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INTERNATIONAL DAIRY FOODS ASSOCIATION℠

Via electronic submission

July 29, 2014

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

Re: FSMA-Sanitary Transportation of Human and Animal Food Proposed Rule; Docket No. FDA-2013-N-0013

To Whom it May Concern:

The International Dairy Foods Association (IDFA) and the National Milk Producers Federation (NMPF) appreciate this opportunity to comment on the Food and Drug Administration's (FDA) proposed rule on Sanitary Transportation of Human and Animal Food, which is part of the agency's implementation of the Sanitary Food Transportation Act of 2005 and the FDA Food Safety Modernization Act (FSMA).

IDFA, Washington, D.C, represents the nation's dairy manufacturing and marketing industries and their suppliers, with a membership of 550 companies within a $125-billion a year industry. IDFA is composed of three constituent organizations: the Milk Industry Foundation (MIF), the National Cheese Institute (NCI) and the International Ice Cream Association (IICA). IDFA's nearly 200 dairy processing members run nearly 600 plant operations, and range from large multi-national organizations to single-plant companies. Together they represent more than 85 percent of the milk, cultured products, cheese, ice cream and frozen desserts produced and marketed in the United States.

The National Milk Producers Federation (NMPF), based in Arlington, VA, develops and carries out policies that advance the well-being of dairy producers and the cooperatives they own. The members of NMPF's cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of more than 32,000 dairy producers on Capitol Hill and with government agencies.

We supported passage of FSMA and have been pleased to assist the agency in its work to implement FSMA's many provisions. Strong collaboration between the agency and all stakeholders can help ensure clear, straight-forward regulatory requirements that improve food safety.

Introduction and Overview

IDFA and NMPF agree with FDA that there is no need to change current sanitary food transportation practices through regulatory requirements. Today, food already is safely transported and there is no identified need to improve upon current, voluntary industry practices.[1] Therefore, we support the agency's goal of issuing regulations that codify existing industry practices, which ensure food is transported safely. As the agency itself noted, FDA's regulations should be drafted such that the agency would "not anticipate large scale changes in practices as a result of the requirements."[2] Likewise, the requirements should be drafted so that "many firms are . . . already [] in compliance"[3] with the proposed rule.

For the most part, FDA's proposed rule succeeds in achieving these goals. There are, however, several areas where improvements are appropriate:

- To align with current, leading industry practices, codified language regarding temperature control should: (1) avoid implying that the agency expects continuous temperature monitoring during transportation; (2) require carriers to demonstrate compliance with the shipper's temperature requirements only in those instances when the receiver or shipper requests it; and (3) make clear that a deviation from the shipper's temperature requirement does not necessarily make the food adulterated.
- FDA should clarify in the preamble to the final rule that frozen dairy desserts, like ice cream, are not "foods that can support the growth of undesirable microorganisms in the absence of temperature control during transportation" and thus are not subject to temperature control related requirements.
- FDA should explicitly recognize that shippers, carriers, and receivers may enter into contracts that allocate responsibilities either between them or to another entity.
- To be risk-based, the requirements should be modified for the following transportation activities to recognize that these activities may not need the same level of oversight as others: (1) short duration transportation operations; (2) the transportation of raw agricultural commodities from farms, regardless of whether a farm is performing the transportation; and (3) intra-company shipments.

In the comments that follow we discuss each of these issues of concern. We also respectfully ask the agency to share its plans for inspections and enforcement. In addition, we express our support for those areas of the proposed rule where we believe FDA's approach is flexible and risk-based. For example, we support the proposed waiver for foods subject to the Pasteurized Milk Ordinance (PMO) and believe the scope of that waiver should be expanded; the agency's practical approach to recordkeeping; the proposed exemption for shelf-stable foods; and the agency's decision not to issue a list of foods/non-foods that cannot be transported together.

In sum, we support sanitary food transportation regulations that are goal-based, broadly framed, aligned with current industry practices, and adaptable to the many different kinds of transportation activities conducted in our industry.

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[1] Not only are sanitary transportation practices the right thing to do for food safety, but our members must ensure their foods arrive safely at their destination or the receiver will reject the shipment.

[2] 79 Fed. Reg. 7006, 7007 (Feb. 5, 2014).

[3] *Id.* at 7011.

I. FDA Should Revise the Temperature Monitoring Requirements to Align with Current Industry Practices that are Adequate to Ensure Food Safety

Under the proposed rule, once the transportation operation is complete, a carrier must demonstrate to the shipper that the temperature conditions during transportation were consistent with those that the shipper specified. Such demonstration "may be accomplished by any appropriate means agreeable to the carrier and shipper such as the carrier presenting printouts of a time/temperature recording device or a log of temperature measurements taken at various times during the shipment." We are concerned that this proposed requirement does not align with current industry practices that are established as adequate for food safety. Further, this regulation suggests a requirement for continuous temperature monitoring, which we believe is not necessary for food safety. In addition, carriers should only be required to demonstrate compliance with the shipper's temperature conditions on an exception basis—if there is a question about the condition of the food—not on a routine basis. Moreover, FDA's requirements should make clear that a deviation from the shipper's temperature requirement does not necessarily make the food adulterated.

A. Temperature Monitoring Requirements Should Avoid Implying that the Agency Expects Continuous Temperature Monitoring

IDFA and NMPF are concerned that the language of the proposed rule suggests a need to engage in either continuous temperature monitoring or to record temperatures throughout transportation. This approach is not consistent with current industry practices, which we explain below. To ensure the proposed rule aligns with current practices, the examples of "any appropriate means agreeable to the carrier and shipper" for demonstrating compliance with temperature requirements should be revised to avoid implying that the agency expects continuous temperature monitoring.

Under current practices, prior to shipment, trucks and other motor vehicles are pre-cooled as needed before food is loaded onto the vehicle. (Not surprisingly, sometimes vehicles do not need to be pre-cooled, such as trucks used to ship food in Minnesota during January.) A typical practice is for the shipper to confirm the ambient temperature of the trailer and that it is set at the appropriate temperature prior to departure. This ensures that the refrigeration unit is working properly and that the trailer is at the right temperature immediately upon loading. Notably, the temperature set by the shipper is often different than the temperature needed for food safety. For example, the temperature may be set lower in the summertime, or if a lower temperature helps ensure product quality.

Then, when the trailer arrives at its destination, the carrier or receiver checks the ambient temperature of the trailer and the temperature setting.[4] In addition, the receiver often conducts a visual inspection to confirm there are no visible signs of temperature abuse, such as sweating, ice crystals, signs of moisture, leaking product, moisture damage to packaging, etc. If there is an indication of a material deviation from the temperature requirements, the receiver will conduct an investigation into the issue to confirm whether there may be a food safety issue. Carriers today do not routinely demonstrate to the shipper through documentation that they have maintained temperature conditions continuously during transportation, as FDA would require.

[4] Some, but not the majority, of industry members check actual product temperature rather than ambient temperature.

Significantly, during shipment, our members do not routinely use continuous time/temperature recorders (TTRs). They are expensive and our members have not found that they are needed to ensure safety, given the checks that take place at the beginning and the end of the shipment. TTRs typically are used only when required by customers. Many trucks do have some temperature recording ability, which often is built into the refrigerator unit itself. This equipment varies as to whether it records the air temperature or the temperature at which the equipment is set. It is expensive and time-consuming, however, to download the information stored on these units. Often the vehicle has to be taken out of service and delivered to a third party to download the data. Thus, this information typically is retrieved only when needed during an investigation into whether a material deviation in the temperature occurred during transportation.

These current industry practices are well-established as adequate for food safety. Indeed, we note that the preamble to the proposed rule includes an example where FDA recognizes that it can be adequate to conduct a pre-loading inspection to verify pre-cooling and to inspect the food upon delivery.[5] We are concerned, however, that this example is limited to transportation over a short distance, whereas current industry practices use this approach regardless of the shipping distance. And, in contrast to the preamble, the examples in the proposed rule—"printouts of a time/temperature recording device or a log of temperature measurements taken at various times during the shipment"[6]—refer to continuous temperature monitoring.

Accordingly, we respectfully request that FDA revise the codified language to avoid suggesting a universal need for continuous temperature monitoring. Specifically, we support the proposed language that the carrier's demonstration of temperature maintenance can be accomplished by "any appropriate means agreeable to the carrier and shipper,"[7] but request that the example be revised to involve temperature verification upon departure and arrival as described above. This would ensure that the regulatory requirements are both adequate for safety and aligned with current industry practices.

B. Carriers Should be Required to Demonstrate Compliance with the Shipper's Temperature Requirements Only in Those Instances When the Receiver or Shipper Requests It

Relatedly, carriers should be required to demonstrate compliance with the shipper's temperature requirements only in those instances when the receiver or shipper requests it, not as a routine requirement for every shipment. As discussed above, upon delivery, the receiver typically checks to confirm that the food has arrived safely by verifying the temperature setting and the ambient temperature in the trailer. In addition, the receiver often conducts a visual inspection to confirm there are no visible signs of temperature abuse. There is no need for the carrier to communicate compliance to the shipper because the receiver is able to review the situation and will inform the shipper if the food is not acceptable. A requirement for the carrier to communicate compliance to the shipper would add an additional compliance burden that is not necessary for food safety. Carriers should only be required to demonstrate their compliance with temperature specifications if the receiver or shipper requests it (i.e., when there is a question about whether the food arrived in a safe condition).

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5 79 Fed. Reg. at 7024.

6 Id.

7 Id.

When Temperature Deviations Occur, Food is Not Necessarily Adulterated

As noted above, the temperature that the shipper specifies to the carrier often is set below the temperature necessary to maintain food safety. This is done for a variety of reasons, such as to account for seasonal variations in temperature, to provide a margin of safety, or to protect the quality of the product. Sometimes food arrives at a higher temperature than that specified by the shipper. That does not mean, however, that the food is necessarily adulterated. Rather, if the carrier is unable to maintain temperature conditions during transportation consistent with those specified by the shipper, FDA's regulations should place responsibility on the shipper to make a science-based determination of whether the temperature deviation makes the food adulterated for its intended use.

II. FDA Should Recognize that Frozen Dairy Desserts Are Not "Foods that Can Support the Rapid Growth of Undesirable Microorganisms in the Absence of Temperature Control"

Frozen dairy desserts, including ice cream, sherbet, frozen yogurt and novelties, are not "foods that can support the rapid growth of undesirable microorganisms in the absence of temperature control."[8] It is well established that microbial growth essentially stops, or slows to within practical limits, at temperatures between 1° and 4°C (34 to 38°F). For all practical purposes, the lowest temperature that would allow for microbial growth of "undesirable microorganisms" (as defined by FDA) in ice cream would be -2°C, and more likely would be 2°C. In producing ice cream, freezing begins at approximately -2°C (28°F). Typical soft-serve ice cream is served at temperatures close to -7°C and typical hard ice cream is served at temperatures around -14°C. If ice cream were to warm up during transportation to a temperature of -2°C, it would essentially be unsalable, as the ice crystals of the product would melt, the flavoring ingredients would begin to settle, and the incorporated air (termed "overrun" – ice cream is a frozen foam) would begin to escape. If ice cream warmed up to -5 to -3°C during transport and then was refrozen, the water would refreeze to very large ice crystals with a coarse, unacceptable texture, again rendering the product unsalable. Accordingly, if ice cream is brought to a temperature above the freezing point of the product, it would result in a noticeable quality issue—and would be rejected—well before any food safety concerns could arise, but it would not be adulterated. As such, frozen dairy desserts, such as ice cream, are not "foods that can support the rapid growth of undesirable microorganisms in the absence of temperature control."[9] Therefore, it is outside the scope of the proposed rule as was discussed at the public meeting at CFSAN on March 20, 2014. See Dr. Kashtock's remarks below. We ask FDA to clarify this point in the preamble to the final rule.

> "If the food can spoil due to the failure to provide temperature control, spoilage renders a food adulterated. It is a different adulteration provision than the one that deals with safety, but it, nonetheless, renders the food adulterated. And that is that middle category of foods that Shannon alluded to where, you know, we would say that a failure to provide refrigeration results in a food that could become adulterated. Even though that adulteration may not be that it could be rendered unsafe, it would be within the scope of the rule. **If, on the other hand, failure to provide refrigeration only affects the quality of the food in some way that does not**

[8] *See* Letter from Dr. Douglas Goff, Professor of Food Science, University of Guelph, to Clay Detlefsen, Vice President and Counsel, International Dairy Foods Association (Apr. 2, 2014) (attached).

[9] Id.

> **render the food adulterated, then it is not within the scope of this rule**, but the question as you posed it to me doesn't necessarily lead me to conclude that ice cream is within that third category. Tell me a little bit more about what could happen to ice cream if it's not properly refrigerated."[10]

To be clear, IDFA and NMPF firmly believe that frozen dairy desserts when subjected to temperature abuse, are exclusively a quality issue, not an adulteration issue.

III. FDA Should Explicitly Recognize that Shippers, Carriers, and Receivers May Enter into Contracts that Allocate Responsibilities Either Between Them or to Another Entity

FDA proposes to define a shipper as "a person who initiates a shipment of food by motor vehicle or rail vehicle." There are many different parties, however, who could be said to "initiate" a shipment of food. For example, a broker may initiate a shipment by identifying and contracting with a third party carrier. A food manufacturer may initiate a shipment by hiring a broker to arrange for product transportation. To reflect common industry practices and to account for all of the various arrangements in the industry, FDA should explicitly recognize that shippers, carriers, and receivers may enter into contracts that allocate responsibilities either between them or to another entity.

In the preamble to the proposed rule, FDA signals that this is acceptable. The agency states:

> The definition of "shipper" provides that the shipper is responsible for all functions assigned to a shipper . . . even if they are performed by other persons such as a person who only holds food and physically transfers it onto a vehicle arranged for by the shipper. For example, a product distributor (the shipper) may initiate a shipment of food by arranging for a carrier to pick up a shipment of fresh produce at a holding facility for transport by truck to a product distribution facility hundreds of miles away. Employees of the holding facility who are not employed by the distributor may load the product onto the truck. Under this proposed rule, the distributor would be responsible, e.g., through contractual arrangements, for ensuring that the employees of the holding facility visually inspect the vehicle for cleanliness and determine that it appears to be in appropriate sanitary condition for the transport of the food . . . .[11]

Thus, FDA acknowledges the potential for parties to contractually allocate their responsibilities under the proposed regulations.

This makes sense because the defined "shipper" (or "carrier" or "receiver") may not always be in the best position to ensure compliance. For example, if a broker is considered to be a "shipper," the broker may designate the food manufacturer as the party who should determine the appropriate temperature for the shipment and who should conduct a pre-loading inspection of the vehicle. Rather than revise the regulatory definitions to account for all variations, in the preamble to the final rule, FDA should explicitly recognize that shippers, carriers, and receivers may enter into contracts

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[10] See Statement from Dr. Michael Kashtock, FSMA Public Meeting Transcript: Proposed Rule on Sanitary Transportation of Human and Animal Food (Mar. 20, 2014), http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM395355.pdf

[11] 79 Fed. Reg. at 7014.

that allocate responsibilities either between them or to another entity and should maintain records documenting these agreements.

IV. To Be Risk-Based, the Requirements Should be Modified for Certain Kinds of Transportation Activities to Recognize that these Activities May Not Need the Same Level of Oversight as Others

There are several areas where we encourage FDA to revise the proposed regulations so that they are more risk-based and recognize that certain kinds of transportation activities do not need the same level of oversight as others. FDA should tailor the regulatory requirements so that they provide oversight where necessary and meaningful, but do not impose additional burdens where they are not needed. IDFA and NMPF urge FDA to modify its requirements for (1) short duration shipments; (2) the transportation of raw agricultural commodities from a farm, regardless of who performs the transportation; and (3) intra-company shipments.

A. Short Duration Shipments

Under the proposed rule, all transportation would be regulated in the same manner—regardless of the duration or distance. This approach is not risk-based, in that it ignores the basic food safety principle of time and temperature's influence over the growth of foodborne organisms, as shorter duration shipments may not require the same level of control and oversight as longer duration transportation. For example, if a company runs a shuttle service between its manufacturing facility and a warehouse a few miles away (e.g., taking only a few minutes to traverse), it may not be necessary to verify that a temperature-controlled container is at the correct temperature nor to check package/product temperature upon arrival at the warehouse because the product temperature, even if able to rise to above refrigeration temperature, would not be at that temperature long enough for rapid growth of undesirable organisms to occur.

Therefore, we respectfully request that FDA modify the regulation to recognize that shorter duration shipments may not need the same level of oversight as other transportation. Specifically, FDA should create a flexible regulatory definition of "short duration transportation operations" to cover food transportation activities that involve only a short duration, whereby the food would not be exposed to temperature/time conditions that would result in adulteration. The regulations should expressly state that only the requirements in Sections 1.906 and 1.908(a), (b)(2), (c), and (d)(6) are applicable to short duration transportation operations.[12] These modifications will help ensure the regulations are risk-based and not overly burdensome.

B. The Transportation of Raw Agricultural Commodities Regardless of Whether a Farm is Performing the Transportation

FDA proposes exempting transportation activities for raw agricultural commodities ("RACs") that are performed by a farm from the definition of "transportation operations" (and therefore from the coverage of the proposed rule). For purposes of the sanitary transportation of food regulations, a "farm" includes facilities that pack or hold food, regardless of whether all food used in such activities

[12] These sections of the regulations address the general requirements for vehicles and transportation equipment and the general requirement for shippers and carriers to take those steps necessary to ensure that food is transported safely.

is grown, raised, or consumed on that farm or another farm of the same ownership. IDFA and NMPF assert that this proposed exemption is too narrow.

There is no food safety reason for distinguishing between different types of shippers in this way. The food safety risk during transportation of RACs from a farm is low regardless of whether a farm contracts with a third party to transport the food or a food processing facility contracts with the same third party to transport the same food. To ensure the regulations are risk-based, FDA should exempt the transportation of raw agricultural commodities from a farm regardless of whether a farm is performing the transportation.

C. Intra-Company Shipments

Many of our members routinely ship products between their own facilities, or act as both the shipper and the carrier for a given shipment. Under the proposed rule, the same requirements apply regardless of whether the shipper and carrier are part of the same corporate entity. Yet, it does not make sense in these situations to apply the same requirements, such as requiring the shipper to specify its transportation requirements to the carrier in writing or to require the shipper to inform the carrier about the previous cargoes transported in a bulk container. Accordingly, the regulations should provide for modified requirements in these situations. It should be adequate for companies to follow their internal Standard Operating Procedures (SOPs).

V. The Agency Should Share Its Plans for Inspections and Enforcement

IDFA and NMPF respectfully request that FDA share its plans for inspections and enforcement in this area. In particular, the agency should provide an opportunity for public input about these plans. At the outset, we have two areas of potential concern. First, FDA investigators should be trained to understand the limitations on records access for this regulation. Because covered parties are required to keep limited records, access also is limited. Second, we want to ensure that inspections and enforcement activities do not compromise the safety of food shipments. For example, if investigators require vehicles to be opened during transport, this could compromise not only the seals on the vehicle, but also could compromise the temperature inside. Thus, on-road enforcement should be approached cautiously.

In addition, there should be an opportunity for investigators in the field to determine when a failure to comply with the requirements of this proposed rule is non-critical and will not result in adulterated food. In particular, IDFA and NMPF recommend that enforcement actions not be pursued for recordkeeping deficiencies when there is otherwise the opportunity to determine whether the food is adulterated. In all cases, the test for enforcement should be whether the food itself it rendered adulterated. We recommend that, to make this clear, FDA revise proposed 1.902(a) as follows:

"(a) The criteria and definitions of this subpart apply in determining whether food is adulterated within the meaning of section 402(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(i)) in that the food has been transported or offered for transport by a shipper, carrier by motor vehicle or rail vehicle, or receiver engaged in transportation operations under conditions that are not in compliance with this subpart so as to render the food adulterated."

VI. Additional Comments

Although there are some areas where we think revisions are appropriate, we also want to express our support for those areas of the proposed rule where we believe FDA's approach is flexible and risk-based. In particular, we support: the proposed waivers for foods subject to the Pasteurized Milk Ordinance (PMO) and believe it should be expanded; the agency's practical approach to recordkeeping; the proposed exemption for shelf-stable foods; and the agency's decision not to issue a list of foods/non-foods that cannot be transported together.

- PMO Waiver. We strongly support the proposed waiver for foods subject to the PMO and wish to make three points regarding its scope:

    - We understand FDA's proposed waiver to apply to inbound shipments of all Grade "A" raw milk when such milk is to be used in a finished Grade "A" milk product. The proposed waiver should be extended to *all transports licensed and regulated under the Grade "A" program hauling milk or milk products*. If a shipper is licensed under the Grade "A" program and the tanker is permitted and regulated under the Grade "A" program, then the milk/milk product, hauler, and the milk producer should be granted a waiver if the milk is used in either a finished Grade "A" milk product or a non-Grade "A" milk product (e.g., cheese or ice cream). Further, the waiver should extend to a shipment of raw milk that is a combination of Grade "A" and non-Grade "A" milk going to a processing facility, provided the truck is licensed/regulated under the Grade "A" program. This scope is warranted because all shipments of Grade "A" raw milk are covered by the PMO.[13] Further, dairy farms supply a variety of entities and milk does not always go to the same place day after day. It would be very confusing for both dairy farms and for shippers if milk from a farm is exempt from this proposed rule one day, but then faces duplicative sanitary food transportation requirements the next day.

    - We believe the PMO adequately addresses not just inbound shipments of unpasteurized raw milk as FDA suggests, but outbound shipments of finished products of pasteurized milk and milk products (such as cream, cottage cheese, and sour cream) as well. For example, Item 21p in the PMO states:

        > All vehicles used for the transportation of pasteurized milk and milk products shall be constructed and operated so that the milk and milk products are maintained at 7ºC (45ºF) or less and are protected from contamination. Milk tank cars, milk tank trucks, and portable shipping bins shall not be used to transport or contain any substances that may be toxic or harmful to humans.[14]

        The PMO explains that this requirement is met when, among other things, vehicles are kept clean, material that is capable of contaminating milk or milk products is not transported with milk or milk products, sanitary conveying equipment is used, and

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[13] U.S. Public Health Service/Food & Drug Admin., Grade "A" Pasteurized Milk Ordinance (2013) (stating that the transportation of all Grade "A" is regulated in accordance with the current Grade "A" PMO).

[14] *Id.*

other equipment is clean and sanitized.[15] Therefore, it is appropriate for outbound shipments also to be covered by the waiver.

- Finally, a shipment that includes products subject to the PMO, as well as those not covered by it (e.g., orange juice), should continue to be exempt from the requirements in the Sanitary Transportation of Food proposed rule with respect to those PMO covered foods.[16]

- Recordkeeping. As we understand it, this regulation is not focused on recordkeeping in the same way as other FSMA regulations like preventive controls. Rather than requiring documentation to be maintained for every individual shipment, the regulation takes a practical approach and focuses on the maintenance of records that demonstrate the information exchange, and related agreements, between shippers and carriers. We support this approach and agree that there should not be any requirement to maintain shipment-by-shipment records.

  We do, however, oppose the proposal to require records to be in compliance with the electronic recordkeeping requirements in 21 CFR Part 11. Consistent with our support for practical recordkeeping requirements, we urge FDA to reconsider this issue. As we have noted with respect to other proposed rules issued under FSMA, it would be extremely burdensome for our members to comply with Part 11 requirements. FDA should exempt sanitary food transportation records from compliance with Part 11 and should take a practical and simple approach to ensuring the authenticity of electronic records.

- Shelf-Stable Foods. We support the exemption for shelf-stable foods fully enclosed by a container from the proposed requirements. We respectfully ask that FDA recognize these foods as exempt even when they are transported with foods that are covered by the proposed regulatory requirements or when they are transported with non-foods. For example, a shelf-stable food that is transported to a retailer with non-food consumer goods should be exempt as there is no increase in risk to the shelf-stable foods. Thus, FDA should revise the regulation so that shelf-stable foods fully enclosed by a container are exempt regardless of whether the transportation activity "solely" includes such foods.

- List of Foods/Non-Foods. We support FDA's decision not to issue a list of foods and non-food products that cannot be transported together. We agree that it is not possible to identify any specific non-food product that may, under all circumstances, adulterate subsequently or simultaneously transported food. It is more appropriate for food transporters, such as shippers and carriers, to conduct this type of evaluation on a case-by-case basis. We agree with FDA's plan to issue guidance identifying factors that shippers and carriers should consider when considering products that may be transported together.

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[15] *Id.*

[16] *See* Statement from Dr. Michael Kashtock, FSMA Public Meeting Transcript: Proposed Rule on Sanitary Transportation of Human and Animal Food (Mar. 20, 2014), http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM395355.pdf (stating that the inclusion of non-Grade "A" products in a shipment covered by PMO and sent by a Grade "A" shipper would not result in a forfeiture of the PMO waiver).

IDFA and NMPF appreciate the opportunity to provide these comments to FDA. We look forward to continuing to work with the agency to make FSMA a success. Thank you for considering our views and do not hesitate to contact us if we can answer any questions or provide additional information.

Respectfully submitted,

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Attachment