

Dioxin and PCB

Dioxins and polychlorinated byphenyls (PCBs) are groups of compounds that include chemicals that may be carcinogens at low levels of exposure over extended periods of time and may have other types of toxicological effects.

Since there are no tolerances or other administrative levels for dioxins in food or feed, the appearance of these compounds in a food or feed supply is of gravest concern. Tolerances for PCBs for feed and foodstuffs can be found in 21 CFR 109.30 and 509.30. FDA, in conjunction with the European Union and the USDA, is addressing both international and domestic dioxin and PCB concerns.

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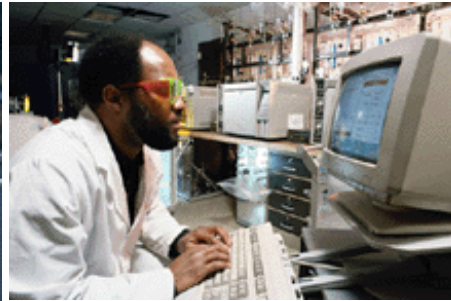
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 - NADA 141-017, Docket No. 01N-0170, CVM 200099. Abbott Laboratories' Sarafloxacin for Poultry; Withdrawal of Approval of NADAs. Pages 21400-21401 [FR Doc. 01-10067] April 30, 2001 | [htm](#) | | [pdf](#) |
 - Effect of the Use of Antimicrobials in Food-Producing Animals on Pathogen Load: Systematic Review of the Published Literature, October 2000 | [PathRpt.doc](#) | | [PathTables.xls](#) (Tables 1,2,3 and 4) | | [PathFigure.doc](#) |
 - Guidance for Industry #121: Expedited Review for New Animal Drug Applications for Human Pathogen Reduction Claims, March 6, 2001 | [doc](#) | | [pdf](#) |
 - Docket No. 00N-1571, CVM 11. Enrofloxacin for Poultry; Opportunity for Hearing; Correction. Pages 6623-6624 [FR Doc. 01-1866]. Written comments by **February 21, 2001** | [html](#) | | [pdf](#) |
 - An Approach for Establishing Thresholds in Association with the Use of Antimicrobial Drugs in Food-Producing Animals, December 19, 2000 | [doc](#) | | [pdf](#) |
 - [NOOH for Poultry Fluoroquinolones — Background Information](#)
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 - Notice of Opportunity for Hearing (NOOH) - Docket No. 00N-1571, CVM 76. Enrofloxacin for Poultry; Opportunity For Hearing. Pages 64954-64965 [FR Doc. 27832], Written comments by January 2, 2001 | [txt](#) | | [pdf](#) |
 - Risk Assessment - [Human Health Impact of Fluoroquinolone Resistant Campylobacter Associated with the Consumption of Chicken](#), dated October 18, 2000, Revised January 5, 2001
 - [Antibiotic Resistance in Livestock](#), USDA/HHS Response to the House and Senate Reports: Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, Appropriations Bill, 2000, September 14, 2000 (pdf)
 - [Draft Public Health Action Plan to Combat Antimicrobial Resistance](#), Centers for Disease Control and Prevention, June 2000
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 - [Draft Public Health Action Plan to Combat Antimicrobial Resistance](#) - HHS Response to House Report 106-157 - Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, Appropriations Bill, 2000, April 28, 2000
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 - [Transgenic Fish Developments: Are Transgenic Fish & Shellfish in Our Future?](#), presented at "Genetically Engineered Advances in Aquaculture: Reshaping America's Seafood Supply", San Francisco Seafood Show, November 4, 1999
 - [How Transgenics are Produced](#) - FDA Veterinarian - July/August 1999
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 - [Transgenic Fish Developments: Are Transgenic Catfish in Our Future?](#), presented at Catfish Farmers of America Annual Meeting, New Orleans, February 1999

- [Biotechnology: Putting Clones in Context](#) - FDA Veterinarian - March/April 1998
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CVM and International Dioxin Concerns

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".

CVM has extended the import ban to all European countries 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. FDA's position is discussed in a June 11, 1999, FDA Talk Paper: [All Egg And Egg-Containing Products From Belgium, France And The Netherlands And Animal Feed From European Countries To Be Detained At Ports Of Entry - June 11, 1999](#), and in another FDA Talk Paper on June 23, 1999, [All Milk And Milk-Containing Food Products From Belgium To Be Detained At Ports Of Entry](#).

In addition to detaining and screening products being presented for import, FDA is tracking and sampling products that may have already been imported during the January to June, 1999, time period. FDA has given this issue Top Priority. CVM and the Office of Regulatory Affairs have been assigned the task of collecting and analyzing animal feeds (medicated and non-medicated), feed ingredients, and pet foods to determine levels of polychlorinated biphenyl's (PCBs) and/or dioxins. In addition they are assigned the task of removing unsafe or violative products from consumer channels. For additional information, please see the "Assignment to Collect and Analyze Domestic-Import Samples Suspected of PCB and Dioxin Contamination". [\[html\]](#) [\[pdf\]](#)

On August 23, 1999, FDA issued a guidance representing the Agency's current thinking on possible dioxin/PCB contamination of animal source material in EU countries: Guidance for Industry: Possible Dioxin/PCB Contamination of Drug and Biological Products. | [html](#) | | [pdf](#) |

Links

[Belgian government](#)

[Center for Food Safety and Nutrition](#)

[European Commission press releases and decision](#)



CVM and Domestic U.S. Dioxin Concerns

In July 1997, FDA found contamination of animal feeds with dioxin, which resulted in elevated levels of dioxin in chickens, eggs and catfish. Dioxins are potent carcinogens with potential additional toxic and reproductive properties. There are no tolerances or other administrative levels for dioxin in food or feed. Dioxin contamination was found in animal feeds distributed to over 3,400 consignees throughout the country.

After lengthy investigation, the source of the dioxin contamination was traced to a mined clay product called "ball clay," which is used as an anti-caking agent in soybean meal, in other feed components, and in complete animal feeds. CVM worked cooperatively with the affected industries to halt any further distribution and use of the feed known to be contaminated with dioxin. This was carried out across the country. FDA is taking steps to ensure that ball clay will not be used in food products in the future.

In FY 1998, FDA initiated steps to determine whether other mined clay products and naturally derived anticaking agents were contaminated with dioxin, similar to the findings in ball clay. Industry associations met with CVM to determine the type of information needed, which resulted in a compilation of industry sampling of anticaking agents for dioxins. FDA, with analytical assistance from EPA, surveyed mined feed ingredients for the presence of dioxins, as a supplement to industry sampling.

The evidence gathered thus far (Spring of 2000) suggests that a primary route for dioxin contamination in food-producing animals can be through their diet and that the non-fodder components of the animal diet deserve additional scrutiny. CVM has issued an assignment to the Field to collect samples of various animal feed ingredients, which will be used to better characterize exposure of animals to dioxins.

Links

[Questions and Answers about Dioxins - July 2000](#) | [pdf](#) |

[Update on Dioxins and the Food Supply, July/August 2000](#) FDA Veterinarian Newsletter

[Letter from L. Tollefson, D.V.M., M.P.H., Director, Office of Surveillance and Compliance, Center for Veterinary Medicine, to Producers and Users of Clay Products in Animal Feeds, October 12, 1997](#)

FR Notice: Guidance for Industry: Dioxin in Anti-caking Agents Used in Animal Feed and Feed Ingredients; Availability
| [pdf](#) | | [txt](#) |

CVM Update: [Revised Guidance on Dioxin in Animal Feed Available, April 20, 2000](#)

[Preliminary National Survey of Dioxin-like Compounds in Animal Fats, Animal Meals, Oilseed Deodorizer Distillates, and Molasses - May 22, 2000](#)

FDA Talk Papers

[Catfish Cleared For Processing and Shipping, July 25, 1997](#)

[Revised Sampling and Testing Program For Catfish, July 16, 1997](#)

[FDA Stops Distribution Of Some Eggs And Catfish Because Of Dioxin-Contaminated Animal Feed, July 7, 1997](#)

Guidance Document

#98. Guidance for Industry: Dioxin in Anti-Caking Agents Used in Animal Feed and Feed Ingredients
(Revised 04/14/2000)
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