



WORLD SHIPPING COUNCIL  
PARTNERS IN AMERICA'S TRADE

August 5, 2003

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

RE: Docket No. 02N-0277, Establishment of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

On May 9, 2003, The Food and Drug Administration ("FDA" or "the Agency") published a notice of proposed rulemaking relating to the Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. 68 Fed. Reg. 25188 (May 9, 2003) ("the NPRM"). The World Shipping Council ("the Council" or "we") respectfully requests that these comments be accepted in the docket and considered in the deliberation of a final rule.

The Council is a non-profit association of more than forty international ocean carriers, which 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 Animal and Plant Health Inspection Service (whose import functions are now under the Department of Homeland Security). A list of our members is attached hereto as "Attachment A."

The Council is concerned about the unnecessary burden that would be imposed by the recordkeeping requirements on transporters. There is no reason for the FDA to require that ocean carriers transporting food cargo to the United States maintain

records of the nature required by the NPRM, particularly since such carriers generally have no obligation to notify FDA of food transported by them to the U.S.<sup>1</sup> The importer/consignee who first receives delivery of the cargo from the carrier upon arrival in the U.S. is the party that has the types of information required to be maintained by the NPRM (including such details as the lot number, brand name, and detailed packaging information—information which a carrier simply would not have). Since the importers are independently required to maintain such records—and are the parties required to provide notice of the importation to FDA along with these details—it would be redundant and burdensome to require ocean carriers to seek out and maintain this information as well.

Proposed sections 1.337 and 1.345 require nontransporters to maintain the exact same information regarding the description of the food (including brand name), lot or code number, details about packaging (such as whether a product is in a 12 or 16 ounce bottle), identity of the nontransporter in possession of the goods immediately before and after them, as well as details about the transporters handling the food both before and after them. Thus if the FDA needs these specific details they can be obtained from the importer and there is no need to require the information to be maintained by an ocean carrier. Further, the importer is the party required to provide notice to the FDA of food being imported for consumption in the United States. The proposed rule regarding advance notification of food imports requires importers give this same information (as well as additional information) to FDA prior to importation. 68 Fed. Reg. 5428 (Feb. 3, 2003).<sup>2</sup> Thus, not only does the importer already have the information that the carrier would be required to keep, so does the FDA.

If the FDA, however, does consider it necessary for ocean carriers to be subject to the recordkeeping requirements, the required records should be limited to information normally available to the carriers and records regularly maintained by them in the course of business. In this respect, we note that carriers already provide a great deal of information regarding in-bound cargoes to U.S. Customs and Border Patrol (“CBP”). (A list of the data elements submitted to CBP prior to arrival of the cargo is attached hereto as “Attachment B”). Further, shipping documents already used and maintained by carriers in the course of business (e.g., bills of lading), include information about the shipper and the receiver, as well as specific routing information. (A copy of a typical bill of lading is attached hereto as “Attachment C”). Bills of lading are already maintained by ocean carriers for at least the two year time frame required by the FDA rule and information provided to CBP as part of the cargo declaration will already be in the government’s possession. Such information should be more than sufficient for any purpose the FDA would have. It would enable the FDA to determine the identity of the shipper, the identity of the receiver, the means of

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<sup>1</sup> In this regard we note that the FDA has proposed that carriers be required to provide notice of food products transiting or being transshipped in the U.S. for delivery to a foreign destination because no importer will exist to do so. The Council has opposed that requirement in separate comments filed on April 4, 2003.

<sup>2</sup> Proposed section 1.288 of the notice rule would require importers to provide the FDA with extensive information that includes: the brand name of the product, the lot or code numbers, the quantity of food described by package; and contact information for the manufacturer, grower, shipper, and carrier. 68 Fed. Reg. at 5461-62.

transport, and a general description of the cargo. Should the FDA need more information about the cargo (for example, the size and description of the packaging) it will, as noted, receive such information from the importer and the records of such information will be retained by that importer.

We appreciate the opportunity to provide these comments. Should you have any further questions, please do not hesitate to contact the undersigned at 202-589-1230.

Sincerely,

A handwritten signature in cursive script, appearing to read "Christopher Koch".

Christopher L. Koch  
President & CEO

# **WORLD SHIPPING COUNCIL**

## **MEMBER LIST**

- APL
- A.P. Moller-Maersk Sealand (including Safmarine and Torm Lines)
- Atlantic Container Line AB
- CP Ships Holdings, Inc. (including Canada Maritime, CAST, Lykes Lines, Italia Lines, Contship Containerlines, TMM lines, and ANZDL)
- China Ocean Shipping Company (COSCO)
- China Shipping Group
- CMA-CGM Group
- Compania Sud-Americana de Vapores (CSAV)
- Crowley Maritime Corporation
- Dole Ocean Cargo Express
- Evergreen Marine Corporation Ltd. (including Lloy & Triestino and Hatsu Marine)
- Great White Fleet, Ltd.
- Hamburg Sud (including Columbus Line Crowley American Transport, South Seas, Empresa and Alianca)
- Hanjin Shipping Company, Ltd. (including Senator Lines)
- Hapag-Lloyd Container Linie GmbH
- HUAL AS
- Hyundai Merchant Marine Company, Ltd.
- Kawasaki Kisen Kaisha Ltd. (K Line)
- Malaysia International Shipping Corporation (MISC)
- Mediterranean Shipping Company, S.A.
- Mitsui O.S.K. Lines
- NYK Line
- Orient Overseas Container Line, Ltd.
- P&O Nedlloyd Limited (including Farrell Lines)
- United Arab Shipping Company
- Wan Hai Lines Ltd.
- Wallenius Wilhelmsen Lines
- Yangming Marine Transport Corporation, Ltd.
- Zim Israel Navigation Company, Ltd.

**Cargo Declaration Data Elements**

- Name of Vessel
- Nationality of Ship
- IMO Number
- Voyage Number
- Name of Master
- Last Foreign Port Before U.S.
- Port of Discharge
- Date and Time of Departure from Port of Loading
- Shipper Notify Address
- Consignee Notify Address
- Bill of Lading Number
- Container Numbers (if applicable)
- Seal Numbers (if applicable)
- Hazardous Material U.N. Code Number (If applicable)
- Number and Kind of Packages
- Description of Goods
- Gross Weight or Measurement
- First Port/Place Where Carrier Takes Possession of Cargo
- Foreign Port Where Cargo is Laden on Board
- Carrier Standard Carrier Alpha Code
- Date of Scheduled Arrival in U.S.

# Ocean Bill of Lading

Exporter		Document Number	Booking Number	
		Export References		
Ultimate Consignee		Forwarding Agent		
Notify Party		Point of Origin		
		Domestic Routing		
Pre-Carriage By	Place of Receipt			
Exporting Carrier	Loading Pier/Terminal			
Port of Unloading	Place of Receipt on Carrier	Type of Move		
Marks and Numbers	Pieces	Description	Weight	Measurement

Shipment Ref No.  XTN  There are  pages, including attachments to this Ocean Bill of Lading

These commodities, technology or software were exported from the United States in accordance with the Export Administration Regulations. Diversion contrary to U.S. law prohibited.  
Carrier has a policy against payment solicitation, or receipt of any rebate, directly or indirectly, which would be unlawful under the United States Shipping Act, 1984 as amended.

FREIGHT RATES, CHARGES, WEIGHTS AND/OR MEASUREMENTS		
SUBJECT TO CORRECTION	PREPAID	COLLECT
GRAND TOTAL:		

Received by Carrier for shipment by ocean vessel between port of loading and port of discharge, and for arrangement or procurement of pre-carriage from place of receipt and on-carriage to place of delivery, where stated above, the goods as specified above in apparent good order and condition unless otherwise stated. The goods to be delivered at the above mentioned port of discharge or place of delivery, whichever is applicable.

IN WITNESS WHEREOF  original Bills of Lading have been signed, not otherwise stated above, one of which being accomplished the others shall be void.

DATED AT \_\_\_\_\_

BY \_\_\_\_\_  
Agent

Mo. \_\_\_\_\_ Day \_\_\_\_\_ Year \_\_\_\_\_

B/L No. \_\_\_\_\_