

U.S. FOOD AND DRUG ADMINISTRATION ASSESSMENT OF UPPER BOUND
LIFETIME RISK FROM VARIOUS PRODUCTS CONTAMINATED WITH
DIOXINS FROM PAPER MILL EFFLUENT OR FROM CONTACT WITH
BLEACHED PAPER PRODUCTS

Henry, S., Bolger, M., Cramer, G., Lorentzen, R., Scheuplein, R., Springer, J.,
Kuznesof, P., Lewis, C., and Schwartz, P.

*Center for Food Safety and Applied Nutrition, Food and Drug Administration,
Washington, D.C., USA.*

ABSTRACT

As part of the U.S. government's effort to assess exposure to dioxins to persons consuming fish caught in the vicinity of pulp mills and to persons consuming food contacting bleached paper, the U.S. Food and Drug Administration has evaluated the associated risks and have concluded that these risks range from 10^{-4} to 10^{-6} .

INTRODUCTION

Studies carried out by the paper industry and the U.S. Environmental Protection Agency (EPA) in 1987-1988 confirmed the presence of trace amounts of dioxins and furans in bleached pulp and in bleached paper used for food packaging, as well as for personal care and other products. In 1988, U.S. EPA entered into a legal agreement with the Environmental Defense Fund and the National Wildlife Federation in which EPA agreed to support a decision on the need for regulation of the pulp and paper industry by April 30, 1990, and to prepare a plan for implementing such regulations. As part of this effort, a number of risk assessments were performed.

In addition, a 1988 preliminary Canadian survey of milk packaged in bleached draft polyethylene-coated paper cartons indicated that dioxin transfer to milk could occur. In response to this discovery, the paper industry initiated studies to determine the migration of dioxin from various paper packaging materials into food. Additionally, in 1989 FDA collected and analyzed samples of homogenized whole milk packaged in bleached kraft polyethylene-coated paper cartons for dioxins and furans. Based on the FDA findings, the agency performed a quantitative risk assessment for cancer risk to consumers of milk contaminated with these contaminants.

RISK ASSESSMENT FOR CANCER AND NON-CANCER ENDPOINTS

FDA has used a level of 0.064 pg/kg bw/day of 2,3,7,8-TCDD as the level which will result in at most a lifetime risk of 10^{-4} of cancer. This level is based on a linear-at-low-dose extrapolation from the Kociba bioassay (1). 2,3,7,8-TCDD has been shown to produce toxicological effects other than cancer, primarily in animal models. An acceptable daily intake (ADI) of 1-10 pg/kg bw/day can be derived for the most sensitive non-cancer endpoint of 2,3,7,8-TCDD, namely reproductive toxicity.

RISKS TO SUBSISTENCE AND SPORTS FISHERMEN FROM CONSUMPTION OF FISH CONTAMINATED WITH DIOXINS CAUGHT NEAR PULP MILLS

Data on levels of dioxin and furan congeners in fish were obtained from the EPA National Bioaccumulation Study. The levels were reported as toxic equivalents (TEQ) of 2,3,7,8-dioxin. (2) Levels of dioxin TEQs found in fish fillets and used for calculations were 6.5 ppt TEQ (weighted mean level) and 20 ppt (highest reported level).

The commonly available nationally representative food consumption surveys contain very few persons who are representative of the at-risk subgroups. In order to estimate intake of fish among subsistence fishermen and their families, a "common sense" scenario was derived by assuming that fish intake among this group is equal to the consumption of red meat among the general U.S. population. Mean red meat consumption for all age groups in a survey commonly used by the agency (1977-78 Menu Census, Market Research Corporation of America) was reported to be 69 g/person/day (mean consumption) and the 90th percentile as 116 g/person/day. These numbers were selected as estimates of chronic fish consumption.

Fish consumption by sports fishermen is likely to be quite variable. The agency used data from the U.S. Department of Agriculture's 1977-78 National Food

Consumption Survey (3-day basis) and the U.S. Department of the Interior 1985 survey of sports fishermen (3). Mean consumption of fish by sports fishermen was estimated to be 13 g/person/day with the 90th percentile estimate 3 times this value or 39 g/person/day.

Using these consumption estimates for sports fishermen and subsistence fishermen, and the previously discussed levels of dioxin TEQs and potency value for TCDD, FDA has estimated upper bound lifetime risks for subsistence fishermen to range from 1×10^4 to 6×10^4 , and for sports fishermen to range from 2×10^4 to 7×10^4 .

RISKS TO PERSONS CONSUMING MILK AND FOODS PACKAGED IN BLEACHED PAPERBOARD CARTONS CONTAMINATED WITH DIOXINS

Levels of dioxins and furans in milk packaged in bleached kraft polyethylene-coated paper cartons were obtained from a limited FDA survey performed in 1989. The mean value found was 0.035 dioxin TEQ. Milk consumption was estimated using data from the U.S. Department of Agriculture 1977-78 Nationwide Food Consumption Survey (3-day basis).

Mean milk consumers were estimated to consume 8.1 g/kg bw/day, while 90th percentile milk consumers were estimated to consume 18.6 g/kg/bw/day. Upper bound lifetime risks, using the previously reported potency estimate, were estimated to range from 4.5×10^6 for the mean consumer to 10.4×10^6 for the 90th percentile consumer of milk. Since this risk assessment was performed, process changes by the paper industry have reduced milk dioxin TEQ levels coming from the carton to no more than 5 ppq, which lowers the upper bound lifetime risks to 2×10^7 and 5×10^7 for the mean and 90th percentile milk consumer, respectively.

Estimates of exposure to dioxin of consumers of other foods packaged in bleached paper have been discussed in an earlier paper in this symposium. Risks to these consumers range from about 3×10^4 to 5×10^6 .

In these risk calculations, conservative assumptions have been made, especially where available data were limited. The linear-at-low-dose method used by the agency to extrapolate from laboratory animal data allows an estimate of the upper bound lifetime risk to humans and may overstate the potency of dioxin. Both fish and milk TEQ levels were based on the analysis of relatively few samples, with assumptions of TEQ levels made where no dioxin or furans were detected. Data on which to base estimates of consumption of fish by subsistence and sports fishermen were sparse. In the milk and other foods risk assessments, all milk and food were assumed to contact paper and paperboard prior to consumption. The agency believes that these risk assessments may overstate the risk from dioxins and furans, but that an upper bound on the true risk has been generated.

REFERENCES

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