

USFDA FOOD MONITORING AND EXPOSURE REDUCTION EFFORTS FOR DIOXINS.

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Introduction

Dioxins are ubiquitous environmental contaminants whose primary route of human exposure occurs via the consumption of fatty foods of animal origin. Recent safety/risk assessments conducted by national and international organizations broadly agree that risk management actions should be developed to decrease exposure. Since the mid-1980s, the US Food and Drug Administration (FDA) has tested specific foods for dioxins with the goal of describing and reducing exposures. Leveraging external resources, FDA has collaborated with US Department of Agriculture's Food Safety Inspection Service and the US Environmental Protection Agency to coordinate research and develop strategies for monitoring and follow-up investigations.

Discussion

Because dioxin analysis is costly and time consuming, available data on background levels in most foods and feeds are limited. In fact, for many foods and most feeds, there are no data. Consequently it is difficult to determine where and how dioxin levels in foods and feeds can be further reduced. Recently, FDA expanded its monitoring program to obtain more comprehensive data on concentrations and "congener fingerprints" of background levels in specific foods as well as to find and reduce pathways of dioxin contamination from environmental sources to food. In 1995, 1996, and 1998 a total of 507 targeted samples of finfish, shellfish and dairy samples were sampled and analyzed by FDA. In 2001 alone over 600 analyses of samples of finfish, shellfish, and vegetable oils were analyzed. The dioxin monitoring program for 2001 consisted of over 400 targeted samples of finfish, shellfish, and vegetable oil, with over 200 Total Diet Study (TDS) composite samples of the table-ready foods most commonly eaten by the US public. For FY 2002 and future years the goal is a similar level of TDS sampling, supplemented by approximately 1000 targeted samples including seafood, feed components, and milk.

FDA employs three methods to identify and quantify 2,3,7,8- substituted PCDDs and PCDFs in foods. The first method is high resolution mass spectroscopy (HRMS), which is the preferred method for high consumption-rate foods with very low or no expected dioxin levels. HRMS is also the preferred method for the TDS samples, given that TDS will be used as the core data for estimating exposure and the level of detection will influence these estimates. The second method is ion trap mass spectroscopy (ITMS), which is the preferred method for lower consumption-rate foods with higher expected dioxin levels. HRMS is also used for duplicate analyses of 10% of all ITMS analyses for quality assurance and calibration of evaluations that include data from both ITMS and HRMS. The third method is the CALUX method, which USFDA currently uses to screen samples during source or pathway investigations requiring rapid evaluation of multiple variables. Subsequent evaluation of samples ranking high with the CALUX analyses is accomplished using either ITMS or HRMS.

Both ITMS and HRMS provide congener-specific estimates of concentration. ITMS method detection levels (MDLs) are often 3 to 10 fold higher (but vary between 2 fold lower and 30 fold

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higher) than HRMS MDLs depending on the congener and/or given food. ITMS uses less expensive and more easily maintained equipment, resulting in a lower per sample cost and a higher total sample throughput compared to HRMS (both on a per dollar and per unit of time basis). The intended result of FDA's multiple method strategy is greater and more rapid sampling coverage with maximization of congener-specific quantification to facilitate investigation of dioxin pathways to food. The tradeoff in uncertainty reduction between sample MDLs for the analytical methods used and sample size will be evaluated as the program proceeds, and as our knowledge of dioxin/furan levels improves.

Because dioxins are widespread in the environment it is not possible within the current state of knowledge to eliminate them entirely from food and feed. The immediate goal of the Dioxin Monitoring Program is therefore to obtain profiles of background levels in a wide variety of foods and feeds. Samples collected under FDA's Dioxin Monitoring Program will be evaluated for their dioxin content relative to historic levels, and the upper 10% further evaluated for similar congener patterns or food production practices that indicate a source for the contamination. Investigations will be undertaken and research initiated to identify further steps that may be taken to reduce or eliminate dioxin sources.

Measures of success for the program will include

1. Identifying foods and feeds with unusually high levels of dioxins. Currently, it is difficult to determine which levels are unusually high in foods and feeds because we do not have enough information to say what is "usual."
 - Trace-back investigations of unusually high levels in foods and feeds to determine if the source of contamination can be reduced or eliminated.
 - Evaluation of unusually high levels in food or feed to determine if they pose a health hazard and warrant taking enforcement actions (e.g., seizure of domestic products or refusal of entry for imports)
3. Improved assessments of human exposure to dioxins that enhance our ability to identify and protect susceptible populations. Exposure assessments can be improved by providing better information about
 - Exposure trends over time.
 - Dioxin levels in foods that provide a significant portion of the total human exposure to dioxins.
 - Exposure variations based on geographic region.
 - Exposure variations based on type of diet.