

Director, Division of Compliance, HFV-230  
Office of Surveillance and Compliance, CVM

"Assignment to Collect and Analyze Domestic-Import Samples Suspected of PCB and Dioxin Contamination"

CVM Assignment # VA9-DXN  
ORA Clearance # 19960621

ALL: RFDDs, DDs, DIBs, DCBs, and Lab Directors:

### **ASSIGNMENT MEMORANDUM-TOP PRIORITY**

Top Priority, takes precedence over work of this and other Centers. This assignment has the concurrence of ORA, concurrence # 19960621

#### **Objective**

To collect and analyze animal feeds (medicated and non-medicated), feed ingredients, and pet foods to determine levels of polychlorinated biphenyl's (PCBs) and/or dioxins. To remove unsafe or violative product from consumer channels.

#### **Background**

FDA has received information that fat from a rendering company in Belgium was contaminated with dioxins and/or PCBs in January of 1999. This product was shipped to animal feed manufacturers and incorporated into animal feed distributed to poultry, hog and cattle farms in Belgium, France, and the Netherlands, with the majority of the product going to Belgium. Analysis of chickens and eggs in Belgium revealed PCBs and dioxins.

On June 4, 1999 FDA issued an Import Bulletin to the field directing animal feed, and animal By-Products for animal food from France, Belgium and Netherlands; and egg-containing products, from Belgium offered for entry into the U.S. to be held at the port of entry. On June 11, 1999 FDA issued Import Alert 99-24 "Detention Without Physical Examination of Human Food Products and Animal Feeds Contaminated with Dioxin and/or PCB Compounds", [Attachment A].

CVM extended the import ban to all European countries (see Import Alert, Attachment A for a complete list) for animal feeds and pet foods because of the uncertainty on the extent of the contamination and the lack of measures to prevent exposed animals from being recycled into the feed supply. CVM is monitoring the situation in Europe daily and will update the field when more information becomes available.

Dioxins and PCBs persist in the environment. Any animals fed contaminated feed products and subsequently slaughtered may have levels of dioxins/PCBs remaining in slaughter by-products. These may be rendered and subsequently used in other animal feeds, allowing the dioxins/PCBs to continue to be recycled through the food chain. It is critical that human foods sampled and found to contain dioxin not be used for animal food. Any requests for reconditioning by this means must be sent to CVM for review.

### **SAMPLING**

This assignment is requesting each district to accomplish the following:

- 1) Collect an official sample(s) of products in attachment C.

When at the firm, check to see if any of the products identified in attachment C as having been manufactured from the foreign manufacturer during 1999 are available. It may be advisable to first telephone the importer listed in attachment C to determine the actual location of the shipment.

The targeted products were selected from printouts of entries from January 1999 to about June 11 and focus on recently arrived large volume entries of high fat content feeds and pet foods.

Collect one product per consignee listed in Attachment C. In some cases multiple shipments for the same consignee are listed to provide the best chance the product will be available. Do not collect more than one sample per product from the same consignee. Where different products have been received by the same consignee, as identified on attachment C, collect one sample of each product.

Samples should not be split. Submit each sample to your district's servicing laboratory for PCB analysis. Do not send samples to another location unless specifically requested. The composite prepared by the field pesticide lab will be used for any subsequent dioxin analyses. CVM will determine which samples will go for necessary dioxin analysis after review of the PCB results.

- 2) If samples are not available at the firms listed in Attachment C:  
If the firm has none of the product available, determine consignees where the product was shipped, shipping dates, quantity of product shipped and an estimate of the expected time the product would normally be available for sale. Record the lot number identified on the product distributed if available.

Districts should use discretion in attempting to follow-up at sub distribution points and issuing assignment for follow-up at sub-distribution point in foreign districts. For instance, consider the size and date of shipment and other pertinent information supplied by the referenced firm when considering the need to follow-up at consignees. Determine if the firm is expecting additional shipments of the product in the near future and when.

While the problem in Europe began in January of this year, it is likely that the consignees may not be able to identify specific codes and dates that the product was manufactured and/or received. Do the best you can.

3. If the firm can conclusively prove (through shipping records, etc.) that the product was manufactured and/or received prior to January 1999, or the product is not labeled as being of animal origin, or is a product of a country other than those listed in the Import Alert #99-24, do not sample. If no country of origin is labeled on the product, assume that the product origin is from the suspect country and collect an official sample.

Use the guidance in the IOM, Sample Schedule Chart 15, Veterinary Products, Feeds, & By-Products for Animal Feeds, for determining sample size.

Inform the firm management of the purpose of your visit and provide the firm with a copy of the FDA Talk Paper 99-27, "All Eggs and Egg-Containing Products From Belgium, France, and The Netherlands and Animal Feed from European Countries To Be Detained At Ports of Entry" (Attachment B), identifying the nature of dioxin/PCB problem in Europe. (Note - this attachment is a text file and needs to be printed out on FDA Talk Paper letterhead). Tell firm management that the samples are to be analyzed by FDA and that the removal of any product found to be violative is the responsibility of the firm. Ask firm management if they have any plans to recover distributed product or to hold sampled product. Report this information in the "Remarks" section of the collection report.

Ship samples for overnight delivery to your district's domestic pesticide servicing laboratory. Coordinate shipment with the lab especially for samples shipped on Thursdays or Fridays.

Districts are to inform Dr. Daniel McChesney, HFV-222 via e-mail or FAX of the results of the sampling effort for each product listed on the attachment. (Responding by fax, please send to 301-594-1812.) For products sampled, fax a copy of each collection report; for products not sampled report on the information obtained above.

### **Analytical**

Analyze all samples for PCBs using PAM Vol. I Chapter 3, section 303 or 304 for non-fatty and fatty foods, respectively. Perform a check analysis immediately for products found to contain PCBs at or above the limit of quantitation of 0.1 ppm on a *whole product basis*. This includes products that have PCB tolerances listed in 21 CFR 509.30 above 0.1 ppm. Original PCB analysis should be completed within 48 hours of sample receipt; check analysis within 24 hours of completion of original analysis.

Laboratories must notify collecting districts IMMEDIATELY of analytical results.

The labs are also to report all analytical results, including negative findings, as they are obtained to CVM, ATT: Dr. Daniel McChesney, HFV-222 via fax or e-mail. (Responding by fax, please send to 301-594-1812.) Maintain composites for all samples until further notice by CVM. CVM will make a determination of further analytical requirements (e.g. dioxin analysis) and analyzing laboratory for selected samples, including some that may have had no PCBs found.

### **REPORTING**

Collection Reports and information on the outcome of the trace-forward on each of the products listed in Attachment C are to be faxed to Dr. Daniel McChesney, HFV-222 phone 301-827-6653, fax 301-594-1812.

PAC: 71R842

Product Codes: See Import Alert and attachment C.

### **Regulatory Action**

Samples that exceed PCB tolerances listed in 21 CFR 509.30 are adulterated and follow-up action would be appropriate. However, some products sampled will not be covered by the tolerances. CVM will evaluate all findings of PCBs for products not covered by CFR tolerances and advise the home district of recommended follow-up action.

For products that exceed CFR tolerances or products containing PCBs at levels CVM determines to be of regulatory significance, immediately notify the firm at which the sample was collected and inquire as to their intentions to recall. If recall is not forthcoming, seizure or other regulatory action, as appropriate should be considered.

This assignment is TOP priority and is to be implemented upon receipt. This assignment has the concurrence of ORA.

**CVM/ORA Contacts**

**CVM-** Assignment and Compliance Issues

Gloria Dunnavan, Director, Division of Compliance HFV-230

301-594-1726

John Young, CSO 301-594-1791

FAX for both, 301-594-1812

**CVM** –Scientific Issues

Dr. Randall Lovell, VMO HFV-222

301-827-0176

**ORA** –Barbara Marcelletti

301-827-5635

DFS Analytical Contact:

Len Valenti, HFC-140,

301-827-1027

Gloria Dunnavan

**Attachments**

Attachment A - Import Alert 99-24

Attachment B- Talk Paper 99-27

Attachment C - Consignee and product listing by country by district.

cc: HFC-1  
HFC-102  
HFC-130 Weitzman, Pierce, Marcelletti  
HFC-140 Olson, Valenti  
HFC-150 Arbaugh  
HFC-170 McCallion, Notzon  
HFV-1 Sundlof  
HFV-200 Tollefson, Raynes, Matheson  
HFV-220 Graber, McChesney, Lovell  
HFV-230 Dunnavan  
HFV-232 Young, Gushee  
HFV-235 Washington  
HFA-224  
Draft: jyoung:6-21-99  
Reviewed: jgushee:6-21-99  
Revised: jyoung:6-22-99  
Final:tvwooten: 6/22/99

ATTACHMENT A

To: ORA IO HQ Alerts@LISTS.local@FDAORAHQ, ORA DDs@LISTS@FDAORAHQ  
cc:ORA RFDDs@LISTS@FDAORAHQ, Deborah Ralston@ORO@FDAORAHQ,  
cc:ORA RFDDs@LISTS@FDAORAHQ, Deborah Ralston@ORO@FDAORAHQ,  
David  
Eggholm@OPPE@FDA.CFSAN, Gloria Duran@OSS@FDACVM, John  
Young@OSC@FDACVM, Matthew Eckel@OGC.FDA@FDAOC, Patrick  
Wilson@OIA@FDAOC, Janice F Oliver@OCD@FDA.CFSAN, ORA IO Systems  
Branch@LISTS.local@FDAORAHQ, Stella Notzon@IO@FDAORAHQ, Joseph

From: Import Alerts@IO@FDAORAHQ  
Date: Fri Jun 11 12:26:28 1999  
Attached: None

DATE: June 11, 1999 (Updated 6/15/99)

FROM: ACTING DIRECTOR, DIVISION OF IMPORT OPERATIONS & POLICYHFC-  
(HFC-170)

SUBJECT: IMPORT ALERT #99-24, "DETENTION WITHOUT PHYSICAL  
EXAMINATION OF HUMAN FOOD PRODUCTS AND ANIMAL FEEDS  
CONTAMINATED WITH DIOXIN AND/OR PCB COMPOUNDS"

TO: IMPORT PROGRAM MANAGERS

TYPE OF ALERT: Detention Without Physical Examination

(Note: This import alert contains the agency's current guidance to FDA field personnel regarding the manufacturer(s) and/or product(s) at issue. It does not create or confer any rights for, or on any person, and does not operate to bind FDA or the public.)

PRODUCTS: HUMAN PRODUCTS  
-All egg and egg containing products  
-Meats

ANIMAL PRODUCTS  
-All medicated and non-medicated animal feed  
-All animal feed ingredients  
-All pet food

PRODUCT CODES: See Attachment

PROBLEM: Chemical Contamination - Dioxin and/or PCB Compounds

PAC FOR  
COLLECTION: 04R842  
71003A

PAF: PES

COUNTRY: HUMAN PRODUCTS: Belgium  
France  
Netherlands

ANIMAL PRODUCTS: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom

MANUFACTURER/ N/A  
FEI:

CHARGE: The article is subject to refusal of admission pursuant to section 801(a)(3) in that it appears to contain dioxins and/or PCB compounds, poisonous or deleterious substances and/or unapproved food additives, which may render it injurious to health [Adulteration, Section 402(a)(1), 402(a)(2)(C)(i), 402(a)(2)(A)].

RECOMMENDING

OFFICE: CFSAN, Office of Field Programs, (HFS-600)  
CVM, Division of Compliance, (HFV-230)

REASON FOR

ALERT: FDA has received information that animal fat from a rendering company in Belgium was contaminated with dioxins and/or PCB compounds in January of 1999. This product was shipped to animal feed manufacturers and incorporated into animal feed. Contaminated feed was fed to chickens, which resulted in contaminated eggs, and may have been fed to other domestic animals. Dioxins and PCBs persist in the environment. Any animals fed contaminated product and subsequently slaughtered may have levels of dioxins/PCBs remaining in slaughter by-products. These may be rendered and subsequently used in other animal feeds, allowing the dioxins/PCBs to continue to be recycled through the food chain.

GUIDANCE: Districts may detain without physical examination shipments of any of the products as noted above and in the attachment.

In order to gain release of detained product, importers should provide laboratory test results for dioxin TEQ (Toxic Equivalents which will include all 17 congeners, 2,3,7,8 chloro-substituted dioxins and furans) and/or for PCBs.

At this time, a government or industry certificate of compliance alone, without laboratory analysis, should not be accepted as evidence for allowing entry of detained product.

CONTACTS: CFSAN, HFS-606, Brian Landesburg (202) 205-5247  
CVM, HFV-230, Gloria Dunnavan (301) 594-1726  
DIOP, HFC-170, Stella Notzon (301) 443-6553

PRIORITIZATION

GUIDANCE: I

FOI: No purging is required

KEYWORDS: Dioxin, feed, egg, PCB

PREPARED BY: CFSAN, HFS-606, Dave Egelhofer  
CVM, HFV-230, Gloria Dunnavan  
DIOP, HFC-170, Stella Notzon

DATE LOADED  
INTO FIARS: June 11, 1999

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Joseph L. McCallion

ATTACHMENT

Product Codes:

A). For Belgium, France, and the Netherlands - [HUMAN PRODUCTS]

03- Bakery Products, Doughs, Bakery Mixes and Icings

All Products EXCEPT:

03L [][[]]- Prepared Dry Cookie, Biscuit & Wafer Mixes w/o Eggs

04- Macaroni and Noodle Products

All Products

07- Snack Food Items (Flour, Meal or Vegetable Base)

07A [][[]]01 - Snack Food, Baked-Bread Sticks, ONLY

07B [][[]]01 - Snack Food, Fried - Bread Sticks, ONLY

13- Ice Cream and Related Products

All Products EXCEPT:

13D[][[]] - Sherbet

13F[][[]] - Fruit Flavored Ices

15- Egg and Egg Products

All Products

16- Fishery/Seafood Products

16W[][[]] - Mixed Fishery/Seafood Products, ONLY

17- Meat/Meat Products

All Products

24-25 Vegetable and Vegetable Products

24V[ ] [ ] [ ] - Leaf & Stem Vegetables with Sauce, ONLY  
25H[ ] [ ] [ ] - Mixed Vegetables with Sauce, ONLY  
25N[ ] [ ] [ ] - Root and Tuber Vegetables with Sauce, ONLY  
25Y[ ] [ ] [ ] - Vegetables & Vegetable Products nec, ONLY

27- Dressings and Condiments

27A[ ] [ ] [ ] - Standardized Dressings, ONLY  
27B[ ] [ ] [ ] - Non-Standardized Dressings, ONLY  
27Y[ ] [ ] 07 - Sandwich Spreads, ONLY  
27Y[ ] [ ] 99 - Condiments, ONLY

35- Gelatin, Rennet, Pudding Mixes and Pie Fillings

35C[ ] [ ] [ ] - Custard Pudding (Pie)Mixes, ONLY  
35D[ ] [ ] [ ] - Pudding (Pie Filling)Mixes other than Custard, ONLY

37- Multiple Food Dinners, Gravies, Sauces and Specialties

All Products

39 - Prepared Salad Products

39B---- Salad with Egg, Meat, or Poultry Products  
39Y----Prepared Salad, n.e.c. (Only those containing Eggs, Egg Yolk  
Solids, Milk/Dairy)

40-Baby (Infant and Junior)Products

40A[ ] [ ] [ ]- Baked Goods  
40C[ ] [ ] [ ]- Formula Products (Milk and Milk Substitutes)  
40F[ ] [ ] [ ]- Meats and Combination Meat Dinners  
40G[ ] [ ] [ ]- Poultry and Combination Poultry Dinners  
40H[ ] [ ] [ ]- High Meat Dinners and Cheese Foods  
40J[ ] [ ] [ ]- Egg Products  
40K[ ] [ ] [ ]- Desserts (puddings, custards, etc.)  
40L[ ] [ ] [ ]- Soups and soup mixes  
40Y[ ] [ ] [ ]- Baby(Infant and Junior)Foods, nec

B. For Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland,  
Ireland, Italy, Liechtenstein, Luxembourg, Netherlands, Norway, Portugal,  
Spain, Sweden, Switzerland, United Kingdom

[Animal Products]

54- Vitamins and Minerals for Animals

All products EXCEPT:  
54A[ ] [ ] [ ] - Vitamins  
54B[ ] [ ] [ ] - Minerals

69- Medicated Animal Feeds

All Products

70- Non-Medicated Animal Feeds

All Products

71- By-products for Animal Food

All products EXCEPT:

71F[ ] [ ] [ ] - Brewery & Distillery

71G[ ] [ ] [ ] - Corn Products

71H[ ] [ ] [ ] - Flour Mill

71I[ ] [ ] [ ] - Rice Mill

71J[ ] [ ] [ ] - Fruit

71K[ ] [ ] [ ] - Vegetable

71L[ ] [ ] [ ] - Oilseed

72- Pet and Laboratory Animal Foods

All Products

ATTACHMENT B

**FDA TALK PAPER**

**T99-27**  
**June 11, 1999**

**Judith Foulke: 202-205-4144**  
**Broadcast Media:**  
**Consumer Inquiries: 888-INFO-FDA**

**ALL EGGS AND EGG-CONTAINING PRODUCTS FROM BELGIUM, FRANCE AND THE NETHERLANDS AND ANIMAL FEED FROM EUROPEAN COUNTRIES TO BE DETAINED AT PORTS OF ENTRY**

The Food and Drug Administration announced today that all imports of eggs, products containing eggs, and game meats (FDA regulated) from Belgium, France and the Netherlands, and all animal products including animal derived medicated and non-medicated feeds, feed ingredients, and pet foods from all European countries will be detained at U.S ports of entry.

These products are being detained because of the possibility that they may be contaminated with polychlorinated byphenyls (PCB's) and dioxins. Dioxins and PCB's are groups of compounds that may be potential carcinogens at low levels of exposure over extended periods of time and may have other types of toxicological effects. FDA is detaining these products as a precautionary step.

FDA is taking this action in response to recent reports that a fat product from a rendering company in Europe was

- MORE -

contaminated with PCB's and dioxins in January 1999. This fat was subsequently sold to European animal feed manufacturers. Most of these feed manufacturers are in Belgium although some of the contaminated feed has reportedly been shipped to feed manufacturers in France and the Netherlands. Food producing animals may have consumed the feed resulting in potentially contaminated food products, for example, eggs. Since some animals that ate the contaminated feed may have been rendered and the renderings added to feed shipped to other European countries, FDA is also detaining all animal-derived feed and feed ingredients as well as pet food from all European countries.

FDA is gathering information on food products that may be affected. Because this was a one-time incident with eggs being only one component of many in egg-containing products, FDA believes that the exposure of U.S. consumers to harmful levels of PCB's and dioxins is minimal. However, FDA is continuing its investigation and is sampling and analyzing products that have been imported since the incident in question. FDA is working with officials in Europe as the investigation progresses.

At this time, in order for products to be released from detention, importers must provide laboratory test results showing PCB's are not detectable and/or that dioxins do not

- MORE -

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exceed 1 part-per-trillion (ppt).

The United States Department of Agriculture is holding poultry and pork from all European Community member states because of the possibility that the livestock may have been fed the contaminated feed. USDA is initiating investigations and analyses of these products.

FDA will continue to provide updates to this information. For updated information, consult the FDA web site at [WWW.CFSAN.FDA.GOV](http://WWW.CFSAN.FDA.GOV), under the heading "What's New."

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