



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
Interim Final Rules Under the Public Health Security and Bioterrorism
Preparedness and Response Act of 2002
Regarding
Prior Notice of Imported Food
(Docket No. 02N-0278)
and
Registration of Food Facilities
(Docket No. 02N-0276)
December 23, 2003

I. Introduction

The World Shipping Council (“the Council” or “we”) submits these comments in response to the Interim Final Rule on Prior Notice of Imported Food (Docket No. 02N-0278), and the Interim Final Rules on Registration of Food Facilities (Docket No. 02N-0276). The Interim Final Rules establish regulations to implement Title III of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (“Bioterrorism Act” or “the Act”).

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.

II. Prior Notice Filing

At a meeting on November 19 between FDA, the Bureau of Customs and Border Protection (CBP) and the World Shipping Council and its Member lines, the industry learned that CBP was programming changes to the Automated Manifest System (AMS) and was considering the possible addition of a new required data field in AMS, in which the filing *carrier* might be required to insert a “yes” if the bill of lading involved food for which a food importer was required to file a Prior Notice (PN), and a “no” if a PN filing was not required by the shipper. We understood that the application of this new “yes/no” filing concept would pertain to all in-bond shipments, and would not apply to shipments where customs entry was made at the arriving port --as the importer/broker in those cases would have filed all necessary information for such shipments with the government prior to entry and release. While this proposal is not part of the existing regulations, and has not been formally proposed by CBP, we wish to use this opportunity to provide some comments on this issue.

First, it is our view that CBP cannot make this change and require carriers to provide this information in their AMS manifest filings without a rulemaking proceeding.

Second, we understand that CBP is considering requiring this indicator in AMS because it is uncertain whether the government can trust all subject food importers or their agents to have filed the necessary PN filings, and it is concerned about releasing in-bond shipments from the arrival port in cases where the necessary filings may not have been made. We also understand that, because CBP has not mandated the use of the harmonized tariff system (HTS) codes in place of text commodity descriptions for in-

bond shipments and because CBP receives the HTS codes after the goods have commenced their in-bond movement from the port of arrival, the agency may be concerned that it would need to review each manifest commodity description in order to determine whether the shipment contains food shipments that require a PN filing, and that requiring a “yes/no” field on every bill of lading filing moving in-bond would simplify this process for the government.

While we appreciate the concerns of CBP in this regard, the Council opposes requiring the filing carrier to inform CBP whether a particular bill of lading does or does not require a PN filing. First, CBP has the same information that the carrier has. Carriers are not in a better position than Customs to perform this function of determining whether a shipper has a legal obligation to file a PN for a particular shipment. In fact, the carrier is in a far inferior position, because it does not have access to the importer’s filings to enter the goods, which CBP does have. Second, if such a requirement were to be considered, it would need to be accompanied by a requirement that the shipper/importer provide this “yes/no” information to the carrier. Third, if the reason for this concept were that the government does not trust the importer to file the necessary PN, the concept would still be relying on the importer to be honest with the carrier about whether a filing was required. Fourth, a single “yes/no” indicator on a bill of lading filing would only indicate that at least one PN existed for that bill of lading and would not indicate how many PNs should have been filed and are to be checked for a particular bill of lading. Fifth, such a requirement would unfairly place unwarranted liabilities on carriers for classification determinations that are not within the direct knowledge or expertise of carriers. If a carrier were to mistakenly state “yes” that a PN was required when it was not, it would cause delays to the goods’ transportation; and if the carrier were to mistakenly state “no” when a PN was required, the carrier could also create problems.

We recognize that there are enforcement complications with this new law, but believe that all approaches to this issue of how best to address food importers’ filing obligations should be articulated and considered, rather than adding a new requirement on carriers to make determinations about what information shippers should or should not be filing. For example, if FDA regulated food importers were required to file their entry documentation earlier, this issue could be addressed by the party with access and knowledge of the product’s details. Finally, as previously noted, we believe that any regulatory requirement for amending carriers’ AMS filings would require a rulemaking procedure.

III. Changes to Prior Notice Filings

According to the PN final rules, if a change occurs to a PN filing that has already been transmitted, that filing cannot be amended but must be cancelled and a new PN must be transmitted with the corrected information. We understand that at the present time there is no capability within the PN system to link new PN information with existing or previously filed PN information for the same shipment. The FDA’s information booklet, which discusses how to comply with the PN regulations, also states that the PN “clock”

restarts when a PN filing with the corrected information is confirmed by FDA. This would appear to mean that a shipment for which PN was filed in a timely manner and confirmed, could be delayed up to 8 hours, simply because one of the data elements in the filing was amended. We do not know how frequently amendments will occur, but we expect that it will not be uncommon. We urge FDA and CBP to consider if there is a way to review amendments that do not affect the security of the cargo in less than the full eight hours, so that the shipments' release from the port is not delayed unduly.

IV. Multiple Containers and PNs Within a Single Bill of Lading

We understand that holds of food shipments would be issued to ocean carriers via AMS at the bill of lading level. Because there may be multiple PN filings in a single bill of lading, the entire bill of lading, which may represent multiple containers of cargo, may be placed on hold. We are concerned that this could cause containers without a problem to be held because, for example, one data element in one PN filing in one container has been amended or needs to be checked further. We therefore urge the FDA and CBP to consider, in cases where a PN issue affects one container in a bill of lading covering multiple containers, developing procedures that would allow the containers without a PN issue to be released and delivered.

V. Facility Registration

The regulations state: "Any facility that manufactures, processes, packs or holds food must register with FDA." (21 C.F.R 1.227(a)(2)). The regulations also provide that: "Transport vehicles are not facilities if they hold food only in the usual course of business as carriers." (21 CFR 1.227(a)(2)).

We fully support the regulations' determination that transport vehicles are not food facilities, and we urge the agency to clarify the regulations in order to provide the same kind of exemption from registration requirements for transportation terminals as the regulations provide for transport vehicles. Specifically, we request that if a transportation facility (such as a marine terminal, rail terminal, or truck terminal) only handles transportation vehicles (such as ships or containers, which may themselves hold food but which are exempt from registration), and does not otherwise handle the contents of the container, then the facility need not register.

The transport vehicle/container, rather than the transportation terminal, is what is "holding" the food, and FDA has already determined that such vehicles/containers are not required to register as facilities. If transport vehicles themselves are not covered as facilities that must register when they operate in the usual course of business, then there is no apparent reason why a transportation terminal that holds such exempt containers in the usual course of the transport business should be covered. A transportation terminal is not a "food facility" in the normal sense of the word, as only a small percentage of the containers in the terminal would be food shipments destined for or arriving in the United

States, the containers are sealed, and all the containers containing the food shipments themselves are exempt. While there may be a legitimate food security interest in having facilities that manufacture, produce or physically handle food register with FDA, there is no apparent food security reason to have transportation terminals that handle conveyances that are already exempted register as food facilities.