leasing

Bud Rodowick – Strategic Relations – Food Safety & OEMs, Thermo King

Contributor:

Stephen Neel, Ph.D. – Senior Technical Director, Global Cold Chain Alliance

Copyright © 2016 by the International Refrigerated Transportation Association

All rights reserved.

No portion of this work may be reproduced or transmitted in any form by any means, electronic or mechanical, including photocopying and recording, or by any information storage or retrieval system without written permission from the copyright holder.

The information promulgated by the International Refrigerated Transportation Association (IRTA) is not intended to be a comprehensive resource with respect to the refrigerated warehousing industry. While the material has been compiled with care, IRTA, and the authors of the manual have not validated all of the information contained herein and do not assume any responsibility for its use, accuracy, or applicability. All users of the information unconditionally agree: (1) not to hold IRTA or the authors responsible in any manner or to any extent for the user's action(s) or the consequences of such action(s) relating to the use of the information provided and (2) to indemnify IRTA, and the authors for all expenses, fees, costs, damages, awards, or other amounts incurred related to or arising from the user's use of the information. As used above, IRTA shall mean the organizations and each organization's directors, officers, employees, volunteers, members, and agents.



About IRTA

The International Refrigerated Transportation Association (IRTA) is a Core Partner of the Global Cold Chain Alliance (GCCA), a trade association that represents all major industries engaged in temperature-controlled logistics. As a GCCA Core Partner, IRTA supports the organization's overall mission of growing the industry and leading the cold chain through the development of best practices, research, networking, and education. IRTA also advocates for members in regulatory arenas.

Vision

IRTA will promote and strengthen the refrigerated and transportation logistics industry.

Mission

IRTA is organized to cultivate, foster and develop commercial and trade relations between those engaged in all aspects of producing, importing, exporting, transporting, warehousing commodities requiring temperature and/or atmospheric controls and related services:

- To gather and disseminate data and information to members.
- To protect the interests of its members from unlawful and unjust measures and practices.
- To conduct activities toward promoting and strengthening the interests of those engaged in the transportation and handling of temperature and/or atmospheric controlled goods and related services.

History

IRTA was established in 1994 to meet a growing demand in the transportation industry. Prior to that time, no single association existed wherein refrigerated transportation companies would have the opportunity to exchange valuable information, ideas, and insights.

More information, including details on members in IRTA, can be found at www.gcca.org.

Table of Contents

Using this Guide	5
STF Overview and Key Requirements	6
STF Compliance Dates to Note:	6
Who is Affected?	6
Driver Training and Written Procedures	6
Record Requirements for Shippers, Loaders and Carriers	7
Enforcement	7
Key Requirements	7
Primary Responsibility	8
Verification Activities	8
STF Compliance Matrix	9

Using this Guide

The International Refrigerated Transportation Association (IRTA) along with the Global Cold Chain Alliance (GCCA) has created resources to facilitate the safe transport of refrigerated food throughout the integrated supply chain, including shippers, loaders, carriers and receivers. This summary and user guide provides the reader with useful information to better understand and become compliant with the FDA's recent final rule for the Sanitary Transportation of Human and Animal Food (STF).

IRTA focuses on refrigerated transport carriers of all types, including but not limited to truck, trailer, rail, ocean and air carriers. However, IRTA and GCCA have developed the following tools primarily for refrigerated carriers utilizing truck, trailer and multi-temperature means of transporting food.

Ultimately, the safe transport of refrigerated food is a collaborative effort between the shipper, loader, carrier and receiver. The burden of safety is shared between all parties involved, and often is supported by legal contracts. It is important for all parties and persons involved in the integrated refrigerated transport supply chain to be aware of regulatory requirements as well as industry best practices to ensure a safe and seamless transfer of refrigerated cargo through the distribution process.

The goal of this summary and user guide is twofold: 1) To guide the user in a better understanding of the FDA's STF final rule; and 2) To provide the various categories of service providers in the integrated industry, including shippers, loaders, carriers and receivers, with information that will assist with final rule compliance and adoption of industry best practices.

This summary and user guide is designed to be a starting point, and the reader should seek out additional and more in-depth information and resources by consulting the IRTA/GCCA unabridged Refrigerated Transportation Best Practices Guide. The Best Practices Guide is a comprehensive collection of information designed to facilitate the safe transportation of refrigerated food. Industry experts have provided information on a wide array of topics, including but not limited to:

- Shipping pre-requisites
- Sanitary condition
- Set-Point temperatures
- Pre-cooling
- Loading trailers
- Staging trailers
- Departure procedures
- En-route compliance
- Load acceptance
- Exchange of data
- Communication and documentation

STF Overview and Key Requirements

The Food Safety Modernization Act or FSMA enables United States Food and Drug Administration (FDA) to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides new enforcement authorities to help achieve higher rates of compliance with risk-based, prevention-oriented safety standards and to better respond to and contain problems when they do occur. In addition, the law contains important new tools to better ensure the safety of imported foods and encourages partnerships with State, local, tribal, and territorial authorities and international collaborations with foreign regulatory counterparts. A top priority for FDA are those FSMA required regulations that provide the framework for industry's implementation of preventive controls and enhance our ability to oversee their implementation for both domestic and imported food.

The FDA's final Sanitary Transportation of Food (STF) rule was published in April 2016 and became effective on June 6, 2016. It is nearly 300 pages in length. This offers a brief summary of the key aspects and requirements. The full ruling can be found on the [Federal Register](#).

STF Compliance Dates to Note:

- April 6, 2017 – One year from rule publication date for businesses not defined as small or otherwise excluded from coverage.
- April 6, 2018 – Two years from rule publication date for small businesses (defined by the Small Business Administration (SBA) as truck transport companies and warehouses with annual receipts of \$27.5 million or less. Consult the [SBA web site](#) for more information on industry size standards).

Who is Affected?

The STF lays out a framework of requirements for **shippers, carriers, loaders and receivers** who transport food (including food for animals) in the United States by motor or rail vehicle, whether or not the food is offered for / or enters interstate commerce. As per the FDA, the STF also applies to persons, e.g., shippers, in other countries who ship food to the United States directly by motor or rail vehicle (from Canada or Mexico), or by ship or air, and arrange for the transfer of the intact container onto a motor or rail vehicle for transportation within the U.S., if that food will be consumed or distributed in the United States.

Driver Training and Written Procedures

The FDA STF final ruling requires that carriers provide awareness training to personnel engaged in transportation operations when the carrier and shipper have agreed via written contract that the carrier is responsible for the sanitary conditions during transportation operations. This includes awareness of potential food safety problems that may occur during transportation and basic sanitary transportation practices to address those problems. This training must be provided upon hiring and thereafter as necessary.

- Date of training

- Type of training
- Person(s) trained

Record Requirements for Shippers, Loaders and Carriers

Records must be maintained of written procedures, agreements and training (required of carriers). The required retention time for these records depends upon the type of record and when the covered activity occurred, but does not exceed 12 months. The final rule allows offsite storage of all records, except for the written procedures required, provided that the records can be retrieved and made available to FDA within 24 hours of a request for official review.

Key Requirements

Essentially, the STF rule allows the transportation industry to continue to use best practices (*i.e.*, “commercial or professional procedures that are accepted or prescribed as being correct or most effective) concerning cleaning, inspection, maintenance, loading and unloading, and operation of vehicles and transportation equipment that it has developed to ensure that food is transported under the conditions and controls necessary to prevent adulteration linked to food safety.

Specifically, the STF rule has established requirements in the following categories:

1. Vehicles and Transportation Equipment
2. Transportation Operations
3. Training Requirements for Carriers Engaged in Transportation Operations
4. Record Requirements for Shippers, Receivers, Loaders and Carriers
5. Waivers

Primary Responsibility

The rule identifies **shippers** as having the primary responsibility in determining appropriate transportation operations. Shippers may rely on contractual agreements to assign some of the responsibilities to other parties. The FDA defines ‘shipper’ as a person (*i.e.*, the manufacturer or a freight broker) who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially. It is important to note that third-party service providers who arrange for transportation, including warehouses and brokers, will be considered shippers when they arrange for transportation of food. Specifically, the rule requires:

- Shippers to develop and implement written procedures to ensure that equipment and vehicles are in appropriate sanitary condition.
- Shippers of food transported in bulk must develop and implement written procedures to ensure that a previous cargo does not make food unsafe.
- Shippers of food that require temperature control for safety must also develop and implement written procedures to ensure that food is transported under adequate temperature control.

Verification Activities

While primary responsibility initially lies with the shipper, the responsibility can be transferred to others via specifications and/or contractual language. Therefore, it is important that all parties and personnel in the integrated supply chain for refrigerated transport of food be prepared to verify and properly document that others with primary responsibility for implementation have done so. Verification activities are particularly important for loaders and receivers. Additional information on primary and secondary implementation and verification responsibilities is outlined in the Compliance Matrix elsewhere in this document.

Enforcement

The Department of Justice (DOJ) has formally announced that it has partnered with FDA and has adopted a policy of initiating criminal investigations against any company (or its employees) that sells a product that cause human illness. In prepared remarks, the Principal Deputy Assistant Attorney, Benjamin C. Mizer indicated that FDA and DOJ view any human illness caused by a food product as a potential violation of the law.

Congress has made the prohibition on introducing adulterated food into interstate commerce a strict liability offense, meaning that a company or individual violates the law and can face criminal charges whether or not it intended to distribute adulterated food.

STF Compliance Matrix

Sanitary Transportation of Food ~ Compliance Checklist										
Matrix Key	Sector Scope		Refrigerated transport of perishable food, within the context of this document, applies to the use of Refrigerated Truck Trailers, Refrigerated Truck Bodies and Multi-Temperature Trailers. This document does not apply to rail, air or ocean transport.							
	Responsibility	I	This sector has PRIMARY responsibility for understanding and IMPLEMENTING the industry Best Practice and/or regulatory requirement to achieve regulatory compliance.							
		V	This sector should understand the industry Best Practice and/or regulatory requirement and has SECONDARY responsibility for VERIFYING that compliance was met by others in the integrated cold chain.							
Sub Section	Best Practice Section	Synopsis of Regulatory Requirement	Sector							
			Shipper /Broker		Loader		Carrier		Receiver	
			I	V	I	V	I	V	I	V
1.906a	3.1	Appropriate vehicle and transportation equipment design for sanitary food transport	✓			✓	✓			✓
1.906b	3.1	Appropriate equipment maintenance for sanitary food transport	✓			✓	✓			✓
1.906c	3.1	Vehicles and transportation equipment properly designed, maintained and equipped for sanitary food transport	✓			✓	✓			✓
1.906d	3.2	Proper storage of vehicles and transportation equipment when not in use	✓			✓	✓		✓	
1.908a	2.2	Competent supervisory personnel	✓		✓		✓		✓	
	3.3, 3.4	Transportation operations conducted in a safe manner	✓		✓		✓		✓	
	3.3, 3.4	Transportation parameters specified	✓			✓		✓		✓
	3.3, 3.4	Written food safety procedures in place	✓		✓		✓		✓	
	3.5	Food safety checks if a temperature deviation occurs							✓	
1.908b	3.8	Shipper provides written sanitary specifications to other parties	✓			✓		✓		✓
	3.3, 3.4	Shipper establishes and provides written notice of temperature parameters to all parties	✓			✓		✓		✓
	3.8, 4.0, 14.3	Shipper develops and implements written procedures for vehicle sanitation	✓			✓		✓		✓

Sub Section	Best Practice Section	Synopsis of Regulatory Requirement	Sector							
			Shipper /Broker		Loader		Carrier		Receiver	
			I	V	I	V	I	V	I	V
1.908b	3.7	Shippers of bulk foods develop and implement written procedures for the sanitary transportation of refrigerated foodstuffs	✓			✓		✓		✓
	3.3, 3.4	Shipper develops and implements written procedures for the sanitary transportation of refrigerated foodstuffs	✓			✓		✓		✓
1.908c	3.8	Loaders to verify the sanitary condition of transportation equipment		✓	✓			✓		✓
	5.0, 14.3	Loaders to verify the proper operating condition of transportation equipment		✓	✓			✓		✓
1.908d	11.0, 14.10	Receivers to assess inbound food for temperature abuse in transit or off condition		✓	✓			✓		✓
1.908e	5.0	Carrier to ensure that vehicles and equipment meet shippers' specifications		✓		✓	✓			✓
	3.3, 3.4	Carrier to provide the operating temperature specified by the shipper and be prepared to demonstrate compliance with specifications		✓		✓	✓			✓
	6.0	Carrier to pre-cool mechanically refrigerated storage compartments as per shipper specifications		✓		✓	✓			✓
	3.7	Carrier to identify previous cargo transported in bulk vehicle if requested by shipper		✓		✓	✓			✓
	3.7	Carrier to provide information about the most recent cleaning of a bulk vehicle if requested by shipper		✓		✓	✓			✓
	3.8, 14.6	Carrier to develop and implement written cleaning, sanitizing and inspection procedures		✓		✓	✓			✓
	4.0	Carrier to develop and implement written procedures describing compliance with temperature control requirements		✓		✓	✓			✓
	3.7	Carrier to develop and implement written procedures describing compliance with bulk vehicle requirements		✓		✓	✓			✓
1.910	2.0	Carrier to establish and maintain training records		✓		✓	✓			✓
1.912a	12.0	Shipper to retain records, written procedures and agreements for 12 months beyond	✓							

		termination of agreement or when procedures are in use										
Sub Section	Best Practice Section	Synopsis of Regulatory Requirement	Sector									
			Shipper /Broker		Loader		Carrier		Receiver			
			I	V	I	V	I	V	I	V		
1.912b	12.0	Carrier to retain records, written procedures and agreements for 12 months beyond when the agreements and procedures are in use					✓					
1.912c	12.0	Carrier to retain training records for 12 months beyond when the person identified in records continues to perform the duties for which they were trained	✓				✓					
1.912d	12.0	Persons subject to STF Rule to retain written agreements assigning tasks covered by the rule for 12 months beyond the termination of the agreement	✓		✓		✓		✓			
1.912e	12.0	Covered parties operating under ownership or control of a single legal entity to retain records of their written procedures for 12 months beyond when the procedures are in use	✓		✓		✓		✓			
1.912f	12.0	Covered parties to make all records available to duly authorized individuals upon request	✓		✓		✓		✓			
1.912g	12.0	Records to be maintained as original, true copies or electronic records	✓		✓		✓		✓			