

02N-0278_emc-000186.txt
From: Schreier, Z 665, BN [w.Schreier-Zoll@DeutschePost.de]
Sent: Friday, May 14, 2004 9:58 AM
To: 'fdadockets@oc.fda.gov'
Subject: Bioterrorism Act 2002; Docket No. 2002N-0278 (prior notice of imported food - reopening of comment period)

Dear Sirs,

attached please find our comments.

we would very much appreciate if you could take it into consideration.

we also send it by fax and mail.

Yours faithfully,

Reinhard Fischer
Corporate Customs & External Trade
Deutsche Post World Net - Headquarters
Charles-de-Gaulle-Str. 20
53113 Bonn, Germany
Phone: +49 228 182 66041
Fax.: +49 228 182 66090
Mail: R.Fischer-Zoll@DeutschePost.de

Headquarters
Head of Tax



MAIL EXPRESS LOGISTICS FINANCE

Deutsche Post AG · Headquarters · Head of Tax · 53250 BONN · GERMANY

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

Your reference 665
Our reference +49 228 182 66040
Phone R.Fischer-Zoll@DeutschePost.de
e-mail 14.05.2004
Date Bioterrorism Act 2002;
Docket No. 2002N-0278 (prior notice of imported food – reopening of comment period)

Dear Sir/Madam,

We have followed with interest the developments surrounding the publication of the “Public Health and Bioterrorism Preparedness and Response Act 2002”. We are pleased to comply with your request for comments on the Interim Final Rule stipulating the submission of prior notice for the dispatch of foodstuffs to the USA.

We welcome the efforts by the USA to safeguard the entire manufacturing and delivery chain for foodstuffs, and hence to lessen the possibility of terrorist attack. It is in the interests of the whole world to take every opportunity to block the activities of terrorist organizations, and as a company with global operations, we are happy to provide the US government with all the support we can possibly give to ensure the highest possible level of security for US citizens.

Our group, Deutsche Post, is the national public postal operator in Germany. We comply with all the rights and obligations contained in the Universal Postal Convention. We fulfill the universal service obligation stipulated by law and make our postal services available to everyone, everywhere. The fulfillment of the obligations contained in the Universal Postal Convention makes it possible for private customers in particular to make use of postal services throughout Germany and at acceptable prices.

Delivery address
Charles-de-Gaulle-Str. 20
53113 BONN
GERMANY

Office
Platz der Deutschen Post
Bonn

Phone + 49 (0) 2 28 1 82-0
Fax + 49 (0) 2 28 1 82-70 99

www.dpwn.com

Banking connection
Deutsche Post AG
Service Niederlassung
Accounting Köln
Postbank Köln
Account number 16
503
Bank code 370 100 50

Board of Management
Dr. Klaus Zumwinkel, Chairman
Dr. Frank Appel
Uwe R. Dörken
Dr. Edgar Ernst
Dr. Peter Kruse
Dr. Hans-Dieter Petram
Walter Scheurle
Prof. Dr. Wulf von
Schimmelmänn

Chairman of the
Supervisory Board
Josef Hatfig

Registered office: Bonn
Commercial Register Bonn
HRB 6792

VAT REG No: DE 1698
38187

The new requirements for the submission of prior notice for foodstuffs to be dispatched to the USA have to be met by our customers also. Unfortunately, we feel that the practical implementation of these requirements will create substantial problems for us and for postal operators around the world. The requirements of the prior notice provisions, which are very complex, will be difficult to implement in an environment where information has hitherto been communicated mainly in paper form, and they can only be implemented within a very wide time slot.

The greatest problem that we currently see in the implementation of the new provisions is the target group affected by the regulations. All senders, including small companies and private customers, are required to submit advance information electronically. In practice, this cannot be implemented within postal traffic.

Many of our private customers have no Internet access, and so are unable to send prior notice electronically. Another problem is language; many of our customers do not speak English, which means that they could only submit a prior notice in German. However, this would require the whole system, including the necessary operating instructions, to be available in German, which is not the case at this time. The details required for the prior notice are very complex, and our customers do not have some of the information that has to be provided.

These obstacles will make it impossible for many private customers and small companies to meet the requirements. On this basis, we would suggest that the entire C2C segment should be exempt from the obligation to submit a prior notice. Moreover, exceptions should also be granted to small companies; for example, the requirement for a prior notice could be waived up to a specified value threshold.

Our initial experience in using the system has shown us and our customers that the entry of the data is very time-consuming and hence costly. In particular, the time taken for a confirmation to be sent from the FDA is not currently acceptable. As the confirmation number has to be written on mail shipments before they can be dispatched, the current slow response times constitute a considerable disadvantage for our customers. Processes have to be completely reorganized to take account of long waiting times before the goods can actually be dispatched. This problem will intensify with Christmas mail, when a vastly increased number of prior notices will arrive at the FDA.

This will place us at a substantial competitive disadvantage in postal communications. Whereas non-postal shipments by air are subject to a notice period of 4 hours before the arrival of the goods, for postal communications the confirmation must be present much earlier. In the view of Deutsche Post, this is unacceptable.

Our large customers are currently striving to meet the new requirements, and use the system on a regular basis. One clear weakness is that every shipment currently has to be notified individually. Even customers who always dispatch the same products, where only the package size varies, are forced to wait for confirmation from the system for each individual shipment.

As stated at the beginning of this letter, we support the efforts of the US government to safeguard the whole delivery chain for foodstuffs, but only a fast and simple system for submitting the prior notices will help to increase acceptance among our customers.

We would therefore suggest providing a simple system with limited data, to enable the requirements of the FDA to be met without lengthy waiting times. Business customers who always dispatch identical products should have the option of entering several shipments at once and obtaining a single confirmation number to cover these shipments. This would substantially reduce the effort involved, without compromising security. We must ensure that, even at peak times, confirmations can be generated without delay.

Consideration should be given to exempting private customers from the obligation completely, and simplifying the process for small companies. Otherwise, these customers will in future be able to dispatch foodstuffs to the USA only with severe restrictions.

We hope you will take note of our comments in the continuing elaboration of these provisions. We will be happy to answer any queries you may have.

Yours faithfully,

Reinhard Fischer
Director
Corporate Customs & External Trade

Sandra Fischer