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May 17, 2005

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

Re: Comments on Compliance Policy Guide – Docket No. 2003D-0554

Dear Sir or Madam:

Eastern Maine Railway Company, Montreal Maine & Atlantic Railway Limited, New Brunswick Southern Railway Company Limited and Sunbury Transport Limited hereby submit comments to Docket No. 2003D-0554 on the “Revised Compliance Policy Guide Regarding Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.” These comments focus on **Section III.C.7** that provides for an alternative method of filing information with the Food and Drug Administration on shipments between two points in the same country: Canada to Canada or Mexico to Mexico.

The companies listed above operate the “Sunbury Train” between Montreal and New Brunswick, Canada. The Train travels for a relatively short time and distance in Northern Maine. It does not pick-up or drop-off railcars in the United States. Moreover, because the operators adhere to tight security measures, the trucks carrying the food on the Train cannot be tampered with or removed. The operation of this Train poses no threat to the U.S. food supply.

The alternative method is a valid approach to helping the Sunbury Train and other similarly-situated land carriers comply with the “Prior Notice” requirements. However, the **examples** contained in **Section III.C.7** (“**Section 7**”) do not provide adequate flexibility. Accordingly, the companies request that (1) Section 7 of the Compliance Policy Guide be amended to reflect the operating circumstances of the Sunbury Train, and (2) the amended policy guidance be included as a specific



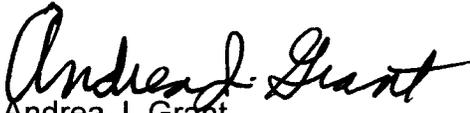
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regulation in the Final Rule on "Prior Notice" to be promulgated by the Food and Drug Administration.

The companies would be pleased to respond to any questions the Agency may have about this submission. Please contact the undersigned. Thank you for your consideration.

Respectfully submitted,

**DLA PIPER RUDNICK GRAY CARY US LLP**

  
Andrea J. Grant  
Counsel

Attachment

## MEMORANDUM

Subject: Compliance Policy Guide – Docket No. 2003D-0554

Eastern Maine Railway Company, Montreal Maine & Atlantic Railway Limited, New Brunswick Southern Railway Company Limited, and Sunbury Transport Limited hereby submit these comments on the Food and Drug Administration (“FDA”) “Revised Compliance Policy Guide Regarding Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.” The companies operate the “Sunbury Train” through Northern Maine. They commend the FDA for providing compliance flexibility for entities transiting portions of the United States but which present little or no risk to the U. S. food supply.

These comments address the new compliance guideline, Section III.C.7 (“Section 7”), permitting the use of an alternative means of filing information under the Prior Notice rules. Further, the companies recommend that the alternative method of filing, as discussed below, be included in the Final Rulemaking on the “Prior Notice” obligations as a regulatory provision. Enforcement flexibility is most helpful, but still leaves the regulatory community with uncertainty about appropriate compliance.

### I. Overview

The Revised Compliance Policy Guide states that food that is shipped by land through the United States is subject to the Prior Notice requirements, 21 CFR 1.277(a), even if it is shipped a short distance and travels from and to the same country. Moreover, the regulations require that notice must be submitted electronically through either the Automated Broker Interface or the Prior Notice Interface. Notice is considered inadequate if submitted in any other form.

Section 7 of the Policy Guide describes the new enforcement treatment for land shipments of food arriving from and exiting to the same country: Canada to Canada, or Mexico to Mexico. The Policy Guide states that if certain conditions are met, the FDA and the U.S. Bureau of Customs and Border Protection “may consider not taking regulatory action” when the shipper faxes a copy of an invoice instead of making the designated electronic submission and provides key information about the cargo but not all of the information that is mandated by the regulations. This flexibility appears to reflect a recognition by the Agency that (1) these types of land shipments pose little risk, and (2) the information obtained from the invoice is sufficient to alert the Agency about the cargo.

As described below, shipments of food on the “Sunbury Train,” moving between points in Canada, generally qualify for use of this alternative method of filing. Moreover, the approach taken is consistent with balancing the needs of protecting U.S. citizens and still maintaining essential transportation services in Northern Maine. The

alternative method is a valid approach to helping the Sunbury Train and other similarly-situated land carriers comply with the “Prior Notice” requirements. However, the examples contained in Section III.C.7 do not provide adequate flexibility. Accordingly, the companies recommend:

1. FDA amend Section 7 of the Compliance Guide to reflect the operations of the Sunbury Train; and
2. FDA convert the amended Section 7 of the Guide into a specific regulatory provision of the Final Rule.

## II. Background

### A. Rail Service – A Key Economic Link in Northern Maine

The Montreal Maine & Atlantic Railway (“MMA”) is a vital transportation link in Northern Maine – an economically-disadvantaged area of the State. Many industries rely on the railroad to transport goods between different areas of the region within Maine and to and from Canada. Without the railroad, the communities and the industries along the northern border become even more isolated and lose a valuable economic asset. Major employers in Northern Maine cannot survive without rail services.

Fortunately, the MMA Railway reached an agreement with Sunbury Transport Ltd., a trucking company, to operate an intermodal train transiting Northern Maine. This “Sunbury Train” has been providing needed revenue to the railroad, thereby assisting the MMA Railway to maintain its economic viability.<sup>1</sup>

### B. Sunbury Train

The “Sunbury Train” is an intermodal train that operates between Montreal and New Brunswick, Canada, via Northern Maine. U.S. Customs has designated Sunbury Transport, the trucking company assembling the train, MMA Railway and the Eastern Maine Railroad as bonded carriers. The “Sunbury Train” is the only railroad operating between two points in Canada through the United States. The Sunbury Train travels 201 miles within the U.S. and only takes approximately twelve hours to transit Northern Maine. The train enters and departs the U.S. under a Customs “transportation and exportation” entry. At no time is the food shipped on the Sunbury Train manufactured,

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<sup>1</sup> Before implementation of the “Prior Notice” regulations, approximately 50% of the shipments were food. However, food is now a relatively small portion of the total shipments because of the burden imposed by the regulations. Total shipments have dropped from approximately 230 per week to about 70.

processed, packaged, unloaded or transferred from conveyance to conveyance, while in the United States. Typical operations of the Train are as follows:

1. At Montreal, Sunbury Transport loads goods from its customers' warehouses onto truck trailers. The trailers are sealed and moved to the rail yard where they are shipped directly to New Brunswick. The train does not stop in the United States to pick up or drop off any cars.

2. It is not possible to remove a trailer from a rail car on the Sunbury Train, tamper with its contents and enter the cargo into the U.S. food supply. Trailers cannot be rolled, driven or pushed from a rail car.

The nose of the trailer is physically attached to the car, and each car is attached to another car on the train. Removal can only take place within a rail yard where there is substantial track capacity to perform a switching operation, and then only in connection with a specially-designed ramp to lower the trailers off of the rail car (the deck of the car is several feet off the ground). An entire crew must follow a series of time-consuming procedures to de-ramp and uncouple cars, sever break lines, and re-attach brake lines. No such rail yard with the specially-designed ramp exists on the rail line traversed by the Sunbury Train within Northern Maine. Thus, the Sunbury Train cannot be unloaded until it reaches its destination in Canada.

### III. Policy Guide Revision

The revised Policy Guide permits the alternative filing method for shipments that pose a low risk. As indicated above, the Sunbury Train meets that definition: (1) It moves between two points in Canada, transiting the United States for a relatively short time and distance; and (2) its method of operation and security prevent tampering with or removal of the loaded trucks.

Therefore, to ensure that the Train and its shipments are covered by the Policy Guide, FDA should amend the conditions that trigger the application of the alternative filing method.

#### A. Average Number of Daily Shipments

The Guide provides that the number of regular/routine shipments by land between the two border points should be relatively low (e.g., an average of less than one shipment per day). The Sunbury Train operates regular/routine shipments approximately twice a day – one train moving goods eastbound and a second moving them westbound. While the Train's operations do not meet the example provided, they certainly meet the "relatively low" or infrequent voyage standard.

Recommendation: The example provided should allow for the operation of at least two trains per day.

## B. Distance of Transportation Route

The Guide provides that the transportation route through the United States should be relatively short (e.g., less than 100 miles). The Sunbury Train operates a relatively short transportation route through the United States. While it does not meet the example provided, its operations certainly qualify as “relatively short” – it travels approximately 201 miles in Northern Maine.

Recommendation: The example provided should allow for a transportation route through the United States of no more than 250 miles.

## C. Geography

The Guide provides that due to geography, the only practical transportation route is shipment through the United States. The Sunbury Train offers shippers a very practical, efficient and rapid delivery. Use of the Train occurs because of these practical commercial issues, rather than the geography of the route.

Recommendation: The requirement that geography serve as the only practical reason for using a U.S. transportation route should be deleted.

## D. 36-Hour Prior Notice

The Guide provides that “Prior Notice” should be received by the FDA at least 36 hours before the shipment arrives at the port of arrival. This requirement is inconsistent with Section 1.279 of the “Prior Notice” regulations, which mandates prior notice be received only four hours prior to arrival by rail and two hours prior to arrival by truck. Even the most stringent “Prior Notice” provision requires notice within eight hours before arrival by water. Moreover, a 36-hour requirement is also inconsistent with Customs’ requirements for advance manifest filing, which must be accomplished two hours prior to arrival by rail and a maximum of one hour before arrival by truck.

Requiring receipt of notice 36-hours in advance of arrival would negate any benefit of this flexible compliance policy. Land shipments are generally made on a short schedule; most shippers and carriers simply do not have commercial invoices 36 hours prior to arrival by truck or rail.

Recommendation: The filing period should be reduced and made consistent with the current “Prior Notice” regulations – four hours prior to arrival by rail; two hours prior to arrival by truck.

## IV. Conclusion

To achieve security for the U.S. food supply and balance that objective with the commercial needs of Northern Maine, FDA should include a regulatory provision in the Final “Prior Notice” regulations that (1) authorizes an alternative method of filing

information about food cargoes shipped between two points in Canada, transiting the United States, and (2) provides sufficient flexibility to cover the unique and secure circumstances surrounding shipments on the Sunbury Train.

Thank you very much.