



WORLD SHIPPING COUNCIL
PARTNERS IN AMERICA'S TRADE

Comments of the
World Shipping Council

Before the
Food and Drug Administration
U.S. Department of Health and Human Services

In the Matter of
Notice of Proposed Rulemaking Regarding
Prior Notice of Imported Food Under the Public Health Security and Bioterrorism
Preparedness and Response Act of 2002

Docket No. 02N-0278

April 4, 2003

I. Introduction

The World Shipping Council (“the Council” or “we”) submits these comments in response to the Notice of Proposed Rulemaking (NPRM) published in the Federal Register by the Food and Drug Administration (FDA) on February 3, 2003. The NPRM proposes regulations to implement Title III of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (“Bioterrorism Act” or “the Act”), which requires that prior notification of certain imported food be provided to the FDA.

The Council, a non-profit association of over forty international ocean carriers, addresses public policy issues of interest and importance to the international liner shipping industry. The Council’s members include the full spectrum of ocean common carriers, from large global operators to trade-specific niche carriers, offering container, roll-on roll-off, car carrier and other international transportation and logistics services. They carry more than 90% of the United States’ imports and exports transported by the international liner shipping industry, or roughly \$500 billion worth of America’s foreign commerce each year. This includes food imports regulated by FDA as well as by the U.S. Department of Agriculture and the Animal and Plant Health Inspection Service (APHIS), now under the new Department of Homeland Security.

The NPRM would require that U.S. importers or their agents provide the prior notification to FDA for food “imported or offered for import into the United States.” The Council cannot comment on the various impacts that the Proposed Rule would have on U.S. food importers, but we are concerned that, if importers cannot reasonably comply with the new rules, ocean carriers, marine terminal operators, and U.S. ports could become congested with cargo that is being held by FDA because of compliance issues. We strongly encourage the FDA to assure itself that this would not be a result of its new rules. We do believe, however, that, to the extent that the government requires advance filing of detailed food product information, the food importer, not the transportation provider, is the appropriate party to provide such information.

However, the Proposed Rule also includes prior reporting requirements for food products that are only being unloaded in a U.S. port for the purpose of being relayed at that port onto a different vessel for transit to a foreign country, and for food products moving in-bond through the United States for export to and consumption in another country.¹ The NPRM proposes to place the burden for this reporting of such “transit” cargo on the “arriving carrier or, if known, the in-bond carrier.”

¹ The NPRM states: “[P]rior notice is required for all food “being imported or offered for import into the United States”. Accordingly, prior notice requirements apply to all food that is brought across the U.S. border ... *regardless of whether the food is intended for consumption in the United States*. In other words, FDA believes that food that is brought into the United States to be put into foreign trade zones, or for the transshipment or reexport immediate or otherwise, is “imported or offered for import” and thus must comply with the prior notice requirements.” 68 Fed. Reg. 5430 (emphasis added). *See also* 68 Fed. Reg. 5432 and 5460.

The Council wishes to express its very strong opposition to the application of the proposed requirements to such “transit” cargo. Our comments are focused on that aspect of the NPRM.

First, we believe that the inclusion of such cargo goes beyond what was intended by Congress and does nothing to promote the goals of the Act, which is to protect U.S. food consumers. Second, there is already in place, through the Customs Service’s Automated Manifest System, advance information on such shipments provided 24 hours before the cargo is even loaded on the vessel in a foreign port, and this process should be adequate to meet any advance screening needs for food product cargo that is not being shipped for consumption in the United States. Third, compliance with the Proposed Rule by ocean carriers for such cargo would be completely and totally unworkable because they do not possess, nor do they have access to, the information required by the Proposed Rule. Finally, the Proposed Rule would seriously disrupt international commerce of food products between foreign countries and seriously impair the use of U.S. ports for the relay and transshipment of such commerce.

II. Regulations Implementing the Act Should Not Cover Food Products That Are Neither Being Delivered to U.S. Importers Nor Are Destined For U.S. Consumers Because Such Coverage is Beyond the Intent of the Act

Title III of the Bioterrorism Act was enacted to protect U.S. consumers and the U.S. food supply from terrorist threats. This intent is clear from the nature of the statutory provisions themselves and also from the statements made by members of Congress in connection with passing the Act. Similarly, the NPRM states that the law is intended “to enhance the security of the *U.S.* food supply”², “to ensure that *consumers in the United States* do not eat food that is contaminated”³, and “to protect *consumers in the United States* from food imports that may be at risk”⁴.

Consistent with this intent, the Proposed Rule would appropriately require that “the purchaser or importer of an article of food which resides or maintains a place of business in the United States, or an agent who resides or maintains a place of business in the United States acting on behalf of the purchaser or importer” shall provide this prior notice for all food “being imported or offered for import into the United States.” The Council agrees that the U.S. importer or its agent/broker is the appropriate party to provide this kind of advance information because it is the party most likely to have direct knowledge of that information.⁵

The Proposed Rule also, however, requires advance notice to be given for food that is brought into the United States temporarily, to be put into foreign trade zones, transshipped, or re-exported.

² 68 Fed. Reg. 5428 (emphasis added).

³ 68 Fed. Reg. 5429 (emphasis added).

⁴ 68 Fed. Reg. 5433 (emphasis added).

⁵ We note that Congress has consistently stated that the policy, when the government acquires cargo information for security screening purposes, should be as follows: “In general, the requirement to provide particular information shall be imposed on the party most likely to have direct knowledge of that information.” Section 343(a)(3)(B) of the Trade Act of 2002, 19 U.S.C. 2071(a)(3)(B). The importer is the appropriate party to provide the kind of detailed cargo information described in the Proposed Rule, and this approach is an appropriate implementation of the stated Congressional policy.

The Proposed Rule places responsibility for reporting this transit cargo on the “arriving carrier or, if known, the in-bond carrier.” There is no legislative history demonstrating that the Act intended to cover such cargo, which is not being transported for the purpose of entering the U.S. food supply or ever reaching U.S. consumers. We do not believe there is any legislative history indicating that Congress intended that European food shipments to Latin America, for example, should have to file this kind of information with the FDA because the container carrying the food was relayed from one ship to another ship in a U.S. port. Furthermore, there is no explanation or evidence that the purpose of the Act -- protection of the U.S. food supply and U.S. consumers-- requires receiving information about food products that are merely transiting through the U.S. to their foreign destination and will not be consumed here. With respect to such cargo, it would appear that the FDA’s only interest should be to ensure that the cargo exits the U.S. as promised. In this respect, we believe that the current Customs Service’s information filing and bonding system provides sufficient safeguard to assure the government that these shipments are, in fact, sent back out of the United States.

III. Existing Government Regulations Adequately Address the Issue of Food Shipments Being Transported from One Foreign Country to Another Foreign Country that Transit Through the U.S. or Are Relayed onto Ships at U.S. Ports

Ocean carriers today provide advance information to the Customs Service for all U.S.-bound cargo, *including transit cargo*, through the Automated Manifest System (AMS) 24 hours before that cargo is loaded aboard a ship at a foreign port. This information⁶ is used by the Customs Service to screen cargo for security purposes. Customs can hold any cargo at the foreign port for inspection. Customs also makes this cargo information available through AMS to other government agencies. Similarly, the U.S. government can hold any cargo at the U.S. port of discharge for inspection. The Animal and Plant Health Inspection Service (APHIS) receives this information directly from Customs for its own screening process. Customs can make this same information available to FDA.

We believe this existing AMS system should be fully adequate to monitor any in transit food shipments for a number of reasons. First, the AMS system provides the government the advance cargo declaration information 24 hours before the cargo is loaded in a foreign port, which is much earlier than noon the day before vessel arrival, as proposed in the NPRM. Second, because FDA has no need to test the food to ensure that it is safe for U.S. consumption, it only needs to ensure that the cargo leaves the country. There is no apparent or articulated reason why this AMS information (already relied upon by Customs and other government agencies) would be inadequate to accomplish this. Nor does the Proposed Rule discuss why the FDA could not obtain the AMS information in a manner similar to that used by APHIS.

⁶ The fourteen data elements provided to Customs 24 hours before containerized cargo is loaded aboard the vessel in a foreign port are: 1) the last foreign port before the vessel departs for the U.S., 2) the carrier’s unique Standard Carrier Alpha Code, 3) the carrier-assigned voyage number, 4) the date the vessel is scheduled to arrive the first U.S. port, 5) the numbers and quantities from the ocean carrier’s bill of lading, 6) the first foreign port where the carrier takes possession of the cargo, 7) a description of the cargo, 8) the shipper’s complete name and address, 9) the complete name and address of the consignee or owner’s representative, 10) the vessel name, country of origin and official number, 11) the foreign port where the cargo was laden on board, 12) hazardous material code, if applicable, 13) container number, and 14) the seal number affixed to the container. See 19 C.F.R. 4.7a(c)(4).

Moreover, as noted in the Proposed Rule, once off loaded at a U.S. marine terminal, transit cargo moves under Customs bonds to other countries – Immediate Export (“IE”) bonds and Transportation for Exportation (“T&E”) bonds. Cargo moving under either bond remains on the ground at the marine terminal for a period of time and could be inspected by the FDA if there is a reason to do so. IE shipments remain in the secure marine terminal and are reloaded aboard another vessel for export. Cargo moving under a T&E bond is taken from the marine terminal by road or rail to a border crossing point and exported to Canada or Mexico.

For IE cargo, the ocean carrier creates an immediate export entry against the inward vessel manifest. The ocean carrier, through this IE bond, is declaring to the U.S. government that it will export the cargo on a named vessel. The Immediate Export entry remains in “open” status until the exporting carrier submits the export bill of lading and a copy of the IE bond to Customs that proves that the cargo has left the United States. The FDA can easily track this cargo by accessing AMS.

A similar process exists for a T&E bond. The ocean carrier opens the T&E against the inward conveyance but leaves the bond open until the export actually takes place. The cargo is turned over to a trucker or railroad that has been investigated and bonded by Customs (including the truck drivers who haul the in-bond cargo). In this case, Customs closes the T&E bond at the Canadian or Mexican border. Proof of export for both bonds is entered in AMS and can be accessed by the FDA.

Furthermore, the NPRM’s proposed information filing requirements for transit cargo would not significantly enhance cargo security. For example, the Proposed Rule states that “if an article of food is imported or offered for import with no prior notice or inadequate prior notice, the food ... must be held at the port of entry....”⁷ Food cargo shipments that are simply being relayed in a U.S. port from one ship to another ship are not going to leave the port of entry anyhow.

In short, the FDA, in cooperation with Customs, can already receive advance cargo declaration information for transit food cargo, can track transit food cargo, and can confirm its departure from the United States. As the NPRM notes, one of the objectives of this rulemaking should be “integrating with U.S. Customs and other agencies to avoid duplication of notification requirements.”⁸ Extending these proposed rules to transit cargo, that is not being received by a U.S. importer and is not destined for U.S. consumers, would be an unjustified duplication of a control mechanism that U.S. Customs already operates.

We appreciate the challenge the FDA faces in implementing a new statute under tight deadlines. That, however, should not prevent the FDA from ascertaining whether existing government information systems and processes can be used to satisfy the objectives and requirements of the new statute for transit cargo. In fact, other government agencies – facing equally significant challenges under tight time frames – have demonstrated a willingness and commitment to explore the potential usage of existing information systems before establishing unnecessary, duplicative systems. For example, the Immigration and Naturalization Service (INS) was required to implement section 402 of the Enhanced Border Security and Visa Entry Reform Act of 2002 (Pub.L. 107-173) that requires the

⁷ 68 Fed. Reg. 5431.

⁸ 68 Fed. Reg. 5429.

advance electronic submission of crew manifests for vessels arriving at and departing from U.S. ports. Instead of establishing a new reporting system for this purpose, the INS analyzed existing reporting systems that could allow it to fulfill its information needs as required by that Act. The INS determined that an existing information system, operated by the Customs Service – the Advanced Passenger Information system (APIS) – with some modest modifications could be used to also collect crew member information even though, as the name implies, APIS originally was designed for another purpose.

This commendable initiative by the INS also resulted in the Coast Guard determining that it could meet its statutorily required advance crew member information through APIS by undertaking some modifications to its own information systems. The Coast Guard also determined that a number of information requirements it had originally proposed using its authority under another statute than the Enhanced Border Security Act should not be pursued because to do so would conflict with the goal of using the information collected in APIS to also meet the Coast Guard’s requirements. The agency is in the process of undertaking these modifications to its own information systems, which – when completed – will allow for the single advance electronic transmission of crew member information to one central government repository (APIS) from which the INS, Customs and the Coast Guard will be able to extract the information needed to allow them to fulfill their statutory and regulatory requirements in regard to foreign crew members.

Similarly, the Coast Guard, which in a post-September 11 rulemaking had proposed distinct cargo reporting requirements for vessels arriving in the U.S., subsequently agreed that if a carrier were in compliance with cargo reporting requirements established by the Customs Service, the Coast Guard would impose no additional cargo information filing requirements.

We encourage the FDA to undertake a similar approach for transit food shipment cargoes and, instead of establishing the proposed information filing system for such cargo, utilize existing information systems being operated by the Customs Service to ensure that transit food shipment cargoes do in fact transit to their intended foreign destination.

III. Carrier Compliance with the NPRM Reporting Requirements for In Transit Cargo Is Totally Impractical

The NPRM proposes a requirement for the “arriving carrier or, if known, the in-bond carrier” to report in advance the information elements listed in the Proposed Rule for transit cargo. Because the in-bond carrier has no advance access to the required information, the requirement would appear to fall on the carrier arriving at a U.S. port. The NPRM would require these carriers to provide the same information for transit cargo as would be provided by an importer. In doing so, FDA apparently and incorrectly assumes that such information will be known or available to the carrier.

The international liner shipping industry and the Council have been working closely with the Customs Service to implement a system of advance reporting of cargo manifests for security screening purposes. As noted above, Customs requires fourteen data elements to be included in the carrier’s manifest, some of which (such as cargo description, carrier, shipper, consignee, and country of origin)

are included in the FDA Proposed Rule. The FDA, however, would require additional information elements that are not required by Customs in advance, are not information items reflected on a carrier's bill of lading, and are not items about which the carrier has any knowledge.

Specifically, the NPRM requires the following information: (1) FDA product code, (2) common, usual, or market name, (3) trade name (if different), (4) quantity of food from smallest package size to largest container, (5) lot or code numbers, if applicable, (6) identity and contact information for the manufacturer, (7) identity and contact information of the growers, plus the growing location, (8) country of origin, (9) identity and contact information of the shipper, (10) country from which food was shipped, (11) anticipated port of arrival and anticipated border crossing; (12) anticipated date of arrival, (13) anticipated time of arrival, (14) port of entry, (15) date of entry, (16) identity of contact information for the importer, (17) identity and contact information for the consignee, and (18) identity and contact information for all of the carriers handling the food.

First, as noted above, the Proposed Rule would not only clearly require far more detailed cargo descriptions than are required by Customs,⁹ but would require information that the carrier simply does not possess. This information is not provided to carriers in the regular course of business, and it is wholly impractical, if not impossible, for the carrier to obtain it. The NPRM states that a "U.S. importer or U.S. purchase who orders or buys the article of food, thereby initiating its importation into the United States ... should possess or have the ability to obtain, the information required to be submitted...."¹⁰ Whether this is correct or not, the Council does not know; however, we do know that the carrier transporting the goods certainly does not have this information and cannot be expected to obtain it from parties who are not shipping their products to the United States.

For example, it is difficult to envision how it would be feasible to require appropriate FDA product codes for a transit shipment. "Common or market names" and "trade names" for the goods may be completely different for the goods in the transit cargo's destination country than in the United States. Similarly, the carrier does not have access to any information regarding the grower or manufacturer of the food, trade names and other matters in the enumerated list.

When carrying such cargo, the carrier will be dealing with foreign shippers who are not sending their goods to the U.S., who are not dealing with U.S. importers, who probably do not have any contacts in the U.S. with respect to the cargo, and who will see absolutely no basis or rationale for providing such detailed information to a carrier for filing with U.S. authorities, especially when such information is not required by the destination country which is importing the goods.

⁹ Moreover, we question whether the level of detailed information required exceeds FDA's authority under the Bioterrorism Act. The Act provides for the agency to request only six specific pieces of information: 1) the article; 2) manufacturer and shipper; 3) the grower, if known; 4) the country of origin; 5) the country of export; and 6) the anticipated port of entry. The NPRM requires significantly more information than this, including product codes, quantities, arrival times, and so forth. Although proposed Senate language in the bill would have allowed for the Secretary to require additional information, the Senate language was not included in the final Act.

¹⁰ 68 Fed. Reg. 5433.

Also, much of the requested information is simply inapplicable to transit cargo. For example, there would be no importer and no U.S. Customs entry information. Also there would not be a consignee to identify in the United States. If the FDA wishes to receive contact information for a consignee outside the U.S. receiving transit cargo, that information is available through Customs' AMS system.

In the NPRM, the FDA, in explaining why it thinks the proposed rule is reasonable, states: "Most of this information [the required data elements] is already supplied by the filer to FDA through ACS as part of the U.S. Customs entry process".¹¹ This statement is clearly incorrect as it applies to transit cargo, because there is no ACS filer today for such cargo and there is no U.S. Customs entry of the goods.

Second, the Proposed Rule is commercially impractical for a number of operational reasons. First, the shipper of the goods may not even know that its cargo is going to transit the U.S.. For example, a container of Danish hams being sent to Toronto may be transported via the ports of Halifax, Montreal, Boston, New York, Philadelphia, Norfolk, or Baltimore. The shipper is only interested in the commitment of the carrier to transport the cargo to Toronto, not which vessel or which route the carrier may choose to use to transport the cargo across the Atlantic. The shipper may not even know the routing used by the carrier. Foreign shippers of such cargo to non-U.S. destinations will not understand why they would need to give ocean carriers this kind of detailed information for filing with the U.S. FDA when they are not sending their products to a U.S. destination.

In addition, even the carrier may not know the routing of the cargo at the time it makes a booking for transporting the goods. Carriers frequently change the routing of cargo at the last minute. The container of Danish hams going to Toronto discussed above may be loaded in a major transshipment port such as Rotterdam, at the carrier's discretion, on various different vessel services that could unload the container at Canadian ports or at different U.S. ports for onward carriage to Canada. The Proposed Rule would, as a practical matter, not allow this because the documentation requirements would vary so greatly depending on whether the cargo was unloaded in a U.S. or Canadian port.

Another example of the practical problems with the proposal may be useful. Consider what would happen if a container of food destined for Canada was scheduled to be unloaded in Halifax, but due to bad weather, the ship skips its Halifax port call and unloads the cargo in New York for transshipment to Canada. (This is not uncommon in the North Atlantic in winter.) The shipment will simply not have the proposed information available, because neither the carrier nor the shipper would have believed it would have been necessary at the time it was shipped.

Third, notwithstanding the fact that the FDA, as noted above, states in the NPRM that a "U.S. importer or U.S. purchaser who orders or buys the articles of food" may be expected to be able to obtain such information, there is no explanation for how a carrier could be expected to obtain such

¹¹ 68 Fed. Reg. 5435.

information.¹² Nevertheless, the NPRM states, “the submitter is the entity responsible for ensuring the adequacy and accuracy of the prior notice.”¹³ The NPRM goes on to state that penalties, including the possibility of criminal penalties, could result from failure to comply with the information filing requirements.¹⁴ It would be wholly inappropriate to penalize a carrier for transmitting information about which it has no direct knowledge, which it receives from a shipper, and which it cannot verify.

Finally, we note that, whereas U.S. food importers will, as a matter of doing business, have to develop systems, programming and personnel to undertake these filing obligations with FDA, carriers have no basis to file such additional information into yet another U.S. government information system – for cargo that is not even being delivered to anyone in the United States. Carriers have in the last six months undergone extensive system redesign, reprogramming, and staffing to comply with the Customs Service’s 24-hour rule. It is unreasonable to expect them to undertake participation in this new FDA filing system when the AMS system is in place, particularly considering they do not have to file information with FDA for food shipments that are being delivered to the United States.

IV. The NPRM’s Application to Transit Cargo Would Disrupt International Commerce and Adversely Affect U.S. Ports

U.S. ports handle a substantial amount of transit cargo that is not destined for U.S. importers or U.S. consumption. Some of this cargo is moved in-bond to Mexico and Canada. Some of this cargo never leaves the U.S. port but is relayed at the port onto another vessel for transportation to a foreign destination, in manner similar to airlines’ hub and spoke systems. For example, a great deal of commerce between Latin American nations is transported on ships leaving one Latin American country, brought to a U.S. port, and then relayed onto another vessel which will transport the cargo to a different country in Latin America. A great deal of commerce between Asia and Latin America flows through U.S. ports. A substantial percentage of Canada’s foreign trade flows through U.S. ports. A substantial percentage of European-Latin American Commerce is relayed at U.S. ports. This large flow of commerce includes a significant amount of food products. In short, to more efficiently serve both America’s international trade and global trade, carriers have built extensive service networks that use U.S. ports as major hubs of international trade. Both American and foreign commerce benefits from the efficiencies of these networks, as do U.S. ports.

It is wholly impractical, however, to expect commerce between two foreign countries, which does not involve an American importer, to comply with the kind of information requirements proposed in the NPRM. For example, because Canadian destination cargo, if transiting through a Canadian port, would not need the information set forth in this aspect of the rule, the burden of this Proposed Rule would virtually necessitate Canadian food cargo to be diverted from U.S. ports to Canadian ports. Similarly, food shipments transported between Latin American nations that are relayed in a U.S. port

¹² Because FDA makes it clear that the proposed filing requirements do not apply to “whole shipments”, but to “each article of food by each manufacturer,” we can only project that application of these filing requirements to carriers of consolidated loads of transit food shipments would be extremely burdensome.

¹³ 68 Fed. Reg. 5433.

¹⁴ 68 Fed. Reg. 5461.

would no longer be routed on vessel calling at U.S. ports. And, if the majority of the cargo on such a vessel service is foreign to foreign commerce (i.e., not U.S. commerce), the carrier might cancel that service's calls at U.S. ports. That is not a theoretical possibility. After Customs implemented the 24-hour rule, for example, a group of carriers that served the Latin America-Europe trade with vessels that called in Puerto Rico as one port of call in their itinerary simply cancelled the vessels' service to Puerto Rico rather than subject the majority of the foreign-to-foreign cargo on board their vessels to the United States' 24-hour rule.

The burden of this proposed rule on the carriage of transit cargo would be substantial and troublesome, and it would definitely and adversely affect the flow of trade through U.S. ports and how ocean carriers plan their services, route their cargo, and utilize U.S. ports.¹⁵

V. Conclusion

The World Shipping Council appreciates the opportunity to submit these comments for FDA's consideration. The Council supports the efforts of Congress and the FDA to protect America's domestic food supply. The liner shipping industry has cooperated fully with the various U.S. government agencies that are working to enhance the security of America's commerce. For the reasons stated above, however, we do not see how the collection of information as set forth in the NPRM for transit cargo will further the goal of protecting the U.S. food supply. The Proposed Rule would also impose substantial burdens on commerce that is not even destined for United States importers or U.S. consumers. The purpose of the Act would appear to be fully achieved by ensuring that the cargo leaves the U.S. as required. Since Customs already has adequate mechanisms in place to ensure that is accomplished, an FDA rule addressing such transit cargo is not required.

To the extent FDA is interested in transit food shipment cargo, it should be able to access the cargo declaration information that carriers file with Customs for such shipments through Customs' Automated Manifest System. In fact that information is available to FDA substantially earlier than the time in the NPRM. The information FDA proposes to collect from carriers that is above and beyond what is in the AMS system is information that a U.S. importer might have, but it is not information available to a carrier. Carriers would simply be unable to comply with the proposed rules as they pertain to transit cargo.

For all the reasons stated above, we respectfully urge the FDA not to interpret cargo food shipments under the Act as "being imported or offered for import into the United States" when there is no U.S. importer of the goods and the carrier is clearly transporting the goods under the Customs Service's oversight and supervision to a foreign destination for delivery.

Thank you for your consideration of our views.

¹⁵ We believe the NPRM is incorrect when it states: "FDA believes that this proposed deadline will have ... almost no effect at water ports." 68 Fed. Reg. 5433. Whether that is true for U.S. import cargo where the information filing is required from importers we cannot say, but as to transit cargo, this proposal would have a substantial impact on U.S. ports.