

LINE NUMBER IS _____ STATE _____ 56

Teleconference High priority Record Keeping (1)

What is your question -- and would you like to ask it live on the air or would you prefer that we write it down?

QUESTION 02N-0277

From: Ross Consulting
Corinth, TEXAS

In following raw agricultural products through ~~the~~ ^{the} chain of custody, wouldn't it be more appropriate to trace these bulk products in such a way as to limit the number of potential sources

Now I'm going to put you on hold. While on hold, you'll be able to hear the program in progress. When you hear the moderator announce your ~~line number~~, turn down your TV set and ask your question. ^{city, state}

of contamination, rather than just listing all of the suppliers?

02N-0277

LST 1

High priority

Leslye

Does the record keeping requirement apply to Customs Brokers and Freight Forwarders who "facilitate" and or arrange the import and transportation of these covered goods.

LINE NUMBER IS _____ STATE _____

Leslye

Teleconference

What is your question -- and would you like to ask it live on the air or would you prefer that we write it down?

QUESTION

Does the recordkeeping rule apply to manufacturers of food packaging materials?

Now I'm going to put you on hold. While on hold, you'll be able to hear the program in progress. When you hear the moderator announce your ~~line number~~, turn down your TV set and ask your question. *city, state*

Boln

Will the bills of Lading
commonly used by trucking
companies suffice for the
transporter record keeping
requirements?

heslaye

The regulation establishes different record keeping for transporters and non-transporters.

Why the difference?

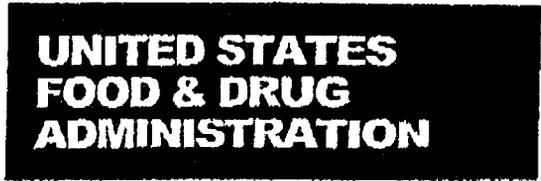
Why the distinction between the two?

Lestye

Are there any record keeping requirements for foreign transporters?

It's not mentioned under foreign facilities —

9901 S. Caga Boulevard, Suite B
Pharr, TX 78577
Phone: 956-283-2190 or 283-2191
Fax: 956-283-2192



Fax

To:	From:
Fax:	Pages:
Phone:	Date:
Re:	CC:

Urgent
 For Review
 Please Comment
 Please Reply
 Please Recycle

• Comments:

→ ONE TRANSPORTATION COMPANY EXAMPLE

WHAT ABOUT WHEN YOU THE PRODUCT IS
SHIPPED TO RETAIL STORES CENTRAL
WAREHOUSE AND THEN FROM THERE
TO RETAIL STORES. WHERE DOES THE
RESPONSIBILITY ~~HE~~ FOR RECORDKEEPING
LIE?

FDA / Atlanta

5/7/03

ARE TRANSPORTATION COMPANIES
REQUIRED TO VERIFY ACCURACY
OF CONTENTS REPORTED BY THE
NON-TRANSPORTING SHIPPING COMPANY?

SID CAMP
ATLANTA, GA

LINE NUMBER IS _____

STATE _____

High priority

Teleconference

Record Keeping

2

What is your question -- and would you like to ask it live on the air or would you prefer that we write it down?

QUESTION

From: Albuquerque, New Mexico
(2 questions)

1. We are a non-profit service provider for persons with mental retardation and developmental disabilities. We purchase, transport and prepare food for the individuals we serve.

~~Does the act require~~ Does the act require that we keep records for all food purchases for two years?

Now I'm going to put you on hold. While on hold, you'll be able to hear the program in progress. When you hear the moderator announce your line number, turn down your TV set and ask your question. city, state

2. Do the record keeping requirements of the Act apply to residential services providers? such as... nursing homes, group homes, etc.?

herby

How would a bottled water processor identify the "non-transporter" [≠] previous source" as to name and responsible individual, address, telephone, FAX, ~~and~~ email address, etc ?

STEVE

FDA was given record review authority when the Bioterrorism Act was signed last June.

Has FDA exercised its new authority to date?

Bob

The legislation refers to food for human consumption.

Packaging materials are not intended for human consumption.

Why are you including food packaging materials in the rule ?

high priority

Would grain elevators under
the jurisdiction of the
US Warehouse Act be
required to keep records?

High priority

state

Does a domestic company have to keep records if they only export product (not to be consumed in the US)?

Unrecorded

What steps are being taken
to avoid the duplication of record-
keeping requirements with U.S. Customs
or ATF?

High
Priority

└ Bob?

High Priority

Public Meeting via Satellite Downlink -- May 7, 2003

RECORDKEEPING AND ADMINISTRATIVE DETENTION PROPOSED RULES

~~to the~~
Bob

Fax Question Sheet

Please print clearly in the space below

Good

IF A MANUFACTURER MAKES CANNED BEANS WITH MEAT, WITH MORE THAN 2% OF MEAT, SO IS UNDER USDA JURISDICTION, MUST HE KEEP RECORDS OF THE INGREDIENTS OTHER THAN MEAT?

~~SUPPOSE A SAUSAGE, WITH ONLY MEAT AND~~

U.S. Food & Drug Administration

Date: May 7, 2003

To: Bioterrorism Downlink Staff

Fax:

Sender:

QUESTION:

Are there penalties for unintentional
errors in the record keeping?

Steve

High
Priority
Leslye

Public Meeting via Satellite Downlink -- May 7, 2003

RECORDKEEPING AND ADMINISTRATIVE DETENTION PROPOSED RULES

Fax Question Sheet

Please print clearly in the space below

Your description of the definition of food did not mention "packaging" or food contact sources where migration occurs. The two previous proposed regulations did describe food to include packaging and migration sources. Are you intending to interpret the meaning of "food" differently than before?

LINE NUMBER IS _____ STATE _____

54

Teleconference

What is your question -- and would you like to ask it live on the air or would you prefer that we write it down?

QUESTION

Does the non-edible
chicken parts from a USDA
chicken-processing facility fall
under this rule if the
non-edible parts are
intended to be used for
pet food.

Now I'm going to put you on hold. While on hold, you'll be able to hear the program in progress. When you hear the moderator announce your ~~line number~~, turn down your TV set and ask your question. *city, state*

How

Will FDA recognize systems and regulations in place and administered by a foreign country's government as being equivalent to the requirements in the proposed rule(s)



DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

*High
Priority
Send*

TOPIC:
RECORD KEEPING AND ADMINISTRATIVE DETENTION
PROPOSED RULES
(OF THE)
BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

FAX FORM

QUESTION When / If product is detained and needs to
be moved to a secured warehouse
can any trucker be used?
What happens if there is pilferage?

((OPTIONAL) SUBMITTED BY:

STATE:

Will the detention proposal
change the relationship between
state and federal enforcement?

Kesbye

DO EITHER OF THE
PROPOSALS DISCUSSED
TODAY APPLY TO FOODS
THAT ARE NOT IN
INTERSTATE COMMERCE?

Will FDA increase personnel
to handle all these proposed changes?

Would a bulk milk hauler need to maintain these records?

- ② The hauler picks up raw milk from the dairy farms and delivers it to a dairy plant.



DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

TOPIC:
RECORD KEEPING AND ADMINISTRATIVE DETENTION
PROPOSED RULES
(OF THE)
BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

FAX FORM

QUESTION As a customs broker, would the records which we normally keep; ex: (Invoices, packing list, Delivery orders, customs/FDA entry) suffice for complying our end as far as record keeping?
If for example the broker only handles paperwork as far as clearing the product and does not deliver or hold the product.

((OPTIONAL) SUBMITTED BY:

STATE: Florida



DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

TOPIC:
RECORD KEEPING AND ADMINISTRATIVE DETENTION
PROPOSED RULES
(OF THE)
BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

FAX FORM

QUESTION PLEASE EXPLAIN THE CHAIN OF RECORD KEEPING
REQS. ON AN IMPORTATION: (AN EXERCISE)

1) STEAMSHIP CO / AIR CARRIER

2) CUSTOMS BROKERS

3) DELIVERING (CONTAINER/PACKAGES) BY TRUCKING COMPANY

4) RESPONSIBILITY OF CONTENT (# CARTONS) ON A CONTAINER
FOR A CUSTOMS BROKER

((OPTIONAL) SUBMITTED BY: EDUARDO TORNER CNB

STATE: FL

FLen: M 86



DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

TOPIC:
RECORD KEEPING AND ADMINISTRATIVE DETENTION
PROPOSED RULES
(OF THE)
BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

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If for example the broker only handles paperwork as far as clearing the product and does not deliver or hold the product.

((OPTIONAL) SUBMITTED BY:

STATE: *Florida*

low
priority

Public Meeting via Satellite Downlink -- May 7, 2003

RECORDKEEPING AND ADMINISTRATIVE DETENTION PROPOSED RULES

Fax Question Sheet

Please print clearly in the space below

HAS FDA Considered How Difficult
 and Expensive it will be for ~~small~~
 manufacturers who deliver their products
directly to retailers to capture
 lot numbers in the required records?
 - what does it mean when you
 say lot numbers if available?

LINE NUMBER IS _____

STATE _____

Teleconference

527-1401

What is your question -- and would you like to ask it live on the air or would you prefer that we write it down?

Denton, TX

QUESTION

Do grain elevators need to keep track of their grains (movement) w/in the elevator?

Now I'm going to put you on hold. While on hold, you'll be able to hear the program in progress. When you hear the moderator announce your line number, turn down your TV set and ask your question. city, state

~~15~~

Public Meeting via Satellite Downlink -- May 7, 2003

RECORDKEEPING AND ADMINISTRATIVE DETENTION PROPOSED RULES

Fax Question Sheet

Please print clearly in the space below

Do records have to be kept by foreign facilities to
delivering to for instance US military bases
located outside the US?

DB

Public Meeting via Satellite Downlink -- May 7, 2003

RECORDKEEPING AND ADMINISTRATIVE DETENTION PROPOSED RULES

Fax Question Sheet

Please print clearly in the space below

WHAT SITUATION WOULD REQUIRE
THAT A CUSTOM HOUSE BROKER
WOULD NEED TO KEEP RECORDS -
IF THEY DID NOT PHYSICALLY
ACCEPT OR HANDLE THE SHIPMENT.
THEY JUST HANDLE CUSTOMS
ENTRY

Public Meeting via Satellite Downlink -- May 7, 2003

RECORDKEEPING AND ADMINISTRATIVE DETENTION PROPOSED RULES

Fax Question Sheet

Please print clearly in the space below

*

you said food packaging is
not covered.
what about food CONTACT
materials.

CDRH Teleconference Questions

From: Kate Chilton [chillybean5@hotmail.com]
Sent: Wednesday, May 07, 2003 1:36 PM
To: TVQUESTION@CDRH.FDA.GOV
Subject: BT QUESTION PLATTSBURGH NY LOCATION

are available records releasable under foia?

MSN 8 with e-mail virus protection service: 2 months FREE*
<http://join.msn.com/?page=features/virus>

Are available records
releasable under FOIA?

CDRH Teleconference Questions

From: Kate Chilton [chillybean5@hotmail.com]
Sent: Wednesday, May 07, 2003 1:39 PM
To: TVQUESTION@CDRH.FDA.GOV
Subject: BT QUESTION PLATTSBURGH NY LOCATION

ARE REQUESTS FOR RECORDS AT THE DISCRETION OF FDA INVESTIGATORS OR WILL REQUESTS REQUIRE DISTRICT APPROVAL?

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<http://join.msn.com/?page=features/junkmail>

Are requests for records at the discretion of FDA investigators or will requests require District approval?

Low Priority



Denver District Office

Virlie Walker

Office of Public Affairs

Phone: 303-236-3018

Fax: 303-236-3551

MAY 7, 2003

INFORMATION TRANSMISSION COVER SHEET

To: To the panel

Fax # 1-888-361-4011

Subject: **Satellite Downlink:** The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act or the Act)

QUESTION FROM DENVER:

this will be answered during broadcast

Who will be viewing the Records

From TRANSPORTATION AND Food

Processing And what Time period will

They Be Review?

From Don Louia

Public Meeting via Satellite Downlink -- May 7, 2003

RECORDKEEPING AND ADMINISTRATIVE DETENTION PROPOSED RULES

Fax Question Sheet

Please print clearly in the space below

Bob

~~HOW MUST RECORDS BE KEPT IN WHAT FORM?~~

COULD CHAIN OF CUSTODY BE MAINTAINED
BY AN INDEPENDENT SERVICE?

[Lined area for handwritten responses]

*low
priority*

Public Meeting via Satellite Downlink -- May 7, 2003

RECORDKEEPING AND ADMINISTRATIVE DETENTION PROPOSED RULES

Fax Question Sheet

Please print clearly in the space below

No

*Is this requirement applicable
to cosmetics or cosmetic ingredients?*

Lined area for handwritten response.

Does record requirements for transporters
of food apply to drugs?

Kansas City District BT Downlink May 7, 2003

FAX Questions

Caller: *MIKE WELCH*

Question:

IF we IMPORT A TREAT SACK FROM H.K., WITH A PAPER NOTE PAD, STICKERS, GAMES AND 3 Pieces OF HARD SUGAR CANDY WRAPPED IN PLASTIC.

This supplier IN H.K. IS JUST A PACKAGER OF these VARIOUS items INTO their TREAT SACK AND Seal the TREAT SACK AND Packed IN MASTER CARTON OF 48 TREAT SACKS.

(This HARD CANDY IS MADE IN CHINA.)

ARE we Responsible TO TRACE THE ACTUAL MFG. OF This CANDY, That is CONTAINED IN these TREAT SACKS,

Public Meeting via Satellite Downlink - May 7, 2003

RECORDKEEPING AND ADMINISTRATIVE DETENTION PROPOSED RULES

Fax Question Sheet

Please print clearly in the space below

IT IS ALL TOO COMPLEX TO HAVE TO DIFFERENTIATE BETWEEN REGULATIONS THAT APPLY TO FOODS THAT THE FDA REGULATES AND THOSE THAT THE USDA REGULATES.

THE AVERAGE PERSON CANNOT COMPREHEND THE SEPARATION, AND THEREFORE THIS PRESENTS A REGULATORY WEAKNESS.

WHY CANT THE FDA AND THE USDA HARMONISE THEIR ACTIVITIES INTO A SINGLE FOOD AGENCY WITH SINGLE LEGISLATION?

**Kansas City District
BT Downlink
May 7, 2003**

per work

FAX Questions

Caller:

Question:

If a company owns a warehouse facility off-site, and ships there from their own processing/manufacturing plant, do both the manufacturing plant and the receiving warehouse have to keep the records of ~~the~~ immediate previous nontransporter (for ~~plant~~^{warehouse}) + immediate subsequent nontransporter (for plant)? ~~Y/N/A~~

Again!

**Kansas City District
BT Downlink
May 7, 2003**

FAX Questions

Caller: Dan Keller - O'Neill + Whitaker Inc

Question: Regarding the Record
Keeping for U.S. Custom Brokers.

What additional records if any
must be kept by the custom Broker
that is not already covered by the
U.S. Custom Service regulations covering
U.S. Custom Brokers.

CDRH Teleconference Questions

From: SCHILLING@AESOP.RUTGERS.EDU
Sent: Wednesday, May 07, 2003 2:16 PM
To: TVQUESTION@CDRH.FDA.GOV

Regarding record keeping.....

Please clarify the implications for foreign facilities-

Example: a tea blending/packaging facility in china gets bulk tea from 10 pre-processing facilities. How far back does the record keeping need to go?

CDRH Teleconference Questions

From: SCHILLING@AESOP.RUTGERS.EDU
Sent: Wednesday, May 07, 2003 1:45 PM
To: TVQUESTION@CDRH.FDA.GOV

Are food grade sanitary lubricants, processing aids, chemicals coming into contact with food contact surfaces, and cleaning/sanitizing chemicals covered under the new law?

repeat

CDRH Teleconference Questions

From: SCHILLING@AESOP.RUTGERS.EDU
Sent: Wednesday, May 07, 2003 1:43 PM
To: TVQUESTION@CDRH.FDA.GOV

Would FDA please comment on the definition of "food" as related to food packaging materials?

(repeat)

Wow

low priority

CDRH Teleconference Questions

From: Kate Chilton [chillybean5@hotmail.com]
Sent: Wednesday, May 07, 2003 1:42 PM
To: TVQUESTION@CDRH.FDA.GOV
Subject: BT QUESTION PLATTSBURGH NY LOCATION

ARE HACCP RECORD KEEPING REQUIREMENTS COMPATIBLE WITH NEW REQUIRMENTS?

Protect your PC - get McAfee.com VirusScan Online
<http://clinic.mcafee.com/clinic/ibuy/campaign.asp?cid=3963>

Are HACCP record keeping
requirements compatible with
new requirements?

Leslye
[scribble]
[scribble]

Public Meeting via Satellite Downlink -- May 7, 2003

RECORDKEEPING AND ADMINISTRATIVE DETENTION PROPOSED RULES

Fax Question Sheet

Please print clearly in the space below

IN THE CASE OF A FINISHED PRODUCT THAT
CONTAINS ITEMS THAT ARE REGULATED BY
BOTH THE FDA AND THE USDA, eg. TV DINNER,
RECORDS HAVE TO BE KEPT FOR THE FDA
ITEMS eg. CHEESE, MACARONI ETC..

ALSO
DO RECORDS HAVE TO BE KEPT FOR THE
USDA ITEMS eg. MEAT OR POULTRY MEAT?

[Lined area for additional questions]

Public Meeting via Satellite Downlink -- May 7, 2003

RECORDKEEPING AND ADMINISTRATIVE DETENTION PROPOSED RULES

Fax Question Sheet

Please print clearly in the space below

When does a feed ingredient that begins as a USDA regulated item (chicken) fall under this rule (when it becomes intended for use as a feed ingredient or it actually enters a feed mill)? Is there a particular event (transfer of ownership) that begins the record keeping requirement?

re-stated:

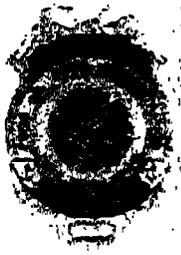
Does the non edible chicken parts from a chicken processing facility, which is under USDA jurisdiction, fall under this record-keeping rule if the non-edible parts are intended to be used for animal pet food.

No.

Are food packaging materials subject to the record-keeping requirements?

Record Keeping

**U.S. Food & Drug Administration
New York District Office
Import Operations Branch
158-15 Liberty Avenue
Jamaica, NY 11433**



FAX COVER SHEET

From: NYK-DO

Voice: (718) 340-7000 ext: _____

Fax: (718) 662-5662 or (718) 662-5663

To: BT Satellite P&A

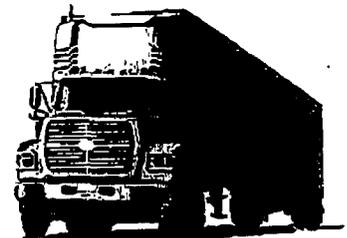
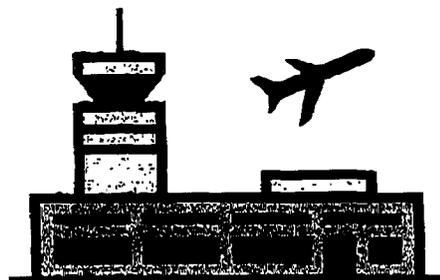
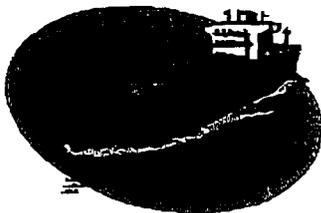
Phone: _____

Fax: 1888-361-4011

Date: _____

Page 1 of _____

Does a Customs Broker need to keep records on shipments where they are only issuing a delivery order to the trucking company to deliver the shipment to their client.



**U.S. Food & Drug Administration
New York District Office
Import Operations Branch
158-15 Liberty Avenue
Jamaica, NY 11433**



Record Keeping

FAX COVER SHEET

From: NYIC-DO

Voice: (718) 340-7000 ext: _____

Fax: (718) 662-5662 or (718) 662-5663

To: _____

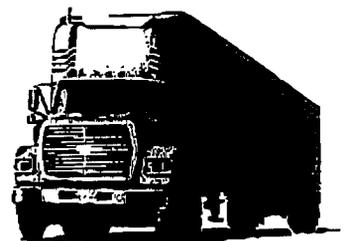
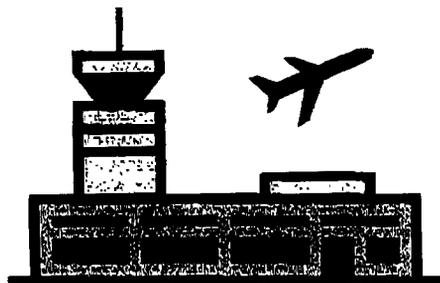
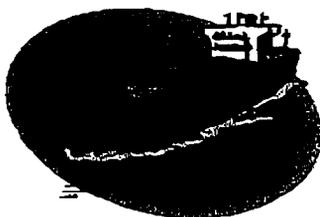
Phone: _____

Fax: 888-361-4041

Date: 5/7/03

Page 1 of _____

~~At~~
Under what circumstances would a
Customs broker be required to
keep records



FDA NEW YORK DISTRICT • 158-15 Liberty Avenue •
Jamaica, NY 11433-1034

Record-keeping

Phone: (718) 340-7000
Fax: (718) 662-5665

FAX COVER SHEET

Date: 5/7/03
Sender: ZAINAB NASSER/EAGLE GLOBAL LOGISTICS
Tel Ext: 516-620-6145 (Director)
No. of Pages: + cover

Recipient: _____

Office: _____

Tel No: _____

FAX No: 1 888 361-4011

Message:

- ① Since a Customs Broker would be receiving/sending documentation to/from transporters, would they be required to maintain records as a non-transporter?
- ② It was mentioned that foreign companies were not required to maintain records. Would this also apply to US owned subsidiaries based overseas?



Denver District Office

Virlie Walker

Office of Public Affairs

Phone: 303-236-3018

Fax: 303-236-3551

MAY 7, 2003

INFORMATION TRANSMISSION COVER SHEET

To: The Panel

Fax # 1-888-361-4011

Subject: **Satellite Downlink:** The Public Health Security and Bioterrorism Preparedness and Response Act of 20002 (the Bioterrorism Act or the Act)

QUESTION FROM DENVER:

Record-keeping

Question about FDA access to ingredients used in food products

How much access does the FDA have to ~~look at~~

proprietary information ~~and~~ ~~confidential~~ that is part of

a company recipe. # Can a company restrict what the FDA sees

in a recipe under the new regulations?
From _____



DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

TOPIC:
RECORD KEEPING AND ADMINISTRATIVE DETENTION
PROPOSED RULES
(OF THE)
BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

FAX FORM

QUESTION Why would a Customs Broker that clears
cargo only that does not touch the
cargo have to keep records under the
new proposed law?

((OPTIONAL) SUBMITTED BY: Sergio Lozano STATE: FL



DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

*Prior Notice
Question*

TOPIC:
**RECORD KEEPING AND ADMINISTRATIVE DETENTION
PROPOSED RULES
(OF THE)
BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002**

FAX FORM

FDA TAMPA

QUESTION Without being hooked up to the AMS System
(Automated Manifest System)
How does FDA plan to monitor shipments
with the carriers - Air & Ocean

813-228-2045

11:49

05/07/2003

((OPTIONAL) SUBMITTED BY: Jim Alberdi/A.J. Arango Inc STATE: Tampa Florida

9901 S. Cage Boulevard, Suite B
Pharr, TX 78577
Phone: 956-283-2190 or 283-2191
Fax: 956-283-2192

**UNITED STATES
FOOD & DRUG
ADMINISTRATION**

*same Q
as previous*

Fax

To:	From:
Fax:	Pages:
Phone:	Date:
Re:	CC:

Urgent For Review Please Comment Please Reply Please Recycle

• **Comments:**

Does a party who is not a transporter or importer, but who facilitates the importation or transportation have any record keeping responsibilities.



Denver District Office

Virlie Walker
Office of Public Affairs
Phone: 303-236-3018
Fax: 303-236-3551

MAY 7, 2003

INFORMATION TRANSMISSION COVER SHEET

To: _____

Fax # 1-888-361-4011

Subject: **Satellite Downlink:** The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act or the Act)

EXAMPLE :

WHOLESALER / DISTRIBUTOR BRINGS IN SEVERAL
OVER THE COURSE OF A YEAR
DIFFERENT LOTS OF THE SAME WINE (SAME VINTAGE)
AND THEN SELLS THESE GOODS TO RETAILERS
@ AN APPROXIMATE FIRST GOODS IN / FIRST GOODS OUT
SELLING METHOD ... DOES THE WHOLESALER / DISTRIBUTOR
NEED TO KEEP TRACK OF EACH RETAILER WHO
PURCHASED THE WINE BY LOT # OR JUST BY

High Priority

No time

Public Meeting via Satellite Downlink -- May 7, 2003

RECORDKEEPING AND ADMINISTRATIVE DETENTION PROPOSED RULES

Fax Question Sheet

Please print clearly in the space below

1. ~~test~~

The proposed rule states that records are to be maintained for two years after the date the food article is "created." How would this time frame apply to raw agricultural commodities? For instance would records applying to corn grown in 2004 be required to be kept by grain elevators and further processors until 2006 rather than from the date the corn was received?

NEW YORK DISTRICT
UPSTATE IMPORT OPERATIONS BRANCH
FACSIMILE TRANSMISSION RECORD

To: (Name, Organization & Mail Code)
From: (Name, Organization & Mail Code)

**BT Bio-terrorism
Fax line**

Facsimile Phone # (if known) **888-361-4011**

X

~~US Food & Drug Administration~~

~~Upstate Import Operations
300 Pearl Street, Suite 100
Buffalo, NY 14202~~

Confirmation: 716/551-4461, ext 3149/50

Transmission: 716/551-3813

No. of Pages

Date:

Operator:

Cover +

5/7/03

MESSAGE:

BT Downlink Question

Leslye commented that mixed dinners containing products regulated by both USDA (meat) and FDA (mashed potatoe + vegetables), would only require records to be kept for the portion regulated by the FDA. Does this mean that no records need to be kept regarding the source of the meat?
Please clarify. Thank you

*3rd time
was it
already
sent
out?
Yes!*

~~ROBERT L. HART, Director
Import Operations Branch (Upstate)
E-mail: rhart@ora.fda.gov
TEL: 716/551-4461 Extension 3142
FAX: 716/551-3813~~

Public Meeting via Satellite Downlink -- May 7, 2003

RECORDKEEPING AND ADMINISTRATIVE DETENTION PROPOSED RULES

Fax Question Sheet

Please print clearly in the space below

Within a food manufacturing operation, if ingredients or food components move from one geographic location to another during processing, are separate records required for transport within a company?
the same

asked
answered

Unclear about packaging - aren't food contact packaging materials required to be in records?
kept one step back and one step forward?

Registration Q

U.S. Food & Drug Administration

Date: May 7, 2003

To: Bioterrorism Downlink Staff

Fax:

Sender:

S.F.

QUESTION:

Will import shipments be held (after 12-12-03)
Pending facility registration?
F.C.E. & S.I.D. info currently take 2-6 months
to input by F.D.A.

Asked

Question: What steps are being taken to avoid the duplication of requirements, including record keeping, where they are already required - for instance for Customs purposes or, in the case of alcoholic beverages, ^{by} the Alcohol and Tobacco Tax and Trade Bureau (TTB)?

Question: There is recognition that companies made need more time to provide records if they are requested at week-ends ^(8 hours rather than 4). Is there any recognition of the problems with time differences. 6.00pm in Washington could be midnight in parts of Europe?



DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

TOPIC:
RECORD KEEPING AND ADMINISTRATIVE DETENTION
PROPOSED RULES
(OF THE)
BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

Repeat

FAX FORM

QUESTION HOW WOULD THIS PROPOSAL APPLY TO
U.S. CUSTOMS BROKERS?

((OPTIONAL) SUBMITTED BY:

STATE:

FL

U.S. Food and Drug Administration
Southwest Imports District
4040 N. Central Expy., Suite 300
Dallas, Texas 75204

(214) 253-5330
Fax (214) 253-5317



Fax

Fax: 888-361-4011	From:	(optional)
Re: Public Meeting on BT proposed regs	Date: 5/7/03	
• Question:		

1) Will Truck Brokers provide Tracking data or the 'owner/operator' / 2nd Party Truckers. Actually owning the Vehicle, provide Tracking? OR Both?
 To meet transporter Tracking information?

same as previous Q

2) Will shipper & Receiver be responsible for transportation info Beyond the 'Truck Broker' / As transporter of Records?

Asked & answered

legible

Public Meeting via Satellite Downlink -- May 7, 2003

RECORDKEEPING AND ADMINISTRATIVE DETENTION PROPOSED RULES

Fax Question Sheet

Please print clearly in the space below

① A question re coordination of different sections.
Does the record keeping requirement include needing to know the registration number of facilities that are required to register under Sec. 203?

② How far down the ingredient list must owner / buyer be known?

③ For food exported from, it is often bought by a broker, the seller does not know who is receiving the shipment?

④ How about products that being ~~shipped~~ harvested product to packing house / processor?

⑤ How is "credible risk" defined?
Who defines " " ?