

Food and Drug Administration, Center for Food Safety and Applied Nutrition

Analysis of Comments Submitted to Docket FDA 2013-N-0013 Regarding Waivers from the Requirements of 21 CFR Part 1, Subpart O – Sanitary Transportation of Human and Animal Food

March 2017

This document presents the Food and Drug Administration (FDA) Center for Food Safety and Applied Nutrition's (CFSAN) analysis of the comments received in Docket FDA-2013-N-0013 in response to our request for comments on the potential waivers from the Requirements of 21 CFR Part 1, Subpart O – Sanitary Transportation of Human and Animal Food (the Sanitary Transportation rule), published in the Federal Register as part of the proposed Sanitary Transportation rule (79 FR 7006).

A. Background

On April 6, 2016, we published a final rule entitled Sanitary Transportation of Human and Animal Food (the Sanitary Transportation rule) (81 FR 20091). We stated in the proposed rule (79 FR 7006 at 7029-7030) that we had tentatively determined that in accordance with the provisions of section 416 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), it would be appropriate to waive the applicable requirements of the rule, if finalized as proposed, with respect to the following classes of persons:

- Shippers, carriers, and receivers who hold valid permits and are inspected under the National Conference on Interstate Milk Shipments (NCIMS) Grade "A" Milk Safety Program, only when engaged in transportation operations involving Grade "A" milk and milk products; and
- Food establishments holding valid permits, only when engaged in transportation operations as receivers, or as shippers and carriers in operations in which food is relinquished to consumers after transportation from the establishment.

We requested comment regarding whether these proposed waivers could result in the transportation of food under conditions that would be unsafe for human or animal health, or could be contrary to the public interest. We did not receive any comments with information indicating that these waivers would lead to these outcomes. However, we did receive comments requesting that we modify or expand the scope of these waivers beyond that which we discussed in the proposed rule. We received additional information from an organization representing institutional foodservice establishments subject to the proposed food establishment waiver that provided relevant details about the operational practices of these establishments relevant to the

scope of the proposed waiver. We have evaluated the comments and information to determine whether we should modify any of these waivers.

In accordance with the provisions of section 416 of the FD&C Act, we have published waivers (with some clarifications and with revisions addressing applicability of one of the waivers) for these classes of persons from the applicable requirements of the Sanitary Transportation rule, and the reasons for the waivers (82 FR 16733). In the final rule, we also stated that “[w]e will also discuss, in [a] subsequent notice, our thinking on comments we received asking us to consider publishing an additional waiver for transportation operations for molluscan shellfish for entities that hold valid State permits under the National Shellfish Sanitation Program” (81 FR 20106). Although we initially concluded that the transportation of molluscan shellfish would be included in the rule, we published an additional waiver for certain persons engaged in transportation operations for molluscan shellfish subject to the National Shellfish Sanitation Program (NSSP), along with the reasons for this additional waiver.

This notice presents our analysis of the comments and information we received in response to our proposal to publish waivers from the requirements of 21 CFR Part 1, Subpart O – Sanitary Transportation of Human and Animal Food, as discussed in the proposed Sanitary Transportation rule.

B. Analysis of Comments

1. Proposed Grade “A” Milk Waiver

(Comment 1) We received several comments in support of the proposed waiver. We did not receive any comments that opposed the proposed waiver. However, one comment stated that the rationale for the waiver assumes the Pasteurized Milk Ordinance (PMO) offers adequate controls for the transportation of milk, and since the PMO is used by State regulatory programs as a model ordinance, it is subject to variation during adoption into State code. The comment stated that critical limits should be established for this sector as well.

(Response 1) The PMO is a model regulation published and recommended by the U.S. Public Health Service/FDA for voluntary adoption by State dairy regulatory agencies to regulate the production, processing, storage and distribution of Grade “A” milk and milk products to help prevent milk borne disease. Currently all 50 States, the District of Columbia, and Puerto Rico have adopted the PMO by reference or have codified the PMO or similar provisions in State regulations. At its biennial conferences, the NCIMS considers changes and modifications to the Grade “A” PMO to further enhance the safety of Grade “A” milk and milk products, including administrative and technical details on how to obtain satisfactory compliance. While regulatory programs of the individual States based upon the model PMO are subject to variation during adoption by States, i.e., they are not identical to the provisions of the PMO, the NCIMS program has been effective from a regulatory standpoint, and has likely had a significant public health

impact in reducing the incidence of foodborne illness attributable to milk and milk products. Therefore, we do not find it necessary that State programs be identical to the provisions of the PMO, nor to impose additional requirements, e.g., critical limits (which are an element of the voluntary NCIMS Hazard Analysis and Critical Control Points (HACCP) Program alternative to the traditional inspection system) upon entities subject to this waiver. All States have programs that adequately address sanitary transportation practices to prevent milk and milk products from becoming unsafe during transportation. We continue to believe that it is appropriate to waive the requirements of the sanitary transportation rule with respect to shippers, carriers, and receivers who hold valid permits and are inspected under the NCIMS Grade “A” Milk Safety Program, only when engaged in transportation operations involving Grade “A” milk and milk products.

(Comment 2) Some comments asked us to also include in the waiver, the transportation of finished packaged Grade “A” milk products by conveyances operated by, and directly transported from, NCIMS-listed milk product plants that are regulated under the NCIMS, and not just bulk milk tankers alone.

(Response 2) We did not intend to restrict the proposed waiver to bulk milk tankers. Any transportation operation for Grade “A” milk products performed by an entity that is permitted and inspected under the NCIMS is subject to the waiver. This includes transportation operations for finished packaged Grade “A” milk products. To make this clear we have revised the waiver to state that it applies to shippers, carriers, and receivers that transport both bulk and finished Grade “A” milk products, provided that they hold valid permits and are inspected under the NCIMS Grade “A” milk safety program. The language of the revised waiver is below.

(Comment 3) Some comments asked us to expand the provisions of the proposed waiver to allow operators to transport products other than Grade “A” milk. One example given in a comment was milk scheduled to be picked up at a farm, and then discovered by the carrier at the time of pickup to not meet the temperature specifications for Grade “A” designation. Other comments requested that we expand the waiver to include all milk and milk products, including bulk shipments of raw milk that are a combination of Grade “A” and non-Grade “A” milk headed to a processing facility. However, some comments supported application of the waiver only to activities subject to the requirements of the NCIMS Grade “A” program.

(Response 3) We recognize that an operator subject to inspection under the Grade “A” program may in the course of its routine transportation operations, transport non-Grade “A” milk. Transportation operations in such circumstances are subject to the Sanitary Transportation rule. However, in circumstances, such as when a carrier learns that milk scheduled for pickup is out of temperature specifications for Grade “A” designation, but is suitable for use as a component of manufactured products, e.g., cheese or butter, we recognize that it would be impractical to expect the carrier to fully comply with provisions of the Sanitary Transportation rule as some of these provisions involve communication and the exchange of written material that generally takes

place in advance of the operation. When such events are occasional, unplanned and involve permitted operators who are subject to the requirements of the Grade “A” program, we generally intend to exercise discretion provided that these operators comply with the generally applicable provisions of the FD&C Act and its implementing regulations that apply to the holding of food, as these are consistent with the general provision of the Sanitary Transportation rule (§ 1.908(a)(3)) that states that “all transportation operations must be conducted under such conditions and controls necessary to prevent the food from becoming unsafe during transportation operations.” When such events are not occasional and unplanned, for instance, the scheduled hauling of non-Grade “A” milk, or of bulk juice on a return trip after a delivery of milk by a tank truck operator, we expect such operators to fully comply with the Sanitary Transportation rule.

(Comment 4) A comment asked us to clarify that the waiver applies to non-listed (by NCIMS) milk tank truck cleaning facilities that hold valid permits or are otherwise certified under the Grade “A” Milk Safety Program, and are subject to state inspections.

(Response 4) Tank truck cleaning facilities are not subject to the Sanitary Transportation rule because they are not shippers, loaders, carriers, or receivers. Therefore, these facilities are not subject to the waiver.

(Comment 5) Some comments stated that a shipment that includes products subject to the NCIMS Grade “A” program as well as those not covered by it (e.g., bulk orange juice), should be exempt from the requirements of the Sanitary Transportation rule with respect to those foods subject to the NCIMS requirements.

(Response 5) We agree. The waiver for entities who hold valid permits and are inspected under the NCIMS does not require that the entity be exclusively engaged in transportation operations for Grade “A” milk products, but would not apply with respect to other types of products transported concurrently with Grade “A” milk. For example, if Grade “A” milk products are transported concurrently with bulk orange juice or non-Grade “A” milk, the bulk orange juice or non-Grade “A” milk is subject to requirements of the Sanitary Transportation rule, and would not fall within the waiver. The transportation operations for the concurrently transported Grade “A” milk products in those examples, would fall within the waiver.

(Comment 6) Some comments stated that if a shipper is licensed under the Grade “A” program and the tanker is permitted and regulated under the same, then the milk and/or milk product hauler and milk producer should be included within the waiver, whether the milk is used in the production of finished Grade “A” milk products or non-Grade “A” milk products.

(Response 6) Inasmuch as a milk producer, as defined in the PMO, is among other things, “[a] person who operates a dairy farm,” a milk producer is not subject to the Sanitary Transportation rule because transportation activities performed by a farm are not “transportation operations”

within the meaning of the rule. With respect to milk haulers, the waiver is applicable only to transportation operations performed by persons that hold a valid permit and are inspected under the National Conference on Interstate Milk Shipments' Grade "A" Milk Safety Program, only when engaged in transportation operations involving bulk and finished Grade "A" milk and milk products. The waiver does not impose any condition on the type of finished Grade "A" milk product that will be produced from milk transported under the waiver. We explained in the proposed rule (79 FR 7006 at 7029-7030) why persons performing transportation operations under the circumstances described in the proposed waiver meet the statutory requirements for a waiver in section 416(d) of the FD&C Act. However, we are not able to conclude that persons engaged in food transportation operations beyond the scope of the proposed waiver meet the requirements of section 416(d) of the FD&C Act, and we are not expanding the waiver to include the operations of a hauler where a product other than Grade "A" milk is being transported, or to the operations of a hauler that is not properly certified and using a permitted vehicle.

In summary, in response to these comments, we have revised the final waiver, which we have published in the Federal Register (see 82 FR 16733), as follows: Shippers, carriers, and receivers who hold valid permits and are inspected under the National Conference on Interstate Milk Shipments (NCIMS) Grade "A" Milk Safety Program, only when engaged in transportation operations involving bulk and finished Grade "A" milk and milk products.

2. Proposed Food Establishment Waiver

We received several comments in support of the waiver. We did not receive any comments that opposed the waiver.

(Comment 1) One comment noted that the waiver as described may be too broad if it were to cover all establishments acting as shippers or carriers. The comment noted that even though such establishments must hold a valid permit issued by a State regulatory authority, they are also likely to use the type of local delivery box trucks that have been found to engage in more unsafe food handling practices than other vehicles. The comment stated that, at the very least, FDA should carefully investigate whether the states focus sufficiently on the trucks serving such establishments in addition to the conditions in each individual facility in order to decide whether a blanket waiver for this segment of the industry is warranted.

(Response 1) While the Interstate Food Transportation Assessment Project discussed in the proposed rule did make note of observed problems with smaller box trucks associated with ethnic food transportation, this finding does not suggest smaller box trucks are inherently incapable of being used to safely transport food. Such vehicles, if properly equipped and operated, are capable of transporting food under adequate sanitary conditions, and are commonly used for food transport. Further, businesses that are not themselves permitted or licensed food establishments, and that only transport food to establishments such as restaurants and retail

outlets, including via local delivery, are not covered by this waiver and are subject the Sanitary Transportation rule as a shipper and/or carrier. The food establishment waiver would apply to authorized food establishments, such as restaurants and retail stores, that are engaged in transporting food for the purpose of delivery to the consumer themselves or through a third-party delivery service. State and local regulations modeled after the Food Code require that such establishments take the necessary steps to prevent food from becoming unsafe or being subject to temperature abuse during its preparation and service to the consumer, including during delivery to the consumer. Delivering food to customers under conditions that may render such products unsafe is a violation of these rules with which foodservice and retail establishments must comply as a condition of their permit to operate. We work closely with our State and local partners to continually enhance the oversight of food establishment practices and to promote compliance with the applicable rules and regulations. We are not aware of any reason to limit the scope of the food establishment waiver to exclude operations by the establishment as a shipper or carrier, nor are we aware of any reason to limit the use of any type of vehicle to transport food under this waiver.

(Comment 2) A comment asked that we extend the proposed waiver to specifically include the operators of food service establishments when the establishment itself is engaged in transporting the food from wholesale/cash and carry facilities to their own food establishment, as long as transport times are 1 hour or less.

(Response 2) When the operator of a foodservice establishment takes possession of the food it intends to sell or serve to its customers, whether it be at the location of the establishment or at the location of another business (e.g., a wholesaler, cash and carry operation, or other retailer), that operator has taken receipt of the food. Therefore such operations by a food establishment holding a valid permit are covered by the food establishment waiver because the establishment is functioning as a “receiver” in this capacity. The handling of the food, at receipt and after it is in the possession of the establishment, is subject to the applicable requirements of the State, local, territorial, and tribal agencies that have primary responsibility to regulate the retail food and foodservice industries in the United States. The scope of the food establishment waiver includes operators of a foodservice establishment who has purchased and received foods at an offsite wholesale or retail facility location and is transporting it to the location of its own food establishment for subsequent sale or service to the consumer.

Response to Additional Information We Received in Response to the Proposed Food Establishment Waiver Providing Details about Operational Practices

In addition, we are also clarifying the scope of the provision of the waiver addressing transportation operations associated with the delivery of food from the establishment, in which a food establishment functions as a shipper or carrier. This waiver applies to such transportation operations whose purpose is to deliver foods from an authorized food establishment location

where it was held or prepared to a different location where the consumer will ultimately take possession of the food. Such operations are associated with the normal business of a retail-level food establishment and can reasonably be expected to be captured under the establishment's authorization to operate. Specifically, transporting food from one location where it was in possession of an authorized food service establishment or retail store location to another location where the consumer will take possession of that food can be assumed to be a delivery function of the food establishment. Such is the case if the location to where the food is delivered is where it is to be served or sold to the consumer by the operator of the originating location or by an operator that has direct affiliation with the originating location, such as a mobile food establishment or a satellite feeding location of a school foodservice authority. The waiver applies to delivery services operated by the food establishment itself or by a third-party that is hired to deliver the food directly to the consumer.

The waiver for shippers and carriers does not, however, apply to an establishment selling food to another establishment, such as when the originating facility is functioning as a wholesale operation or ingredient supplier, and thus outside the normal constraints of a permit to operate a retail food establishment.

3. Molluscan Shellfish waiver

(Comment 1) Commenters asked that we consider issuing a waiver for shippers, carriers, and receivers of shellfish that hold valid State permits in accordance with the provisions of the NSSP, which has specific transportation requirements that would support a similar waiver for applicable molluscan shellfish shippers and dealers.

(Response 1) Under the standard set forth in section 416(d)(1), FD&C Act and 21 CFR 1.914, and as discussed further in the paragraphs that follow, we have determined that it would be appropriate to waive the applicable requirements of 21 CFR part 1, subpart O, with respect to shippers, loaders, carriers, and receivers who are certified and inspected under the Interstate Shellfish Sanitation Conference's (ISSC) NSSP, when engaged in transportation operations involving molluscan shellfish in vehicles that are permitted by the State NSSP certification authority.

Participants in the NSSP include agencies from shellfish producing and non-producing States, FDA, the Environmental Protection Agency, the National Oceanic and Atmospheric Administration, and the shellfish industry. Under international agreements with FDA, foreign governments also participate in the NSSP. The purpose of the program is to promote and improve the sanitation of shellfish (oysters, clams, mussels and scallops) moving in interstate commerce through federal/state cooperation and uniformity of State shellfish programs. The NSSP uses as its basic standard the Guide for the Control of Molluscan Shellfish (GCMS), which incorporates a Model Ordinance and related materials. The Model Ordinance provides readily

adoptable standards and administrative practices necessary for the sanitary control of molluscan shellfish. Provisions of the GCMS and the NSSP address several aspects of the transportation of molluscan shellfish in interstate commerce including requirements for conveyances, containers used for holding product during transportation, sanitation and temperature control. Through their participation in the NSSP and membership in the ISSC, states have agreed to enforce the Model Ordinance as the requirements which are minimally necessary for the sanitary control of molluscan shellfish.

The GCMS, and the state regulations modeled after it, specify that every shellstock shipper, i.e., a dealer who grows, harvests, buys, or repacks and sells shellstock (live molluscan shellfish in the shell) shall be certified by a State shellfish control authority or its designated agents. Furthermore, when any requirement of the NSSP is violated, the shipper could be subject to decertification.

We have determined that waiving the requirements of subpart O with respect to shippers, loaders, carriers, and receivers who are appropriately certified and inspected under the NSSP, when engaged in transportation operations for molluscan shellfish in vehicles that are permitted by the State NSSP certification authority, would not result in the transportation of food under conditions that would be unsafe for human or animal health and would not be contrary to the public interest. Specifically, we have determined that shippers, loaders, carriers, and receivers who are appropriately certified and are inspected under the NSSP, when engaged in transportation operations for molluscan shellfish in vehicles that are permitted by the State NSSP certification authority, by virtue of complying with requirements that are based upon those set forth in the GCMS, are using sanitary transportation practices to ensure that molluscan shellfish are not transported under conditions that may render such products adulterated.

For example, under the requirements of the NSSP, a conveyance used to transport shellstock to the original dealer shall be properly constructed, operated, and maintained to prevent contamination, deterioration, and decomposition. In States in which the State NSSP certification authority permits vehicles that transport molluscan shellfish, the transport vehicles, which may transport shellfish not completely enclosed by a container, are subject to inspection by the State NSSP authority, which is the appropriate entity for performing such sanitation focused inspections. Containers used to transport shellstock must be constructed to allow for easy cleaning; and operated and maintained to prevent product contamination. Requirements also specify permissible agents for the cleaning of containers. The program includes requirements to ensure the protection of the shipment from cross-contamination. Furthermore, under the program, shellfish dealers must ship shellstock that is adequately iced, or in a conveyance pre-chilled at or below 45°F ambient air temperature. Furthermore, dealers receiving shellstock from another certified dealer for shucking and packing must document and maintain a record that the shellstock was received iced; in a conveyance at or below 45°F (7.2°C); or at an internal temperature of 50°F (10°C) or less. Dealers receiving shellstock from another certified dealer

must also document and maintain a record that the shipment was accompanied by documentation indicating (1) time of shipment; (2) that conveyance was pre-chilled; and (3) notice if shellstock was shipped prior to meeting required internal temperature and notice of a time/temperature device indicating that continuous cooling has occurred. Based on our analysis of these provisions, and other requirements of the NSSP, and the inspection, certification and permitting processes that currently exist within the NSSP, we have determined that the requirements of subpart O would not be necessary to ensure that molluscan shellfish products are not transported under conditions that may render such products unsafe. Accordingly, we are waiving the requirements of subpart O with respect to shippers, loaders, carriers, and receivers who are appropriately certified and are inspected under the NSSP, when engaged in transportation operations for molluscan shellfish in vehicles that are permitted by the State NSSP certification authority.

C. Waivers as Published in the Federal Register (82 FR 16733)

1. Businesses subject to the requirements of 21 CFR Part 1, Subpart O, that hold valid permits and are inspected under the National Conference on Interstate Milk Shipments' Grade "A" Milk Safety Program, only when engaged in transportation operations involving bulk and finished Grade "A" milk and milk products; and
2. Businesses subject to the requirements of 21 CFR Part 1, Subpart O, that are permitted or otherwise authorized by the regulatory authority to operate a food establishment that provides food directly to consumers (i.e., restaurants, retail food establishments and nonprofit food establishments as defined in 21 CFR 1.227), only when engaged in transportation operations as:
 - a. receivers, whether the food is received at the establishment itself or at a location where the authorized establishment receives and immediately transports the food to the food establishment;
 - b. shippers and carriers in operations in which food is transported from the establishment as part of the normal business operations of a retail establishment, such as:
 - i. delivery of the food directly to the consumer(s) by the authorized establishment or a third-party delivery service; or
 - ii. delivery of the food to another location operated by the authorized establishment or an affiliated establishment where the food is to be sold or served directly to the consumer(s).
3. Businesses subject to the requirements of 21 CFR Part 1, Subpart O, that are appropriately certified and are inspected under the requirements established by the Interstate Shellfish Sanitation Conference's National Shellfish Sanitation Program, only when engaged in transportation operations involving molluscan shellfish in vehicles that are permitted by the State NSSP certification authority.