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Integrated Risk Assessment for Dioxins and Furans from Chlorine Bleaching in Pulp and Paper Mills

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EXECUTIVE SUMMARY

Introduction

This report presents the key findings, assumptions, and uncertainties of an assessment of risks from exposure of humans, terrestrial and avian wildlife, and aquatic life to dioxins and furans formed during chlorine bleaching at kraft and sulfite pulp and paper mills. The report provides condensed versions of eight major exposure/risk assessments and other support documents prepared by program offices within the U.S. Environmental Protection Agency (EPA), the U.S. Food and Drug Administration (FDA), and the U.S. Consumer Product Safety Commission (CPSC). Risks were evaluated from roughly 120 potential pathways of exposure to pulp and paper products, pulp and paper mill sludges, and pulp and paper mill effluents. The development of this assessment and the individual Agency exposure/risk assessments were coordinated by the Federal Interagency Working Group on Dioxin-in-Paper. The Background Document to this Integrated Assessment contains detailed summaries of the individual exposure/risk assessments.

Scope of Assessment

Because 2,3,7,8-TCDD is the most potent carcinogen evaluated to date by EPA, a major focus of the Integrated Assessment is the assessment of cancer risks. All of the major source documents prepared for the Integrated Assessment estimated individual lifetime cancer risks. Some, but not all, of the source assessments also estimated exposed population sizes and resulting population risks and subpopulation risks. Population risks were calculated in the following source reports:

- Worker exposure/risk;
- Risks from use and disposal of sludge;
- Risks from incineration of sludge; and
- Risks from use of consumer body contact papers.

Population risks were not estimated in the following source reports:

- Risks from discharge of effluents;
- Risks from use of medical devices;
- Risks from use of food paper packaging and cellulose food additives; and
- Risks from use of cellulose additives in cosmetic products.

However, estimates of sizes of potentially exposed populations were provided in the medical devices report, and comparison of the predicted risks with the estimated population sizes indicates minimal population risks (less than 0.005 cancer incidence/year for any product). Although FDA did not estimate exposed population sizes, it can be presumed that tens of millions or more people are exposed to the risks estimated for food paper packaging/cellulose food additives and cellulose additives in cosmetic products. Neither EPA nor FDA have reliable estimates of the size of potentially exposed subsistence and sports fisher populations that may be exposed to effluent discharges from pulp and paper mills. EPA has contacted regional and state officials and has confirmed that commercial, sport, and subsistence fishing does occur downstream from several mills. However, scant information is available on sizes or characteristics of these populations. Because information is lacking on potentially exposed populations eating contaminated fish near the mills, EPA has initiated a program to develop a uniform methodology to estimate these populations at elevated risk.

Human risks of non-cancer effects resulting from long-term, low-level exposures and relatively brief exposures to media such as contaminated fish were also examined.

<u>Results and Discussion</u>

Table E-1 presents a listing of all exposure scenarios addressed in the Integrated Assessment for which the estimated reasonable worst-case individual cancer risks exceeded 10^{-6} based on EPA's slope factor. The range of risks presented in Table E-1 for any given exposure pathway span at least an order of magnitude because the range reflects, in part, the differences in cancer slope factors used by EPA, FDA, and CPSC for 2,3,7,8-TCDD. Although the agencies' differences with respect to selection of animal data and details of extrapolation of animal data to humans result in risk estimates that differ by nearly an order of magnitude, the agencies agreed that this Integrated Assessment would report cancer risk estimates calculated using each agency's slope factor.

For some exposure pathways in Table E-1, the range of risks spans more than an order of magnitude. The source(s) of this additional variability is discussed below for each pathway where appropriate.

The results in Table E-1 indicate that the following types of individuals may be at significant risk:

- <u>Sport and subsistence fishers</u> - 2,3,7,8-TCDD and 2,3,7,8-TCDF have been positively identified in fish collected downstream from many pulp and paper mills. Although not yet well characterized, sports and subsistence fishers are known to be using some of these waters. State agencies have issued public health advisories warning against any consumption of fish or recommending limited consumption for many of these water bodies. For this risk

Table E-1. Summary of Reasonable Worst-Case Individual Cancer Risks Exceeding 10^{-6}

Source	Pathway	Exposed Individuals	Upper bound individual lifetime cancer risk ($\geq 10^{-1}$, 10^{-2}, 10^{-3}, 10^{-4}, 10^{-5}, 10^{-6}, $\leq 10^{-7}$)
Effluent discharge	Ingestion of fish[a] (EPA site-specific)	Average	10^{-2} – 10^{-7}
		Sports fishers	10^{-1} – 10^{-7}
		Subsistence fishers	10^{-1} – 10^{-6}
	Ingestion of fish[b] (FDA generic)	Sports fishers	10^{-3} – 10^{-5}
		Subsistence fishers	10^{-3} – 10^{-4}
	Ingestion of water	Individuals near mills	10^{-4} – 10^{-7}
Sludge disposal (occupational)	Dermal contact w/sludge or sludge-amended soil	Pulp mill WWT workers	10^{-4} – 10^{-6}
		Land disposal workers	10^{-5} – 10^{-6}
	Inhalation of particulates	Land disposal workers	10^{-4} – 10^{-6}
	Inhalation of vapors	Land disposal workers	10^{-5} – 10^{-6}
Sludge disposal (ambient)	Dermal contact w/sludge-amended soil	Gardeners/subsistence farmers	10^{-4} – 10^{-6}
	Ingestion of sludge-amended soil	Gardeners/subsistence farmers	10^{-4} – 10^{-6}
	Ingestion of food produced on sludge-amended soil	Gardeners/subsistence farmers	10^{-2} – 10^{-3}
	Inhalation of particulates	Individuals near land application sites	10^{-5} – 10^{-6}
	Inhalation of vapors	Individuals near land application sites	10^{-4} – 10^{-5}
	Ingestion of fish contaminated by runoff from land disposal and land application sites	Individuals near land disposal and land application sites	10^{-1} – 10^{-3}
	Ingestion of water contaminated by runoff from land disposal and land application sites	Individuals near land disposal and land application sites	10^{-4} – 10^{-5}
Pulp/paper manuf. (occupational)	Inhalation of particulates	Paper mill workers	10^{-3} – 10^{-5}
		Paper converting workers	10^{-3} – 10^{-4}
		Nonwoven operations workers	10^{-5} – 10^{-6}

Table E-1. (continued)

Source	Pathway	Exposed Individuals	Upper bound individual lifetime cancer risk ($\geq 10^{-1}$, 10^{-2}, 10^{-3}, 10^{-4}, 10^{-5}, 10^{-6}, $\leq 10^{-7}$)
	Dermal contact w/ pulp/paper	Pulp mill workers	10^{-5} – 10^{-6}
		Paper mill workers	10^{-6} – $\leq 10^{-7}$
		Paper converting workers	10^{-6} – $\leq 10^{-7}$
Paper food-contact (general pop.)	Ingestion of food	Users of paper cartons:	
		Milk	10^{-6} – $\leq 10^{-7}$
		Juice	10^{-6} – $\leq 10^{-7}$
		Ice cream	10^{-5} – 10^{-6}
		Bakery	10^{-6} – $\leq 10^{-7}$
		Users of ovenable board:	
		Meals-seas. meat, veg.	10^{-5} – 10^{-6}
		Users of cup stock:	
		Coffee	10^{-6} – $\leq 10^{-7}$
		Soup	10^{-5} – 10^{-6}
		Users of plates	10^{-5} – 10^{-6}
		Users of coffee filters	10^{-6} – $\leq 10^{-7}$
		Users of tea bags	10^{-6} – $\leq 10^{-7}$
		Users of microwave popcorn	10^{-6} – $\leq 10^{-7}$
		Users of butter wraps	10^{-6} – $\leq 10^{-7}$
Cellulose food additives	Ingestion of food	Users of "all foods"	10^{-6} – $\leq 10^{-7}$
		Users of high-fiber bread	10^{-6} – $\leq 10^{-7}$
		Users of tablet binders	10^{-6} – $\leq 10^{-7}$
		Users of laxatives	10^{-6} – $\leq 10^{-7}$

[a] As discussed on pages xiii and xvi, EPA performed site-specific modeling assessments for each mill in the 104-Mill Study that discharges to receiving streams for which flow data were available. The wide range of estimated risks for each of the types of consumers reflects the range in risks estimated across the sites. Variability between the risks for these types of consumers is the result of different bioconcentration factors and fish consumption rates that were assumed.

[b] As discussed on pages xiii and xvi, FDA used monitoring data levels of 2,3,7,8-TCDD and 2,3,7,8-TCDF in the edible portion of fish collected near pulp and paper mills to assess potential risks. The variability between the risks for these two types of consumers is the result of different fish consumption rates that were assumed.

assessment, two general approaches were used to estimate potential individual cancer risks: surface water modeling (EPA) and fish tissue monitoring data (FDA). Results are presented in Table E-1 for both approaches; risks for several types of consumers (i.e., average, sports fishers, and subsistence fishers) were estimated to reflect the range of uptake of 2,3,7,8-TCDD and 2,3,7,8-TCDF by fish and the range of possible fish consumption rates. The wide range in risks estimated using the effluent modeling approach, $\geq 10^{-1}$ to 10^{-7}, reflects differences in effluent concentrations of 2,3,7,8-TCDD and 2,3,7,8-TCDF, effluent flows, and receiving stream flows at sites that were modeled. The use by FDA of available monitoring data on residues of dioxin TEQs in the edible tissues of fish collected near pulp and paper mills (mean and maximum values across all sites) results in estimates of risks ranging from 10^{-3} to 10^{-5}, using all three slope factors.

- Persons obtaining drinking water immediately downstream from pulp and paper mills - This exposure scenario assumes that individuals are actually drinking untreated water immediately downstream from these mills. However, data to document this assumption are currently not available. A preliminary survey of EPA drinking water data bases indicates that there are no major public drinking water utilities (i.e., serving 5,000 or more people) immediately downstream from any mill but that there are some within 100 miles of some of the 104 pulp and paper mills. The wide range in risks estimated in this assessment, 10^{-4} to $\leq 10^{-7}$, reflects differences in effluent concentrations of 2,3,7,8-TCDD and 2,3,7,8-TCDF, effluent flows, and receiving stream flows at sites that were modeled. It should be noted that this assessment assumed, as a worst case, that all 2,3,7,8-TCDD/TCDF discharged remains in the water column and is not removed during drinking water treatment.

- Workers who handle sludge - The results in Table E-1 indicate that workers in pulp and paper mill wastewater treatment plants involved in sludge handling, as well as workers involved in subsequent disposal of sludge via land disposal, could be at risks ranging from 10^{-4} to 10^{-6} if the sludge contains dioxin toxic equivalents (TEQs) at the maximum concentration found in the 104-Mill Study. It should be noted that the extent of use and effectiveness of personal protective equipment and engineering controls in this industry are not well known. Therefore, the assessment assumed no use of protective equipment (e.g., gloves and respirators) that could minimize potential exposures. Similarly, the frequency and duration of potential dermal and inhalation exposures were not well characterized. Reasonable worst-case assumptions were used for these parameters in the assessment.

- Gardeners/subsistence farmers using sludge-amended soil - These individuals could be at risks ranging from 10^{-4} to 10^{-6} from inhalation, dermal contact, and direct soil ingestion if the sludge contains 469 ppt of dioxin TEQs (i.e., the 90th percentile TEQ concentration from the 104-Mill Study). Subsistence farmers relying to a major extent upon meat, produce, and dairy products produced on sludge-amended soil could be at risks ranging from 10^{-2} to 10^{-3}.

- Persons obtaining drinking water and ingesting fish from water bodies downstream from pulp and paper mill sludge land disposal and land application sites - Runoff from land application sites and from poorly managed land disposal sites into small water bodies could result in risks ranging from $\geq 10^{-1}$ to 10^{-3} to consumers of fish and water from those water bodies if the sludge contains 469 ppt of dioxin TEQs (i.e., 90th percentile TEQ concentration from the 104-Mill Study). However, no data are currently available to EPA to establish that poor sludge management practices are followed at any specific land disposal sites.

- Pulp and paper manufacturing workers - Depending upon the nature of their work duties, certain workers could be at risks as low as 10^{-5} from dermal contact with pulp/paper and as low as 10^{-3} from inhalation of particulate matter. As was the case for assessing risks to workers who handle sludge (above), this assessment assumed no use of personal protective equipment.

- Consumers of food packaged in or contacting bleached paper - Millions of people could be at risks as high as 10^{-5} from the migration of dioxin from paper packaging into food during storage or food preparation activities if the paper contains dioxin TEQs at the average level found in the 104-Mill Study.

- Consumers of food and drug products containing cellulose derivatives - Millions of people could be at risks as high as 10^{-6}, if the cellulose derivatives contain dioxin TEQs at the average level found in the 104-Mill Study.

Although specific population sizes were not estimated for the types of individuals listed above, it can reasonably be assumed that more than 1 cancer incidence per year could be expected for several of these types of individuals. Populations exposed to effluent discharge could exceed one cancer case per year by virtue of the very high individual risks. Populations exposed to food packaging and cellulose derivatives exceed one cancer case per year because of the large numbers of individuals exposed (tens of millions).

Estimation of risks of non-cancer effects indicated that effluent discharges from 27 percent of mills could cause toxic liver effects with one 4-ounce serving of fish caught immediately downstream from the mills, based on a 1-day health advisory dose of 100 pg/kg/day and assuming an effective BCF of 50,000 for edible tissues; even more mills discharged effluents that may cause reproductive effects from long-term, low-level exposure, based on a reference dose of 1 pg/kg/day. Similarly, an FDA analysis indicated that subsistence fishers could be at risk for reproductive effects.

Summary of Estimated Risks to Aquatic Organisms and Terrestrial Wildlife

Risks to Aquatic Organisms

It was assumed for the purpose of this assessment that concentrations of 2,3,7,8-TCDD in water greater than 0.038 pg/l will exhibit toxic effects to some aquatic species. Applying the same approach to 2,3,7,8-TCDF, a concentration greater than 0.41 pg/l was assumed to exhibit toxic effects for some aquatic species. Water column concentrations of 2,3,7,8-TCDD immediately downstream from 89 percent of the mills evaluated were estimated to exceed 0.038 pg/l under low stream flow (7Q10) conditions. Water column concentrations of 2,3,7,8-TCDF immediately downstream from 82 percent of these mills were estimated to exceed 0.41 pg/l under 7Q10 conditions.

Risks to Terrestrial Wildlife

This assessment did not attempt to quantify the effects of 2,3,7,8-TCDD and 2,3,7,8-TCDF on populations or ecosystems. However, the results of the assessment show that at certain sites where sludge is land applied, the reproductive capability of individuals of certain terrestrial species may be affected, assuming that wild species are at least as sensitive to the effects of 2,3,7,8-TCDD and 2,3,7,8-TCDF as laboratory species. Species that ingest prey items such as earthworms (which bioconcentrate dioxins) are particularly at risk. Effects on the reproductive capability of a sufficient number of individual members of a species may lead to overall population effects for that species in that area, but no assessment of population effects was performed.

Potential for Aggregate Risk

In general, this assessment focused on estimating risks for single exposure pathways. It must be noted, however, that some individuals or subpopulations can be exposed from more than one source of dioxins and furans originating from bleached kraft pulp and paper mills. Under such circumstances, the risks estimated would be summed and those individuals or subpopulations would be at higher risk than other individuals or subpopulations. The potential for aggregate risks to be of greatest concern exists for those individuals or specific subpopulations that

(1) live in the vicinity of and/or work at bleached kraft pulp and paper mills; (2) live or work in areas where pulp and paper mill sludge is land-applied; and (3) consume unusually large amounts of several different foods contaminated with dioxins and furans as a result of contact with or packaging of food in bleached paper.

Uncertainties and Conclusions

The Integrated Assessment identified the following risks of concern:

- Risks to humans from food packaging;
- Risks to terrestrial and avian organisms from land-spreading of pulp and paper mill sludge;
- Risks to humans and aquatic organisms from effluent; and
- Risks to humans and wildlife from land-applied pulp and paper mill sludge runoff.

The assessment also identified the following risks of possible concern:

- Risks to workers who handle pulp and paper mill sludge, and
- Risks to subsistence farmers from land-applied pulp and paper mill sludge.

As in other assessments of risk, this assessment contains uncertainties connected with the establishment of the health hazards and with the development of exposure scenarios. For example, it is recognized that there are legitimate differences of opinion within the international scientific community regarding the quantification of the cancer risk to humans from dioxins/furans. This is an area of continuing research and reappraisal. Future epidemiological and pharmacokinetic studies will hopefully answer the major question of the extent of CDD/CDF toxicity to humans. Since CDDs/CDFs are known to readily bioconcentrate in tissues of animals and humans and to have a long half-life in the body (7-10 years), it appears reasonable to use a conservative approach in considering the potential health risks of these chemicals.

Since EPA, FDA, and CPSC use a linear low-dose model for cancer risk estimation, it should be emphasized that the individual cancer risk is expressed as an upper bound limit, meaning that the risk will not likely be higher than the upper bound, but could be as low as zero.

Many uncertainties appear within the risk assessment concerning the various exposure estimates. However, the risks of concern listed above are of concern not only because the individual calculated risks are high and/or they may affect considerable numbers of individuals, but also because they are based on sufficient empirical data and established modeling techniques. The identified risks of possible concern have more data gaps and are therefore of lesser certainty. The exposure modeling for consumer products other than food/paper contact items estimated levels of exposure yielding low individual risks. These exposure estimates also contain various uncertainties; it is not felt, however, that the degree of uncertainty is great enough to convert these low risks to high risks.

Most noteable of the areas where there are data gaps is the nearly total lack of actual sampling data on stack emissions of CDDs/CDFs from the incineration of pulp and paper mill sludge. Only one actual measured stack gas level of CDDs/CDFs was available for use in the incineration exposure estimate. Although estimated airborne emissions and risks appear low (using modeling and the very limited stack monitoring data), incineration may become a more frequently used method of pulp and paper sludge disposal.

There is also a lack of monitoring data on employee exposure to CDDs/CDFs under actual working conditions. The occupational exposure assessment estimates were made using surrogate data from a study of particulate exposures, but with no actual CDD/CDF exposure data. Similarly, only very limited site-specific data on industrial sludge land disposal practices, locations, and associated exposed populations are available to identify actual risks from land application of pulp and paper sludge. Many of the individual risks calculated from modeled exposures were quite high; without site-specific data, however, these exposure scenarios remain hypothetical.

Data on marketing and consumer use of many of the new paper-packaged and microwaveable food items is also very limited. In addition, available information is not adequate to enable an assessment of risks to infants who do not consume packaged foods at all, but rather consume CDD/CDF-contaminated mother's milk. (Studies indicate infants are 10 times more sensitive than adults to deleterious effects of CDD/CDF; further, studies of monkeys indicate that breast milk accumulates about three times the CDD/CDF concentrations of fat tissue (Bowman et al. 1989).)

This assessment was begun as a specific response by the Agency to its discovery that chlorine bleaching of wood pulp can result in dioxin contamination of pulp and paper, wastewater effluent, and wastewater treatment sludges. The narrow focus is not meant to imply that the bleached pulp and paper industry is the only or even the major source of CDDs/CDFs in the U.S. Other known sources of CDDs/CDFs include chemical synthesis of chlorophenol products and derivatives, and stationary combustion sources such as municipal waste combustors, electrical equipment fires, and automobiles.

The risk assessment is also not a complete assessment of the health risks due to chemical contamination from the bleached pulp and paper industry. Chlorination of wood pulp produces numerous toxic compounds. Although the only requirement of the consent decree was to investigate CDDs/CDFs, EPA is aware that many other chlorinated organic compounds (OCOs) are produced during pulp bleaching and processing operations. These include chlorinated phenolic compounds, chlorinated guaiacols, chlorinated catechols, chloroform, and hundreds of others. Further, these other chemicals can be released to the environment in large quantities. For example, a search of the 1987 Toxic Release Inventory (TRI) data base indicated that 68 of the facilities in the 104-Mill Study reported environmental releases of chloroform. For some facilities, the releases were considerable, especially releases to air (as high as 1,700,000 lb/yr from just one site). Even though other compounds may be present at relatively low concentrations in pulp and paper mill effluents, sludges, and pulps, the cumulative effect of CDDs/CDFs and OCOs on exposed populations could be significant. Screening-level analyses of OCOs in pulp mill effluents have been performed, although similar analyses for the industrial sludge and pulp mass streams have not. EPA's current effluent information, along with its understanding of the toxicological aspects of these compounds, is presently insufficient to support risk assessments on human and wildlife exposures to OCOs. Although this risk assessment does not address risks associated with these other chlorinated organics, the Office of Water will be considering many of them in its effluent limitations guidelines and standards revision.

1. INTRODUCTION

1.1 Purpose

The purpose of this report is to present the key findings, assumptions, and uncertainties of an assessment of risks from exposure of humans, terrestrial and avian wildlife, and aquatic life to dioxins and furans formed during chlorine bleaching at kraft and sulfite pulp and paper mills. This report contains condensed versions of eight major exposure/risk assessments and other support documents prepared by program offices within the U.S. Environmental Protection Agency (EPA), the U.S. Food and Drug Administration (FDA), and the U.S. Consumer Product Safety Commission (CPSC). Risks were evaluated from roughly 120 potential pathways of exposure to pulp and paper products, pulp and paper mill sludges, and pulp and paper mill effluents. The development of this assessment and the individual Agency exposure/risk assessments was coordinated by the Federal Interagency Working Group on Dioxin-in-Paper. The Background Document to this Integrated Assessment contains detailed summaries of the individual exposure/risk assessments.

1.2 Background

1.2.1 Nature of the Problem

The term "dioxin" commonly refers to a family of 210 structurally related chlorinated aromatic compounds known as chlorinated dibenzo-p-dioxins (CDDs) and chlorinated dibenzofurans (CDFs). The most toxic member of this family is 2,3,7,8-tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD). During the past 20 years, many studies have been performed to determine the toxic effects of 2,3,7,8-TCDD. While data generated from these studies have not answered all questions regarding the toxicity of 2,3,7,8-TCDD, the data do show that 2,3,7,8-TCDD can produce a variety of toxic effects, including cancer and reproductive effects in laboratory animals at very low doses (USEPA 1989a). While some reports in the literature suggest that the chemical can produce similar effects in humans, more definitive information should be forthcoming from epidemiological studies currently in progress (USEPA 1989a).

Based on the results of animal studies, EPA has classified 2,3,7,8-TCDD as a "B2" (or probable) human carcinogen with a plausible upper bound slope factor, q_1^*, of 1.6×10^{-4} $(pg/kg\text{-}d)^{-1}$, by far the most potent carcinogen evaluated to date by the Agency (USEPA 1989a). This chemical is also the most potent reproductive toxin yet evaluated by EPA (USEPA 1989a). The closely related compound 2,3,7,8-tetrachlorodibenzofuran (2,3,7,8-TCDF) is assumed by EPA (through use of the dioxin Toxicity Equivalency Factor (TEF) method adopted by the Agency in 1987) to be one-tenth as potent as 2,3,7,8-TCDD.

Recent studies (USEPA 1988, 1989b) have confirmed earlier reports that both of these compounds can be formed when chlorine is used as a bleaching agent for brightening and purifying wood pulp. These studies indicate that the 2,3,7,8-TCDD and 2,3,7,8-TCDF formed can contaminate the wastewater discharged from bleached kraft and sulfite pulp and paper mills, the wastewater sludge generated at these mills, and the pulp and paper products produced at these mills.

1.2.2 Discovery of the Problem

Theories about the formation of 2,3,7,8-TCDD and its presence in various media have generated many studies. One landmark study was EPA's National Dioxin Study, begun in 1983 and published in August 1987. This was a nationwide, multimedia evaluation initiated at the request of Congress in House Report 98-223. The study was requested in response to growing public concern over the high toxicity and persistence of 2,3,7,8-TCDD and the numerous incidents of dioxin contamination and exposure in the United States and abroad.

Results of the National Dioxin Study (USEPA 1987) indicated the presence of 2,3,7,8-TCDD in fish and river sediment samples collected downstream from some bleached kraft pulp and paper mills located in the United States. In addition, 2,3,7,8-TCDD and other polychlorinated dibenzodioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) were detected in wastewater sludges from bleached kraft pulp and paper mills. These findings prompted the EPA, the American Paper Institute (API), and the National Council of the Paper Industry for Air and Stream Improvement (NCASI) to enter into an agreement, dated June 20, 1986, to jointly perform the "USEPA/Paper Industry Cooperative Dioxin Screening Study" (USEPA 1988) at five bleached kraft pulp and paper mills. The results of this cooperative study, commonly referred to as the "5-Mill Study," indicated that dioxins were present in the treated effluent at three of the five mills, in wastewater treatment sludges of all five mills, and in bleached pulps at four of the mills. The principal PCDDs and PCDFs found at the mills were 2,3,7,8,-TCDD and 2,3,7,8-TCDF. Results of the 5-Mill Study indicated that 2,3,7,8-TCDD and 2,3,7,8-TCDF were formed during the bleaching of kraft pulps with chlorine and chlorine derivatives.

Another study, performed by Arthur D. Little, Inc. (ADL 1987) under contract to the EPA Office of Water (OW), was initiated to determine whether CDD contamination of paper products had the potential for significant risk to consumers. This scoping study (made available as a draft report in 1987), though based almost entirely upon hypothetical assumptions, demonstrated the possibility that risks from CDD-contaminated food- and body-contact papers could be of concern.

1.2.3 Federal Response

To coordinate the federal government's response to the findings of the three studies, an interagency workgroup was formed in 1987 among the Food and Drug Administration (FDA), the Consumer Product Safety Commission (CPSC), and various program offices within EPA including the Office of Toxic Substances (OTS), the Office of Solid Waste (OSW), the Office of Research and Development (ORD), the Office of Air Quality Planning and Standards (OAQPS), and the Office of Water (OW). The National Institute of Occupational Safety and Health (NIOSH) joined later.

The mission of the interagency workgroup was to conduct a coordinated assessment of the problem of CDDs/CDFs in bleached wood pulp, and, as appropriate, to provide the vehicle for a coordinated agency response. Analytical responsibilities were divided among the agencies/offices and were split into three broad "tiers." Tier one is the determination of CDD/CDF levels in pulp, effluent, and industrial sludge for bleached kraft and sulfite pulp and paper mills in the United States. Tier two is the risk assessment for paper product contamination, effluent discharge, and sludge disposal. Tier three is the examination of technological options for reducing CDD/CDF formation and release from bleached chemical pulp and paper facilities.

Tier one, the EPA/Paper Industry Cooperative Dioxin Study of 104 pulp and paper mills, began in April 1988 when EPA, API, NCASI, and 44 paper companies signed an agreement outlining the data to be collected and submitted to EPA for use by the Interagency Working Group. This study, commonly referred to as the "104-Mill Study" involved measurement of 2,3,7,8-TCDD and 2,3,7,8-TCDF concentrations in the treated wastewater effluents, wastewater sludges, and all bleached pulp lines at 87 kraft pulp mills and 17 sulfite pulp mills in the United States. Data on wastewater treatment operations, wastewater discharge characteristics, and sludge management practices were also collected during the course of this study. Results of the 104-Mill Study indicated that concentrations of 2,3,7,8-TCDD in kraft pulp were considerably higher than concentrations of 2,3,7,8-TCDD in sulfite pulp. In addition, concentrations of 2,3,7,8-TCDF measured during the 104-Mill Study were roughly an order of magnitude greater than those of 2,3,7,8-TCDD. Furthermore, results of the 104-Mill Study indicated that the presence of 2,3,7,8-TCDD and 2,3,7,8-TCDF in treated effluent, wastewater sludges, and bleached pulps from pulp and paper mills using chlorine-based bleaching processes was widespread. Table 1 provides a general summary of the results of the 104-Mill Study.

The tier two exposure analysis and risk characterization has been divided among the various agencies/offices who have jurisdiction over the media of concern. OTS was assigned the lead on this tier for coordinating and generating an integrated exposure and risk assessment.

Table 1. Summary Results of the 104 Mill Study[a]

	Range[b] (ng/kg)	Mean (ng/kg)	Median (ng/kg)	Std. Dev. (ng/kg)	No. of mills with no detected values
Pulp					
2,3,7,8-TCDD	ND-116	8.8	4.9	11.8	21
2,3,7,8-TCDF	ND-2,620	94.9	19.0	283.7	6
Effluent					
2,3,7,8-TCDD	ND-0.640	0.068	0.023	0.106	20
2,3,7,8-TCDF	ND-8.400	1.033	0.094	2,358	7
Sludge					
2,3,7,8-TCDD	ND-3,800	77.5	18.0	163.9	2
2,3,7,8-TCDF	2.4-17,100	749.6	89.0	2,079	0

[a] Based on final results obtained from EPA's Office of Water Regulations and Standards in October 1989.

[b] The analytical objectives for detection limits of both compounds were 0.01 ng/kg (or ppt) for effluents and 1 ppt for pulps and sludges.

Tier three of the analytical responsibilities is a review of current technologies for CDD/CDF control and abatement in the three mass streams. OW, the lead office, is assessing the effectiveness of numerous control technologies for reducing CDD/CDF formation in the pulp and paper industry. OW is now preparing a technology review document, which will draw on information from National Pollutant Discharge Elimination System (NPDES) permits being negotiated with pulp and paper mills around the country, as well as from the continuing efforts under the effluent limitations guidelines and standards revision project and the 104-Mill Study. The document will not be finalized until after the industry census and mill sampling programs are complete.

1.2.4 Consent Decree

On October 22, 1984, the Environmental Defense Fund (EDF) and the National Wildlife Federation (NWF) filed a citizen's petition with EPA under Section 21 of the Toxic Sustances Control Act (TSCA). The petitioners requested that EPA take regulatory action under Sections 4, 6, and 8 of TSCA to prevent and reduce environmental contamination by CDDs and CDFs. EPA decided in January 1985 that in general it would deny the request to regulate the specified CDDs/CDFs under a multimedia TSCA approach.

In March 1985, the petitioners filed a lawsuit with the U.S. District Court challenging EPA's denial of their request. Before the case was to go to trial, a settlement was reached and a consent decree (Civil Action No. 85-0973) was signed on July 27, 1988, settling the dispute. The consent decree obligated EPA to undertake or complete various actions/investigations of CDDs/CDFs, including the CDD/CDF work related to the pulp and paper industry.

The consent decree set a schedule for assessing both occupational and general population health risks and environmental risks to terrestrial and avian wildlife and aquatic life from CDD/CDF-contaminated pulp and paper mill wastewater, wastewater sludge, and paper products. Although the interagency workgroup was formed before the consent decree with EDF/NWF, the workgroup has served as the mechanism for coordinating federal government efforts to meet the consent decree requirements.

1.3 <u>Scope and Organization of the Integrated Risk Assessment</u>

The Integrated Assessment includes the following components in the order listed:

- An analysis of the chemistry and environmental fate of 2,3,7,8-TCDD and 2,3,7,8-TCDF;

- An assessment of the hazard/toxicity of 2,3,7,8-TCDD and 2,3,7,8-TCDF to humans, aquatic organisms, and avian and terrestrial wildlife;

- An assessment of exposures and risks to workers in the pulp and paper industry;

- Assessments of exposures and risks to the general population from:

  - Use and disposal of pulp and paper mill wastewater sludge and land disposal of paper waste,

  - Discharge of effluents from the pulp and paper industry,

  - Incineration of pulp and paper mill wastewater sludge,

  - Use of pulp-containing medical devices,

  - Use of paper consumer products,

  - Ingestion of foods packaged in or contacting bleached paper products, and

  - Use of food, drug, and cosmetic products containing cellulose derivatives;

- An assessment of exposures and risks to avian and terrestrial wildlife from land application of sludge and to aquatic organisms from the discharge of pulp and paper mill effluents; and

- A screening analysis of information on chlorinated chemicals other than PCDDs and PCDFs (OCOs) identified in pulp and paper mill effluents, sludges, and pulps.

Summaries of the individual chapters of the Background Document to the Integrated Risk Assessment are presented in the same sequence in this Integrated Assessment as they appear in the Background Document. For each chapter of the Background Document, Section 2 of this Integrated Assessment provides the following:

- A discussion of the exposure pathways considered;

- A description of the general methodology employed; and

- A presentation of the key findings or results and a discussion of the key findings, major assumptions, and associated uncertainties.

2. INTEGRATED RISK ASSESSMENT

2.1 Common Assumptions

This section provides a summary of the methodologies used, major assumptions, results and key findings, and uncertainties associated with each exposure/risk assessment performed as part of the Integrated Risk Assessment for the Dioxin-in-Paper Project. This section is organized to reflect the organization of the Background Document to the Integrated Assessment.

Although many scenarios using different methodologies were assessed by the various agencies and offices participating in the Dioxin-in-Paper Project, several common assumptions were agreed to by the participants.

(1) The Toxicity Equivalency Factor (TEF) method states that 2,3,7,8-TCDF is assumed to have one-tenth the potency of 2,3,7,8-TCDD. EPA and FDA agreed to employ this policy for this assessment. Because CPSC does not place similar emphasis on risks calculated by the TEF method, it was agreed that, to the extent possible, CPSC risk estimates for each scenario would be based on the contribution to risk of 2,3,7,8-TCDD alone.

(2) The assessments focused on exposures and risks to 2,3,7,8-TCDD and 2,3,7,8-TCDF. Based on the TEF values formally adopted by EPA in 1987, the results of the 5-Mill Study indicated and the results of the 104-Mill Study confirmed that these two dioxin congeners generally account for more than 90 percent of the dioxin toxic equivalents (TEQ) found in pulps, sludges, and effluents from the pulp and paper mill samples analyzed.

(3) EPA, FDA, and CPSC have each derived an estimated slope factor (q_1* or q_1) for 2,3,7,8-TCDD based on a multistage model with linear-at-low-dose extrapolation procedures. However, because the agencies differ with respect to selection of animal data and details of extrapolation, the risk estimates differ by as much as a factor of 10. The agencies agreed that this Integrated Assessment would report cancer risk estimates calculated by each agency.

(4) The analytical results of the 104-Mill Study (i.e., 2,3,7,8-TCDD and 2,3,7,8-TCDF concentrations in pulp, effluents, and sludge) were to be used in all assessments unless use of alternate data (e.g., product-specific concentrations) could be justified.

(5) With the exception of risks calculated by EPA/OSW and EPA/OW, all estimated human cancer risks were calculated by multiplying the estimated lifetime average daily doses (LADD) by the slope

factor (q_1* or q_1) for 2,3,7,8-TCDD and dividing by the fraction of TCDD absorbed (A) during the animal bioassay from which the slope factor was derived:

$$Risk = (LADD \times q_1)/A$$

The value of A depends on the fraction of 2,3,7,8-TCDD absorbed by the test animals during the bioassay used to estimate q_1 or q_1*. For the EPA and FDA slope factors, which are based on a dietary bioassay, A is assumed to equal 0.55 since it was estimated that 55 percent of the 2,3,7,8-TCDD was absorbed by the test animals; similarly, for the CPSC slope factor, which is based on a gavage bioassay, A is assumed to equal 0.75. The total or population risk was estimated by multiplying the average lifetime risk by the number of persons exposed and dividing by the average life expectancy.

(6) With the exception of the bioavailability values used by EPA/OSW for each ingestion pathway applicable to sludge disposal and use, standard values developed for the bioavailability, or fraction of 2,3,7,8-TCDD and 2,3,7,8-TCDF absorbed, were developed and used for each exposure route and pathway. For the inhalation exposure route, the bioavailability was assumed to be 100 percent for 2,3,7,8-TCDD and 2,3,7,8-TCDF vapors and 100 percent for particulate-bound 2,3,7,8-TCDD and 2,3,7,8-TCDF that reach the alveoli. Standard values for the bioavailability of 2,3,7,8-TCDD and 2,3,7,8-TCDF were assumed to be 100 percent for ingestion of drinking water, 85 to 95 percent for ingestion of fatty or oily foods (e.g., milk, fish, meats), 60 to 70 percent for ingestion of paper dust and sludge, and 45 to 55 percent for ingestion of soil. EPA/OSW, however, assumed 100 percent absorption for each exposure pathway applicable to sludge disposal and use except for dermal exposures. For dermal exposures, a dermal transfer coefficient of 0.012/hour is assumed for 2,3,7,8-TCDD and 2,3,7,8-TCDF that are not bound up within a matrix (e.g., soil or paper products).

A variety of terms were used in the source documents for the Integrated Assessment to describe the exposure case or exposed individual for which risks were estimated. Many of these terms are presented in the Background Document to the Integrated Risk Assessment and in Section 2 of this report as they appear in the source document. These exposure case descriptions include low, high, average, typical, reasonable worst case, extreme worst case, and maximum exposed individual (MEI). Such exposure case descriptions are used by exposure/risk assessors to describe where in the range of exposures possible for a given scenario they either know (from a statistical array of exposures or exposure parameter values) or judge the calculated exposure to reside. Historically, there has been no generally accepted convention or guidance specifying what defines a given exposure description. Therefore, the use of these terms is not consistent within this report.

To provide some consistency in summarizing the results of the Integrated Assessment source documents, the various exposure case descriptions used in the source documents have been reduced in this section into the following two classifications: typical and reasonable worst-case. The majority of exposure cases developed in the source documents fit into one of these two categories if the following somewhat broad definitions are used:

Typical exposure - exposure parameter values selected are (1) values conventionally used for certain exposure parameters; (2) average or most probable values when distribution data for the parameter are available; or (3) values considered "typical" or frequently observed based on best professional judgment.

Examples of the types of exposures mentioned in this report that would be characterized as typical include inhalation of volatilized 2,3,7,8-TCDD/TCDF; inhalation of particulate matter (i.e., paper dust or sludge) containing 2,3,7,8-TCDD/TCDF; dermal contact with pulp, paper, or sludge containing 2,3,7,8-TCDD/TCDF; and ingestion of food, water, and drugs containing 2,3,7,8-TCDD/TCDF.

Reasonable worst-case exposure - similar to typical exposure with the exception that values for one or more significant exposure parameters are selected within the upper portion of the range of actual or expected values so that the resulting exposure calculated represents a relatively high but possible exposure.

Examples of the types of exposures mentioned in this report that would be characterized as reasonable worst-case include those cases in which an individual is exposed to the highest possible concentration (i.e., 90th percentile and above) or instances where an individual is exposed at a frequency or duration higher than what is typically observed.

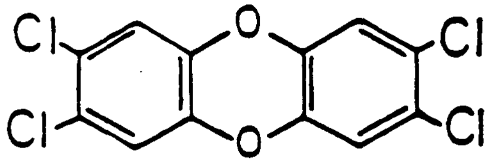
2.2 Summary of the Chemistry and Fate of 2,3,7,8-TCDD and 2,3,7,8-TCDF

The primary source document used for this chapter in the Background Document is the following:

Versar, Inc. 1989. Chemistry and fate of dioxins and furans. U.S. Environmental Protection Agency (EPA), Exposure Evaluation Division, Office of Toxic Substances. Contract No. 68-02-4254, Task 231.

2.2.1 Chemistry and Fate of 2,3,7,8-TCDD

2,3,7,8-Tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD) is one of the 75 compounds known as chlorinated dibenzo-p-dioxins (CDDs). The structure of 2,3,7,8-TCDD is:



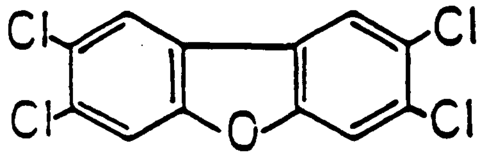
2,3,7,8-TCDD is very sparingly soluble in water (20 ng/l at 22°C), has a high octanol-water partition coefficient (log P = 6.64), shows strong sorption to organic matter (log K_{OC} = 7.2), and has a low vapor pressure (7.4 x 10^{-10} torr at 25°C) but will volatilize into the air under favorable conditions.

2,3,7,8-TCDD is persistent in soils. Upon deposition of 2,3,7,8-TCDD onto surfaces, there is a high initial loss due to photodegradation and perhaps volatilization. Once 2,3,7,8-TCDD moves into soils or sediments, however, it is apparently strongly sorbed. Some recent studies, however, have shown that there may be slow rates of vapor phase transport out of soils, although other recent studies have shown very low mobility.

The only environmentally significant path for destruction of 2,3,7,8-TCDD appears to be photodechlorination. This process, however, requires the presence of another organic material to donate hydrogen atoms. Observations of bioaccumulation indicate that 2,3,7,8-TCDD is readily bioconcentrated in fish, but the data for humans are inconclusive. Dioxins in soil and sediments are considered to be essentially nonbiodegradable. Erosion and aquatic transport of sediment appear to be the main transport mechanism of sorbed dioxins. Table 2 is a summary of the environmental fate of 2,3,7,8-TCDD.

2.2.2 Chemistry and Fate of 2,3,7,8-TCDF

2,3,7,8-Tetrachlorodibenzofuran (2,3,7,8-TCDF) is one of the 135 compounds characterized as chlorinated dibenzofurans (CDFs). The structure of 2,3,7,8-TCDF is:



2,3,7,8-TCDF has a low solubility in water (estimated solubility of 4.3 μg/l at 25°C), has a high octanol-water partition coefficient (log P = 5.8), and has a low vapor pressure (9.2 x 10^{-7} torr at 25°C).

Table 2. Summary of Environmental Fate of 2,3,7,8-TCDD

Environmental process	Summary statement	Confidence in data
Photolysis	May be only natural mechanism leading to destruction of dioxins.	High
Oxidation	Dioxins are stable to oxidation.	Low
Hydrolysis	Dioxins are stable to hydrolysis.	High
Volatilization	Possible important mechanism for transport from water. Volatility depressed by presence of organic solids.	Medium
Sorption	Dioxins strongly sorbed by solids, especially with high organic content.	High
Bioaccumulation	Available data indicate process may be important. The data show high degree of confidence for bioconcentration in fish, but low confidence in the limited data concerning bioaccumulation in humans.	Medium
Biodegradation	Considered essentially non-biodegradable.	Medium

Polychlorinated dibenzofurans can be photodechlorinated by sunlight in the presence of organic substances that can serve as donors of hydrogen atoms. This process of photodechlorination is similar to what occurs in the degradation of dioxins, and it is probably the only degradative fate pathway for dibenzofurans in the environment.

Since there is little or no information on dibenzofurans for other environmentally relevant processes, fate and transport pathways must be derived from the behavior of structurally similar dioxins. 2,3,7,8-TCDF can be expected to be sorbed strongly to soils and sediments, to be bioconcentrated in fish, and to be essentially nonbiodegradable in the environment. Erosion and aquatic transport of sediment will be the main transport pathway. Table 3 is a summary of the environmental fate of 2,3,7,8-TCDF.

2.3 Summary of Hazard Assessment for TCDD/TCDF

The hazard assessment considered carcinogenic and noncarcinogenic effects on humans, toxicity to aquatic organisms, and toxicity to avian and terrestrial wildlife. The primary source documents used for this chapter in the Background Document are the following:

Human health section:

Lee CC. 1989. Human health hazard assessment of dioxins/furans. U.S. Environmental Protection Agency, Office of Toxic Substances. Memorandum to L. Dicker, EPA, Office of Toxic Substances, October 31, 1989.

Ecological effects section:

Rabert WS. 1989. Update of aquatic toxicity and bioavailability data of polychlorinated dibenzo-p-dioxins and polychlorinated dibenzofurans. U.S. Environmental Protection Agency, Office of Toxic Substances. Memorandum to S. Kroner, EPA, Office of Water Regulations and Standards, July 28, 1989.

Wildlife effects section:

USEPA. 1990. U.S. Environmental Protection Agency. Assessment of risks from exposure of humans, terrestrial and avian wildlife, and aquatic life to dioxins and furans from disposal and use of sludge from bleached kraft and sulfite pulp and paper mills. Washington, DC: Office of Toxic Substances and Office of Solid Waste. EPA 560/5-90-013.

2.3.1 Human Hazard Assessment

Among the 210 congeners of CDDs and CDFs, the compound that appears to be the most toxic and has generally raised the greatest health

Table 3. Summary of Environmental Fate of Dibenzofurans

Environmental process	Summary statement	Confidence in data
Photolysis	May be only natural mechanism leading to destruction of dibenzofurans.	Medium
Oxidation	No information found.	Low
Hydrolysis	Dibenzofurans are stable to hydrolysis.	High
Volatilization	No information found.	Low
Sorption	Dibenzofurans strongly sorbed by solids, especially with high organic content.	Medium
Bioaccumulation	No specific information found; potential is inconclusive.	Low
Biodegradation	Probably nondegradable in the environment.	Low

concerns is 2,3,7,8-TCDD. 2,3,7,8-TCDD is classified by the EPA as a probable human carcinogen based on sufficient evidence in animals but inadequate evidence in humans. The EPA cancer risk estimate is represented as the upper bound slope factor, q_1*. The CPSC cancer risk estimate is represented as the maximum likelihood estimate of the extra risk, q_1. The FDA approach is an upper bound estimate of the unit risk or potency by means of the linear-at-low-dose extrapolation. The cancer risk estimates derived for 2,3,7,8-TCDD by EPA, FDA, and CPSC differ by as much as a factor of 10, with a value of 1.6×10^{-4} $(pg/kg/day)^{-1}$ estimated by EPA, a value of 6.7×10^{-5} $(pg/kg/day)^{-1}$ estimated by CPSC, and a value of 1.8×10^{-5} $(pg/kg/day)^{-1}$ estimated by FDA. The estimated exposures giving an upper bound excess lifetime cancer risk of one in one million based on the upper bound slope factor or maximum likelihood of extra risk are 0.006 pg/kg/day (EPA), 0.015 pg/kg/day (CPSC), and 0.06 pg/kg/day (FDA). Although all three agencies based their estimates on linear-at-low-dose extrapolation procedures, they differ with respect to selection of animal data and details of extrapolation.

In the spring of 1987, EPA formally adopted an interim procedure for estimating risks associated with exposures to mixtures of the 210 congeners of CDDs and CDFs, including 2,3,7,8-TCDD. This interim procedure was updated in 1989. The procedure uses a set of derived toxicity equivalency factors (TEFs) to convert the concentration of any CDD/CDF congener into an equivalent concentration of 2,3,7,8-TCDD. In this procedure, 2,3,7,8-TCDD is assigned a TEF of 1. The TEF for 2,3,7,8-TCDF is one-tenth that for 2,3,7,8-TCDD. It must be noted that, although FDA concurs with EPA on the use of TEFs, CPSC does not. Because of the limited carcinogenicity studies for individual dioxin congeners, CPSC prefers to estimate cancer risks using a method based on 2,3,7,8-TCDD alone rather than using the method based on TEFs.

In assessing the risk of non-cancer effects, adverse effects resulting from long-term, low-level exposure and from relatively brief exposure to a high dose must be considered. The Reference Dose (RfD) is used to evaluate long-term oral exposures to a chemical. The RfD is an estimate of the lifetime daily exposure to which humans can be exposed without any appreciable risk of experiencing deleterious effects. The Health Advisory (HA) is used to evaluate brief exposures to high doses of a chemical. EPA determined that reproductive effects and developmental toxicity in animals are the most critical or sensitive noncarcinogenic effects to consider for assessing risks from exposure to 2,3,7,8-TCDD. For purposes of this assessment, EPA estimated an RfD for 2,3,7,8-TCDD of 1 pg/kg/day based on studies conducted to assess the possible adverse effects of chronic oral 2,3,7,8-TCDD exposure on reproductive capacity. For purposes of this assessment, EPA estimated a 1-day HA of 300 pg/kg/day and a 10-day HA of 30 pg/kg/day based on studies conducted to assess the potential developmental toxicity of short-term exposure to 2,3,7,8-TCDD during pregnancy. For purposes of this assessment, EPA estimated a 1-day HA of 100 pg/kg/day and a 10-day HA of 10 pg/kg/day based on studies conducted to assess potential systemic effects (liver pathology).

2.3.2 Aquatic Organism Hazard Assessment

To assess the toxicity of chemicals to aquatic species, the highest concentration at which no adverse effect is observed (NOEC) should be determined. A definitive NOEC has not been reported for 2,3,7,8-TCDD. Even the lowest test concentration among all known 2,3,7,8-TCDD studies (0.038 ng/l) produced 45 percent mortality in rainbow trout exposed to 2,3,7,8-TCDD for 28 days. Data from testing laboratories suggest that an exposure duration of greater than 71 days is required to achieve a steady-state bioconcentration factor (BCF) in fish.* The NOEC reported for 2,3,7,8-TCDF is 0.41 ng/l. This value for NOEC is also uncertain because of the limited duration of the study. The toxicity data available on 2,3,7,8-TCDD and 2,3,7,8-TCDF do not adequately define the inherent toxicity of these two chemicals for two reasons: (1) the exposure periods are of insufficient duration for a steady-state equilibrium to be reached, and (2) the studies do not address sublethal effects for the most sensitive life stages, such as effects on developing embryos resulting from deposition of either 2,3,7,8-TCDD or 2,3,7,8-TCDF in the eggs by the female.

Since definitive chronic toxicity values are not available for 2,3,7,8-TCDD and 2,3,7,8-TCDF effects on aquatic species, especially fish, chronic toxicity values were estimated from the results of the tests discussed above through use of an estimation factor of 1,000. The Office of Water uses values of this magnitude for certain chemicals when chronic toxicity data are not available. In addition, OTS uses a factor of 1,000 to predict the chronic toxicity of a substance from a single LC_{50} value in the Premanufacture Notice process of Section 5 under TSCA. The OTS factor of 1,000 does not include any safety factor; rather, the factor of 1,000 consists of a series of intervals with average factors of 10. Included in the three factors of 10 are (1) a range of differences in species sensitivity; (2) an acute to chronic toxicity (i.e., LC_{50} to the maximum acceptable toxicant concentration (MATC) value); and (3) the differences in field-to-laboratory toxic effects. Given the fact that the LC_{50} value for 2,3,7,8-TCDD could be lower than 38 pg/l for fish, a 1,000 factor was deemed to be appropriate for purposes of this study as an estimate for chronic toxicity. This factor is justified for use in this study because the exposure duration was too short to achieve a steady-state condition and the tests did not involve developing eggs, which are, to date, the life stage found to be the most sensitive. Consequently, it was assumed for the purpose of this assessment that concentrations of 2,3,7,8-TCDD in water greater than 0.038 pg/l will exhibit toxic effects to some aquatic

*Personal communication between William Rabert, EPA/OTS Washington, DC, and Phil Cook, EPA/ERL, Duluth, MN.

species. Applying the same approach to 2,3,7,8-TCDF, it was assumed that concentrations of 2,3,7,8-TCDF greater than 0.41 pg/l will exhibit toxic effects for some aquatic species.

2.3.3 Wildlife Hazard Assessment

The adverse effects to individual laboratory and wildlife species from exposure to 2,3,7,8-TCDD have been documented in laboratory studies. Extrapolation of these results to wild populations has some limitations. The route and medium of administration and the duration of exposure to 2,3,7,8-TCDD for laboratory animals usually differ from those for wild animals. Using laboratory studies to assess effects on wild species assumes that the wild species are as sensitive or more sensitive to 2,3,7,8-TCDD than the laboratory species. Many of the tests conducted with terrestrial laboratory species identified toxic effects at elevated exposure levels for a short observation period. However, it was noted in tests with aquatic organisms that more than 71 days of exposure was necessary for equilibrium and that toxic effects may not appear until 30 to 80 days after initiation of exposure. Furthermore, in assessing the effects of chemicals on fish and wildlife, the impacts on a population or ecosystem are of interest. The methods for predicting the effects of chemicals on terrestrial wildlife populations and ecosystems, however, are still under development. In the absence of sophisticated predictive methods, measures of the effects of chemicals on reproduction are useful indicators of possible effects on the populations of the species of the wild.

To assess toxic effects to birds, the estimated daily exposure to adult wild birds was compared to a no observable adverse effects level (the NOAEL) of 100 ng/kg/day reported in a 21-day exposure period laboratory study with white leghorn chickens. This laboratory dose was converted to an equivalent exposure over the length of time that wild species of birds may be exposed to 2,3,7,8-TCDD from sludge applied to agricultural or forested areas. Because migratory birds were assumed to reside in the land-treated area for 6 months (180 days), the NOAEL was adjusted by a "residence time/exposure period" factor of 180/21 (or about 9). Thus, the adjusted NOAEL for migratory birds is 11 ng/kg/day. Non-migratory birds were assumed to remain onsite for the entire year. Thus, for non-migratory species, the NOAEL is adjusted by a "residence time/exposure period" factor of 365/21 (or about 17). The adjusted NOAEL for non-migratory species is therefore 6 ng/kg/day.

The life stage in avian species most sensitive to 2,3,7,8-TCDD is the developing embryo during resorption of the yolk. To assess toxic effects on bird eggs, the predicted 2,3,7,8-TCDD concentration in wild bird eggs was compared to the lowest observable adverse effects level (the LOAEL) reported in a laboratory study with chicken embryos, 65 ppt; no NOAEL was found.

To assess toxicity to wild mammals, the predicted exposures were compared to the lowest concentration observed to cause reproductive effects in laboratory animals. For small mammals, a LOAEL of 10 ng/kg/day was used based on the results of a multi-generational study with rats. For large mammals, a LOAEL of 1.7 ng/kg/day was used based on a reproductive effects study with Rhesus monkeys.

2.4 Summary of Risks to Workers

2.4.1 Introduction

This risk assessment is discussed in more detail in Chapter 4 of the Background Document. The primary source documents used for this chapter in the Background Document are the following:

PEI. 1990a. PEI Associates, Inc. Estimated worker exposure to 2,3,7,8-TCDD and 2,3,7,8-TCDF in the manufacture, processing, and commercial use of pulp, paper, and paper products. Washington, DC: U.S. Environmental Protection Agency, Office of Toxic Substances. Contract No. 68-D8-0112. March 1990.

PEI. 1990b. PEI Associates, Inc. Estimated worker exposure to 2,3,7,8-TCDD and 2,3,7,8-TCDF from processing and commercial use of pulp and paper mill sludge. Washington, DC: U.S. Environmental Protection Agency, Office of Toxic Substances. Contract No. 68-D8-0112. April 12, 1990.

This assessment examined risks to workers in the following industries:

- Pulp manufacturing;
- Paper manufacturing;
- Paper converting;
- Nonwoven fabric production;
- Commercial users of bleached paper (i.e., office workers, salespersons, mail/message distributors, medical workers); and
- Sludge processing and commercial use operations (i.e., handling/processing, landfilling, composting, land application, etc.).

The assessment identified those job categories in each industry with the potential for exposure via one or more of the following exposure pathways:

- Inhalation of 2,3,7,8-TCDD and/or 2,3,7,8-TCDF vapors;
- Inhalation of particulate matter (i.e., paper dust or sludge particles); and/or
- Dermal contact with pulp, paper, or sludge.

2.4.2 Methodology

In assessing risks to workers, low and high individual risks and low and high population risks were estimated using generic exposure scenarios. The lowest and highest dioxin TEQ concentrations reported in the 104-Mill Study for the matrix of concern were used to estimate the "low" and "high" estimates of risk, respectively. For example, risk estimates for workers involved in composting operations are based on the lowest and highest dioxin TEQ concentrations in sludge from those mills that report using composting as a sludge disposal reuse method.

Exposure via volatilization pathways was estimated using models that were based on either a mass balance approach for specific activities (e.g., for pulp testers during sampling) or an approach that estimated maximum air concentrations based on the partial pressures of 2,3,7,8-TCDD and 2,3,7,8-TCDF. Estimates of exposure via inhalation of particulate matter during paper converting and nonwoven operations were based on monitored air concentrations of particulates. For all other paper manufacturing and processing operations, data from NCASI on particle size distribution of paper dust were used to estimate concentrations of particulates in air. For operations involving processing and commercial use of sludge, particulate matter emission rates were estimated based on EPA's widely used AP-42 Compilation of Air Pollution Emission Factors. Measured concentrations of 2,3,7,8-TCDD and 2,3,7,8-TCDF in paper were not available; it was, therefore, assumed that concentrations of 2,3,7,8-TCDD and 2,3,7,8-TCDF in paper were the same as the concentrations of these chemicals in pulp. In addition, the concentrations of 2,3,7,8-TCDD and 2,3,7,8-TCDF in the particulates from sludge or paper were assumed to be the same as in the source material (i.e., sludge or paper). Dermal exposures were estimated using a two-step model that first considers partitioning of the 2,3,7,8-TCDD/TCDF from the matrix (i.e., sludge, pulp, etc.) to a liquid (water, skin oil) and then considers percutaneous absorption of 2,3,7,8-TCDD/TCDF from the liquid.

2.4.3 Results and Discussion

Table 4 presents estimates of risk by exposure pathway for each job category for workers involved in manufacturing, processing, and commercial use of pulp, paper, and paper products. Table 5 presents similar results for workers involved in processing and commercial use of pulp and paper mill sludge.

As evident in Tables 4 and 5, only "high" individual risks were estimated to be greater than 10^{-5}. Estimates of "high" individual risk represent those plants in which the medium to which the worker is exposed contains the maximum dioxin TEQ concentrations. Risks greater than 10^{-5} result from inhalation of particulate matter and dermal contact.

It should be noted that the extent of use and effectiveness of personal

Table 4. Summary of Individual and Population Cancer Risks for Workers Involved in Manufacturing, Processing, and Commercial Usage of Pulp, Paper, and Paper Products

Job category	No. of workers	Exposure pathway	Estimated risk[a]			
			Individual risk		Population risk (# cases/yr)	
			Low	High	Low	High
Pulp manufacturing operations						
- Bleach plant operator	434	Inhalation-volatilization	$4x10^{-7}$ (0.08)	$5x10^{-7}$ (0.08)	$4x10^{-6}$	$5x10^{-6}$
		Dermal	$2x10^{-13}$ (47)	$5x10^{-10}$ (4)	$3x10^{-12}$	$6x10^{-9}$
- Pulp testers	433	Inhalation-volatilization	$1x10^{-19}$ (0.03)	$2x10^{-15}$ (0.002)	$1x10^{-18}$	$3x10^{-14}$
		Dermal	$2x10^{-12}$ (47)	$3x10^{-9}$ (4)	$2x10^{-11}$	$4x10^{-8}$
- Utility operator	433	Inhalation-volatilization	$1x10^{-6}$ (0.08)	$1x10^{-6}$ (0.08)	$1x10^{-5}$	$2x10^{-5}$
		Dermal	$4x10^{-12}$ (47)	$7x10^{-9}$ (4)	$4x10^{-11}$	$7x10^{-8}$
Pulp drying operations						
- Pulp drying operator	160	Inhalation-volatilization	$2x10^{-11}$ (0.03)	$2x10^{-7}$ (0.002)	$7x10^{-11}$	$9x10^{-7}$
		Dermal	$9x10^{-10}$ (29)	$3x10^{-6}$ (2)	$4x10^{-9}$	$1x10^{-5}$
- Pulp drying utility operator	80	Inhalation-volatilization	$2x10^{-11}$ (0.03)	$2x10^{-7}$ (0.002)	$3x10^{-11}$	$4x10^{-7}$
		Dermal	$2x10^{-13}$ (29)	$5x10^{-10}$ (2)	$5x10^{-13}$	$1x10^{-9}$
Paper manufacturing operations						
- Wet-end operator	10,667	Inhalation-volatilization	$2x10^{-11}$ (0.03)	$2x10^{-7}$ (0.002)	$5x10^{-9}$	$6x10^{-5}$
		Dermal	$2x10^{-13}$ (47)	$5x10^{-10}$ (4)	$7x10^{-11}$	$1x10^{-7}$

Table 4. (Continued)

Job category	No. of workers	Exposure pathway	Estimated risk[a]			
			Individual risk		Population risk (# cases/yr)	
			Low	High	Low	High
Paper manufacturing operations (continued)						
- Dry-end operator	12,445	Inhalation-volatilization	3×10^{-11} (0.03)	4×10^{-7} (0.002)	1×10^{-8}	1×10^{-4}
		Inhalation-particulate matter	2×10^{-10} (29)	1×10^{-5} (2)	6×10^{-8}	5×10^{-3}
		Dermal	2×10^{-10} (29)	7×10^{-7} (2)	6×10^{-8}	2×10^{-4}
- Utility operator	8,888	Inhalation-volatilization	5×10^{-11} (0.03)	7×10^{-7} (0.002)	1×10^{-8}	1×10^{-4}
		Inhalation-particulate matter	8×10^{-9} (29)	8×10^{-5} (2)	2×10^{-6}	2×10^{-2}
		Dermal	3×10^{-10} (29)	1×10^{-6} (2)	6×10^{-8}	2×10^{-4}
Paper converting operations						
- General worker	129,000	Inhalation-particulate matter	4×10^{-10} (29)	5×10^{-5} (2)	1×10^{-6}	2×10^{-1}
		Dermal	4×10^{-10} (29)	1×10^{-6} (2)	1×10^{-6}	4×10^{-3}
Nonwoven operations						
- General worker	15,000	Inhalation-particulate matter	4×10^{-10} (29)	3×10^{-6} (2)	1×10^{-7}	1×10^{-3}
		Dermal	8×10^{-13} (29)	3×10^{-9} (2)	3×10^{-10}	1×10^{-6}

Table 4. (Continued)

Job category	No. of workers	Exposure pathway	Estimated risk[a]			
			Individual risk		Population risk (# cases/yr)	
			Low	High	Low	High
Commercial users[b]						
- Group 1	2,639,000	Dermal	$7x10^{-11}$ (29)	$3x10^{-7}$ (2)	$5x10^{-6}$	$2x10^{-2}$
- Group 2	26,933,000	Dermal	$5x10^{-11}$ (29)	$2x10^{-7}$ (2)	$3x10^{-6}$	$1x10^{-2}$
- Group 3	5,004,000	Dermal	$2x10^{-11}$ (29)	$8x10^{-8}$ (2)	$1x10^{-6}$	$5x10^{-3}$
- Group 4	14,095,000	Dermal	$2x10^{-11}$ (29)	$8x10^{-8}$ (2)	$2x10^{-6}$	$6x10^{-3}$
- Group 5	793,000	Dermal	$3x10^{-10}$ (29)	$8x10^{-7}$ (2)	$2x10^{-5}$	$5x10^{-2}$

[a] EPA has classified 2,3,7,8-TCDD as a "B2" carcinogen. Values in parentheses represent percent exposure to 2,3,7,8-TCDD. Risks presented were calculated using the EPA unit risk estimate for 2,3,7,8-TCDD and the TEQ method. This unit risk estimate was derived using the EPA carcinogenic slope factor for 2,3,7,8-TCDD ($1.6x10^{-4}$ $(pg/kg/d)^{-1}$). Had risks been calculated using FDA's potency estimate ($1.8x10^{-5}$ $(pg/kg/d)^{-1}$), then the risks and incidences would be a factor of 8.9 lower than those presented in the table. Had risks been calculated using CPSC's potency estimate ($6.7x10^{-5}$ $(pg/kg/d)^{-1}$), then the risks would be "at least" a factor of 2.3 lower than those presented in the table. The term "at least" is used because, as discussed in Section 2.3 of this report, CPSC does not place the same emphasis on risks calculated by the TEQ method as it does for 2,3,7,8-TCDD itself when estimating carcinogenic potency.

[b] Group 1 includes accountants, auditors, architects, librarians, archivists, curators, and duplicating and mail/message distribution occupations.
Group 2 includes lawyers, judges, computer programmers, computer operators, records processors, managers, and those in miscellaneous administrative support occupations.
Group 3 includes secretaries, stenographers, and typists.
Group 4 includes teachers and sales representatives.
Group 5 includes medical workers who may come into contact with nonwoven products such as garments and masks.

Table 5. Summary of Individual and Population Cancer Risks for Workers Involved in Processing and Commercial Usage of Pulp and Paper Mill Sludge

Job category	No. of workers	Exposure type[b]	Estimated risk[a]: Individual risk, Low	Individual risk, High	Population risk (# cases/yr), Low	Population risk (# cases/yr), High
Sludge handling/processing						
- Waste treatment plant operators	1300	Inhalation-volatilization[c]	$2x10^{-12}$ (0.6)	$9x10^{-9}$ (0.2)	$2x10^{-11}$	$9x10^{-8}$
		Inhalation-particulate matter[d]	$2x10^{-11}$ (19)	$7x10^{-8}$ (8)	$2x10^{-10}$	$7x10^{-7}$
		Dermal[e]	$1x10^{-7}$ (19)	$4x10^{-4}$ (8)	$1x10^{-6}$	$4x10^{-3}$
- Sludge haulers/front-end loader operators	400	Inhalation-volatilization[c]	$2x10^{-11}$ (0.6)	$2x10^{-7}$ (0.2)	$8x10^{-10}$	$5x10^{-6}$
		Inhalation-particulate matter[c]	$1x10^{-10}$ (19)	$5x10^{-7}$ (8)	$4x10^{-9}$	$2x10^{-5}$
		Dermal[d]	$6x10^{-9}$ (19)	$3x10^{-5}$ (8)	$2x10^{-7}$	$8x10^{-4}$
Landfilling operations						
- Equipment operators	400	Inhalation-volatilization[f]	$5x10^{-10}$ (0.6)	$2x10^{-6}$ (0.2)	$5x10^{-9}$	$2x10^{-5}$
		Inhalation-particulate matter[f]	$1x10^{-8}$ (19)	$2x10^{-5}$ (6)	$1x10^{-7}$	$2x10^{-4}$
		Dermal[d]	$6x10^{-9}$ (19)	$1x10^{-5}$ (6)	$6x10^{-8}$	$1x10^{-4}$
Land application operations						
- Equipment operators	20	Inhalation-volatilization[f]	$3x10^{-8}$ (0.6)	$9x10^{-7}$ (1)	$1x10^{-8}$	$4x10^{-7}$
		Inhalation-particulate matter[f]	$1x10^{-6}$ (19)	$6x10^{-5}$ (35)	$5x10^{-7}$	$3x10^{-5}$
		Dermal[d]	$1x10^{-7}$ (19)	$7x10^{-6}$ (35)	$5x10^{-8}$	$4x10^{-6}$

Table 5. (Continued)

Job category	No. of workers	Exposure pathway[b]	Estimated risk[a]			
			Individual risk		Population risk (# cases/yr)	
			Low	High	Low	High
Composting operations						
- Equipment operators	150	Inhalation-volatilization[f]	$1x10^{-7}$ (0.2)	$6x10^{-6}$ (0.2)	$5x10^{-7}$	$2x10^{-5}$
		Inhalation-particulate matter[f]	$3x10^{-7}$ (8)	$1x10^{-5}$ (6)	$1x10^{-6}$	$4x10^{-5}$
		Dermal[d]	$4x10^{-9}$ (8)	$2x10^{-7}$ (6)	$2x10^{-8}$	$9x10^{-7}$
- Compost haulers	50	Inhalation-volatilization[c]	$3x10^{-10}$ (0.2)	$1x10^{-8}$ (0.2)	$4x10^{-10}$	$2x10^{-8}$
		Inhalation-particulate matter[c]	$3x10^{-8}$ (8)	$1x10^{-6}$ (6)	$4x10^{-8}$	$2x10^{-6}$
		Dermal[d]	$4x10^{-9}$ (8)	$2x10^{-7}$ (6)	$5x10^{-9}$	$3x10^{-7}$
- Screen operators	20	Inhalation-volatilization[f]	$1x10^{-9}$ (0.20)	$7x10^{-8}$ (0.2)	$7x10^{-10}$	$3x10^{-8}$
		Inhalation-particulate matter[f]	$2x10^{-6}$ (8)	$7x10^{-5}$ (6)	$9x10^{-7}$	$4x10^{-5}$
		Dermal[c]	$2x10^{-7}$ (8)	$8x10^{-6}$ (6)	$9x10^{-8}$	$4x10^{-6}$

[a] EPA has classified 2,3,7,8-TCDD as a "B2" carcinogen. Values in parentheses represent percent exposure to 2,3,7,8-TCDD. Risks presented were calculated using the EPA unit risk estimate for 2,3,7,8-TCDD and the TEQ method. This unit risk estimate was derived using the EPA carcinogenic slope factor for 2,3,7,8-TCDD ($1.6x10^{-4}$ $(pg/kg/d)^{-1}$). Had risks been calculated using FDA's potency estimate ($1.8x10^{-5}$ $(pg/kg/d)^{-1}$), then the risks and incidences would be a factor of 8.9 lower than those presented in the table. Had risks been calculated using CPSC's potency estimate ($6.7x10^{-5}$ $(pg/kg/d)^{-1}$), then the risks would be "at least" a factor of 2.3 lower than those presented in the table. The term "at least" is used because, as discussed in Section 2.3 of this report, CPSC does not place the same emphasis on risks calculated by the TEQ method as it does for 2,3,7,8-TCDD itself when estimating carcinogenic potency.

[b] The frequency of exposure was assumed to be 250 days per year.

[c] Duration of exposure assumed to be 4 hours per day.

[d] duration of exposure assumed to be 1 hour per day.

[e] Duration of exposure assumed to be 2 hours per day.

[f] Duration of exposure assumed to be 8 hours per day.

protective equipment and engineering controls in this industry are not well known. Therefore, the assessment assumed no use of protective equipment (e.g., gloves and respirators) that could minimize potential exposures.

Similarly, the frequency and duration of potential dermal and inhalation exposures were not well characterized. Typical to reasonable worst-case assumptions were used for these parameters in the assessment. More accurate information could result in increased or decreased individual risks.

The estimated population risks are very low even if the high individual risk estimates are used as a basis. The highest estimated risk is 0.2 excess cancer cases per year for a general worker involved in paper converting operations. The next highest population risk is an order of magnitude lower. One should note, however, that had mean or median 2,3,7,8-TCDD TEQ concentrations rather than the highest concentrations in the matrix of concern been used to predict population risks, the predicted risks could be significantly lower; risks based on the mean dioxin TEQ pulp level from the 104-Mill Study would have been 18 times lower.

2.5 Summary of Risks Resulting from Use and Disposal of Pulp and Paper Mill Sludge and Land Disposal of Paper

2.5.1 Introduction

This section summarizes estimates of human exposures and risks associated with the use and disposal of sludge from kraft and sulfite pulp and paper mills that employ chlorine bleaching and with the disposal of paper wastes in municipal landfills. Exposures and risks associated with the potential release into the environment of PCDDs/PCDFs from incineration of sludge are summarized in Section 2.7 of this report. The assessment of risks resulting from disposal and use of sludge and land disposal of paper wastes is discussed in more detail in Chapter 5 of the Background Document to the Integrated Risk Assessment. The following is the major source document used in the Background Document:

USEPA. 1990. U.S. Environmental Protection Agency. Assessment of risks from exposure of humans, terrestrial and avian wildlife, and aquatic life to dioxins and furans from disposal and use of sludge from bleached kraft and sulfite pulp and paper mills. Washington, DC: Office of Toxic Substances and Office of Solid Waste. EPA 560/5-90-013.

Conclusions drawn from this assessment are applicable only to pulp and paper mill sludges. At this time, EPA has not assessed risks to human health and the environment from the use and disposal of sludges generated at publicly and privately owned treatment plants that treat domestic sewage. This evaluation, with potential subsequent regulation of sewage sludges, will be performed in the next 2 to 3 years in the second round of sewage sludge regulations under 40 CFR Part 503.

Using the Toxicity Equivalency Factor (TEF) values formally adopted by the Environmental Protection Agency in 1987, 2,3,7,8-TCDD and 2,3,7,8-TCDF generally accounted for more than 90 percent of the dioxin toxic equivalents (TEQ) found in samples of pulp and paper mill sludge analyzed as part of the 5-Mill Study (USEPA 1988) and the 104-Mill Study (Helms 1989). Consequently, risks estimated from disposal and use of these types of sludges were based on exposures to these two dioxin congeners. Table 6 presents the distribution of 2,3,7,8-TCDD and 2,3,7,8-TCDF sludge concentrations for all bleached kraft and sulfite pulp and paper mills for which sludge concentrations were reported as part of the 104-Mill Study (USEPA 1990).

Pulp and paper mill sludge management practices considered in this assessment include landfilling, surface impoundment, land application, and distribution and marketing. Approximately 2.5 million metric tons of pulp and paper mill sludge are generated annually. Table 7 presents information from the 104-Mill Study regarding the amount of sludge received annually for each pulp and paper mill sludge disposal and use practice. Landfilling is the most common method of disposal of this sludge, accounting for 44 percent of the total pulp and paper mill sludge generated annually. About 75 percent of all mills that landfill pulp and paper mill sludge dispose of this sludge on-site; the remaining 25 percent dispose of the sludge in municipal landfills. Surface impoundment is the next most common method of disposal of pulp and paper mill sludge accounting for 24 percent of the total pulp and paper mill sludge generated annually. About 12 percent of the total pulp and paper mill sludge generated annually is land-applied. Of the amount that is land-applied, roughly 80 percent is applied to forest land, about 10 percent is applied to reclaimed mine sites, and the remaining 10 percent is applied to land used for agriculture. The amount of sludge incinerated is approximately equal to the amount that is land-applied on an annual basis. About 8 percent of the total pulp and paper mill sludge generated annually was reportedly distributed and marketed as a soil amendment (USEPA 1990).

2.5.2 Methodology

In assessing potential carcinogenic risks to the general population from pulp and paper mill sludge management practices, 21 exposure pathways were examined. The exposure pathways considered for each sludge management practice are presented in Table 8. Two approaches were used to estimate potential risks to the general population from exposure to 2,3,7,8-TCDD and 2,3,7,8-TCDF as a result of pulp and paper mill sludge

Table 6. Distribution of 2,3,7,8-TCDD and 2,3,7,8-TCDF Sludge Concentrations for All Plants in the 104-Mill Study[a]

Distribution descriptor	2,3,7,8-TCDD concentration (ng/kg or ppt)	2,3,7,8-TCDF concentration (ng/kg or ppt)	Distribution descriptor	2,3,7,8-TCDD concentration (ng/kg or ppt)	2,3,7,8-TCDF concentration (ng/kg or ppt)
100th percentile	3,800	17,100	25th percentile	12	34
95th percentile	680	2,940	10th percentile	3	6
90th percentile	293	1,760	5th percentile	1.9	2.4
75th percentile	119	799	Mean	162.9	885.4
50th percentile	51	158	Standard Deviation	464.7	2,303

[a]Based on data from 79 pulp and paper mills.

Source: USEPA (1990)

Table 7. Use and Disposal Methods for Pulp and Paper Mill Sludge

Pulp and paper mill sludge disposal/use method	Number of mills	Quantity of sludge received[a] (dry tons/yr)	Percent of total
Landfill[b]	59	1,100,000	44
Surface impoundment	20	600,000	24
Land application[c]	7	300,000	12
Incineration[d]	21	300,000	12
Distribution and marketing	7	200,000	8
Total	104	2,500,000	100

[a] Some plants use more than one sludge reuse or disposal method. Where plants reported multiple sludge reuse or disposal methods, reported quantities were divided among relevant categories.
[b] About 75 percent of all mills that landfill pulp and paper mill sludge dispose of sludge on-site; the remaining 25 percent dispose of sludge in municipal landfills.
[c] Of the quantity of pulp and paper mill sludge that is land-applied, roughly 80 percent is applied to forest land, about 10 percent is applied to reclaimed mine sites, and the remaining 10 percent is applied to land used for agriculture.
[d] Not considered in this section; see Section 2.7.

Table 8. General Population Cancer Risks Estimated Using Generic Exposure Scenarios Associated With Each Pulp and Paper Mill Sludge Management Practice and with Disposal of Paper Wastes

Disposal practices/exposure pathway	MEI risk[a] (lifetime^{-1})	Typical risk[a] (lifetime^{-1})	Exposed population[b]	Population risk[c] (cases/year)
Landfills				
Ingestion exposure from drinking surface water contaminated by surface runoff (Percent TCDD)[d]	$7x10^{-4}$ (0.6)	$5x10^{-8}$ (0.6)	6,980,000	$5x10^{-3}$ (0.6)
Ingestion exposure from fish caught in surface water contaminated by runoff (Percent TCDD)[d]	$5x10^{-2}$ (63)	$8x10^{-8}$ (65)	14,200,000	$2x10^{-2}$ (65)
Inhalation exposure to air contaminated by volatilization from landfills (Percent TCDD)[d]	$4x10^{-7}$ (4)	$1x10^{-9}$ (4)	12,800,000	$2x10^{-4}$ (4)
Ingestion exposure from drinking ground water contaminated by leachate (Percent TCDD)[d]	$1x10^{-9}$ (2)	$1x10^{-10}$ (8)	19,000	$3x10^{-8}$ (8)
Surface impoundments				
Ingestion exposure from drinking surface water contaminated by surface runoff (Percent TCDD)[d]	$2x10^{-3}$ (0.6)	$7x10^{-8}$ (0.7)	2,330,000	$2x10^{-3}$ (0.7)
Ingestion exposure from fish caught in surface water contaminated by runoff (Percent TCDD)[d]	$1x10^{-1}$ (63)	$1x10^{-7}$ (65)	4,760,000	$7x10^{-3}$ (65)
Inhalation exposure to air contaminated by volatilization from surface impoundments (Percent TCDD)[d]	$1x10^{-6}$ (0.6)	$4x10^{-8}$ (0.7)	7,100,000	$4x10^{-3}$ (0.7)
Ingestion exposure from drinking ground water contaminated by leachate (Percent TCDD)[d]	$3x10^{-8}$ (0.4)	$5x10^{-10}$ (0.7)	6,000	$4x10^{-8}$ (0.7)
Distribution and marketing				
Dermal exposure from contact with soil (Percent TCDD)[d]	$1x10^{-4}$ (63)	$3x10^{-8}$ (59)	3,500,000	$1x10^{-3}$ (59)
Exposure from direct ingestion of soil (Percent TCDD)[d]	$1x10^{-4}$ (57)	$3x10^{-7}$ (56)	3,500,000	$1x10^{-2}$ (56)
Inhalation exposure to air contaminated by volatilization from soil (Percent TCDD)[d]	$6x10^{-7}$ (5)	$5x10^{-8}$ (6)	3,500,000	$3x10^{-3}$ (6)

Table 8. (Continued)

Disposal practices/exposure pathway	MEI risk[a] (lifetime^{-1})	Typical risk[a] (lifetime^{-1})	Exposed population[b]	Population risk[c] (cases/year)
Inhalation exposure to soil particulates	$2x10^{-7}$	$5x10^{-9}$	3,500,000	$3x10^{-4}$
(Percent TCDD)[d]	(64)	(71)		(71)
Dietary exposure from produce grown in gardens	$2x10^{-8}$	$5x10^{-11}$	3,500,000	$3x10^{-6}$
(Percent TCDD)[d]	(62)	(71)		(71)
<u>Land application</u>				
Dermal exposure from contact with soil	$4x10^{-5}$	$3x10^{-7}$	40	$2x10^{-7}$
(Percent TCDD)[d]	(62)	(65)		(65)
Exposure from direct ingestion of soil	$4x10^{-5}$	$1x10^{-6}$	40	$7x10^{-7}$
(Percent TCDD)[d]	(62)	(65)		(65)
Inhalation exposure to air contaminated by	$2x10^{-4}$	$1x10^{-5}$	40	$7x10^{-6}$
volatilization from soil (Percent TCDD)[d]	(4)	(4)		(4)
Inhalation exposure to particulates from soil	$4x10^{-6}$	$7x10^{-7}$	40	$4x10^{-7}$
(Percent TCDD)[d]	(62)	(65)		(65)
Ingestion exposure from drinking surface water contaminated by surface runoff from	$2x10^{-3}$	$3x10^{-7}$	333,000	$1x10^{-3}$
agricultural land application (Percent TCDD)[d]	(0.6)	(0.6)		(0.6)
Ingestion exposure from drinking surface water contaminated by surface runoff from land application to mines/forests	$3x10^{-3}$	$3x10^{-7}$	833,000	$4x10^{-3}$
(Percent TCDD)[d]	(0.6)	(0.6)		(0.6)
Ingestion exposure to fish contaminated by surface runoff from agricultural land	$1x10^{-1}$	$5x10^{-7}$	679,000	$4x10^{-3}$
application (Percent TCDD)[d]	(63)	(65)		(65)
Ingestion exposure to fish contaminated by surface runoff from land application to	$2x10^{-1}$	$5x10^{-7}$	1,700,000	$1x10^{-2}$
mines/forests (Percent TCDD)[d]	(63)	(65)		(65)
Dietary exposure from produce, meat, and dairy products grown in sludge-amended soil	$1x10^{-2}$	$2x10^{-10}$	240,000,000	$7x10^{-4}$
(Percent TCDD)[d]	(62)	(65)		(65)

Table 8. (Continued)

Disposal practices/exposure pathway	MEI risk[a] (lifetime^{-1})	Typical risk[a] (lifetime^{-1})	Exposed population[b]	Population risk[c] (cases/year)
Ingestion exposure from drinking ground water contaminated by leaching from soil	$<3x10^{-7}$	$<3x10^{-7}$	NA[e]	NA[e]
(Percent TCDD)[d]	(0.2)	(0.2)		
Landfill disposal of paper wastes				
Inhalation exposure from volatilization from municipal landfills in which paper is disposed:	$<9x10^{-7}$	$<9x10^{-7}$	NA[e]	NA[e]
(Percent TCDD)[d]	(16)	(16)		
Ingestion exposure from drinking groundwater contaminated by leachate from municipal landfills in which paper is disposed:	$<2x10^{-9}$	$<2x10^{-9}$	18,500,000	$<4x10^{-4}$
(Percent TCDD)[d]	(53)	(53)		(53)

[a] EPA has classified 2,3,7,8-TCDD as a "B2" carcinogen. Risks presented were calculated using the EPA unit risk estimate for 2,3,7,8-TCDD and the TEQ method. This unit risk estimate was derived using the EPA carcinogenic slope factor for 2,3,7,8-TCDD ($1.6x10^{-4}$ $(pg/kg/d)^{-1}$). Had risks been calculated using FDA's potency estimate ($1.8x10^{-5}$ $(pg/kg/d)^{-1}$), then the risks and incidences would be a factor of 8.9 lower than those presented in the table. Had risks been calculated using CPSC's potency estimate ($6.7x10^{-5}$ $(pg/kg/d)^{-1}$), then the risks would be "at least" a factor of 2.3 lower than those presented in the table. The term "at least" is used because, as discussed in Section 2.3 of this report, CPSC does not place the same emphasis on risks calculated by the TEQ method as it does for 2,3,7,8-TCDD itself when estimating carcinogenic potency.

[b] Estimates of exposed population are based on typical risk.

[c] Calculated as: [Typical Risk x Exposed Population] / [Life Expectancy].

[d] All percent TCDD values are indicated in parentheses in the table:

$$\text{Calculated as: } 100 \times \frac{[\text{Exposure to TCDD}]}{[\text{Exposure to TCDD}] + (1/10)[\text{Exposure to TCDF}]}$$

[e] NA = Not applicable.

Source: USEPA 1990.

management practices. The primary difference in these two approaches is the distribution of pulp and paper mill sludge concentrations of 2,3,7,8-TCDD and 2,3,7,8-TCDF used to estimate risks.

One approach used the distribution of concentrations of 2,3,7,8-TCDD and 2,3,7,8-TCDF reported in the 104-Mill Study data base to be present in sludge for each management practice to estimate risks to the general population from each pulp and paper mill sludge management practice considered (USEPA 1989c, 1990). In the future, however, these mills could employ sludge management practices different from those reported in the 104-Mill Study data base. The distribution of 2,3,7,8-TCDD and 2,3,7,8-TCDF concentrations in pulp and paper mill sludge handled by each management practice could change, and the estimates of risks from these practices would, therefore, also change. Consequently, a second approach based on the distribution of sludge concentrations of 2,3,7,8-TCDD and 2,3,7,8-TCDF from all pulp and paper mills in the 104-Mill Study data base was used to assess risk to the general population from each sludge management practice.

Using the second approach, these practices could be compared so that those with which the highest risks were associated could be determined without considering the influence of differences in concentrations of 2,3,7,8-TCDD and 2,3,7,8-TCDF in pulp and paper mill sludge. This second approach, also referred to as the "generic" approach, estimated typical individual risks based on mean concentrations of 2,3,7,8-TCDD and 2,3,7,8-TCDF in sludge and estimated maximum exposed individual (MEI) risks based on 90th percentile concentrations of these two dioxin congeners. The mean and 90th percentile concentrations of 2,3,7,8-TCDD in pulp and paper mill sludge were 163 ppt and 293 ppt, respectively; the mean and 90th percentile concentrations of 2,3,7,8-TCDF were 885 ppt and 1,760 ppt, respectively (USEPA 1990).

Various mathematical models were used to estimate concentrations of 2,3,7,8-TCDD and 2,3,7,8-TCDF in environmental media. These include the Seasonal Soil (SESOIL) model for fate and transport in soil (Bonazountas and Wagner 1984); the Analytical Transport One-, Two-, and Three-Dimensional (AT123D) model for fate and transport in aquifers (Yeh 1981); and the Industrial Source Complex Long-Term (ISCLT) dispersion model for fate and transport in air (Bowers et al. 1980). A detailed discussion of the methods and assumptions used to estimate environmental releases and concentrations of 2,3,7,8-TCDD and 2,3,7,8-TCDF from pulp and paper mill sludge in environmental media is provided in the risk assessment for disposal and use of pulp and paper mill sludge prepared under the guidance of the Office of Toxic Substances and the Office of Solid Waste of the U.S. Environmental Protection Agency (USEPA 1990).

2.5.3 Results and Discussion

Three types of potential carcinogenic risks were estimated: maximum exposed individual (MEI) risks, typical individual risks, and population risks. Estimates of potential general population cancer risks associated with each pulp and paper mill sludge management practice are presented in Table 8. These estimates were based on the generic approach. In general, risks estimated by the two approaches differed by no more than an order of magnitude. In all cases, exposure to 2,3,7,8-TCDF was assumed to be one-tenth the exposure to 2,3,7,8-TCDD based on the toxicity equivalency factor method (USEPA 1989a). Estimates of risks were based on the EPA slope factor of 1.6×10^{-4} $(pg/kg\text{-}day)^{-1}$. Estimates of potential MEI risks exceeded 1×10^{-6} for 15 of the 21 exposure pathways examined. The exposure pathway with the greatest potential MEI risk was ingestion of fish from surface water contaminated by runoff from landfills, surface impoundments, and land application sites. Estimates of MEI risk from this pathway ranged from 10^{-1} to 10^{-2}. Ingestion of surface water contaminated by runoff from landfills, surface impoundments, and land application sites resulted in MEI risks on the order of 10^{-3}. For land application of pulp and paper mill sludge, the second highest MEI risk resulted from ingestion of produce, meat, and dairy products grown on sludge-amended soil; the MEI risk estimated from this pathway was roughly 10^{-2}. The subsistence farmer (i.e., farmer that grows all or almost all food required by the farm family) represented the MEI for this exposure pathway. Most of the exposure pathways examined for land application of pulp and paper mill sludge resulted in MEI risks greater than 1×10^{-6}.

The only typical individual risk estimated to be greater than 10^{-6} occurs as the result of inhalation of dioxin vapors from sludge applied to agricultural land; the typical individual risk estimated from this exposure pathway was on the order of 10^{-5}. Population risks for pathways with typical individual risks greater than 10^{-6} were estimated to be very low because of the small population sizes associated with these estimates of typical risk. As with the MEI risk estimates, consumption of fish from surface water contaminated by surface runoff poses the highest population risk because of the large number of people potentially exposed; the population risk estimated from this exposure pathway was on the order of 10^{-2} excess cancer cases per year.

Because of a lack of site-specific data, hypothetical scenarios were examined; there is no direct evidence that the MEI exposure scenarios depicted actually occur. Because scant information was available regarding sludge management practices at sites receiving pulp and paper mill sludge, estimates of potential individual risk were based on exposure scenarios that depicted poor sludge management practices. For example, estimates of both typical and MEI risks assumed that runoff from landfills and surface impoundments was not controlled and would enter receiving streams used as sources of drinking water and fish ingested by humans. More sound management practices would tend to mitigate these risks. Also, because the location and hydrogeologic characteristics of the sites are not well known, generic data were used for parameters on the topography and geology of each site, the hydrology of nearby surface water bodies, the distance of each site from surface water, the land area of each site, and the quantity of sludge received at each site. Values assumed for these parameters in each typical scenario were different from those used in each MEI scenario. Assumptions used for each scenario to determine typical individual and MEI risks are presented in the risk assessment for disposal and use of pulp and paper mill sludge (USEPA 1990).

2.6 Summary of Risks to Humans from Wastewater Discharges

2.6.1 Introduction

The assessment of risks to humans from discharge of pulp and paper mill effluents is discussed in more detail in Chapter 6 of the Background Document to the Integrated Risk Assessment. The major source documents used in the Background Document for this chapter are the following:

USEPA. 1990. U.S. Environmental Protection Agency. Risk assessment for 2,3,7,8-TCDD and 2,3,7,8-TCDF contaminated receiving waters from U.S. chlorine-bleaching pulp and paper mills. Washington, DC: Office of Water Regulations and Standards, U.S. Environmental Protection Agency. August 1990.

USFDA. 1990. U.S. Food and Drug Administration. Carcinogenic risk assessment for dioxins and furans in fish contaminated by bleached-paper mills. Report of the Quantitative Risk Assessment Committee. Washington, DC: U.S. Food and Drug Administration. January 19, 1990.

Exposure pathways considered in this assessment include ingestion of untreated water downstream from pulp and paper mill effluents and ingestion of fish caught in the vicinity of pulp and paper mill effluents. Risks from ingestion of contaminated fish were estimated for average individuals who eat fish and for sports and subsistence fishers.

2.6.2 Methodology

Three approaches were used to estimate and compare exposures of humans to 2,3,7,8-TCDD and 2,3,7,8-TCDF from consumption of fish that may be contaminated by effluent discharges from pulp and paper mills. In the first approach, a simple dilution model was used by EPA to estimate in-stream contaminant concentrations and fish tissue residues downstream from each of the 104 pulp and paper mills that use chlorine as a bleaching agent. The highest estimated steady-state in-stream concentrations in the immediate downstream vicinity of the mills (assuming fully mixed conditions) were used to estimate exposure to fish. Mill-specific 5-day effluent composite concentrations of 2,3,7,8-TCDD and 2,3,7,8-TCDF collected as part of the 104-Mill Study were used for these calculations. (It is not known how representative these samples are of long-term mill discharges; also, any changes in effluent concentrations resulting from recent changes in mill processes or operations are not reflected in these data.) Similarly, mill-specific receiving stream flow rates (i.e., harmonic mean flow or zone of initial dilution information) were used in the calculations. It was assumed that 100 percent of the in-stream contaminants (both dissolved and adsorbed to suspended solids) are bioavailable to fish and that fish tissue bioavailability to humans ingesting fish is 95 percent.

The second approach used the Exposure Assessment Modeling System (EXAMS II) to partition the site-specific in-stream steady-state water column contaminant concentrations between dissolved and particulate forms. However, only the dissolved contaminant concentration predicted by EXAMS II was considered in determining exposure and risk. Because no comprehensive studies on 2,3,7,8-TCDD and 2,3,7,8-TCDF accumulation in sediments and bioaccumulation up the food chain exist, no attempt was made in the EXAMS II approach to estimate fish exposure to contaminants associated with suspended particulates, bed sediments, or the food chain.

For the third approach, FDA used actual measured residues of 2,3,7,8-TCDD and 2,3,7,8-TCDF in fish collected near pulp and paper mills as part of EPA's National Bioaccumulation Study (USEPA 1989b). FDA combined the data to develop an average fish tissue TEQ concentration, which was then used to estimate generic exposures and risks.

Tissue residue levels for fish exposed to the in-stream contaminant concentrations estimated by the first and second approaches were calculated by multiplying the highest in-stream contaminant concentration by estimated bioconcentration factors (BCFs) for 2,3,7,8-TCDD and 2,3,7,8-TCDF. BCFs of either 5,000 or 100,000 (for 2,3,7,8-TCDD) and 3,900 (for 2,3,7,8-TCDF) were used. The BCF for 2,3,7,8-TCDD of 5,000 is based on fish fillet residue levels, not whole body levels, and is the value currently used in EPA's Ambient Water Quality Criteria for 2,3,7,8-TCDD; the second BCF of 100,000 was developed primarily from the results of EPA Duluth Laboratory's recent studies on the bioconcentration of 2,3,7,8-TCDD by fish. The BCF for 2,3,7,8-TCDF is based on the geometric mean of the three measured BCF values for whole body levels reported in a recent literature review (Nabholz 1989). The BCFs (100,000 for 2,3,7,8-TCDD and 3,900 for 2,3,7,8-TCDF) developed from more recent studies were for whole body levels; to obtain estimates of levels in the edible portion of the fish, whole body levels were divided by 2, resulting in effective BCFs of 50,000 for 2,3,7,8-TCDD and 1,950 for 2,3,7,8-TCDF.

Human exposures and risks resulting from ingestion of contaminated fish were calculated for several fish consumption rates:

- 6.5 g/day (EPA--estimated average fish/shellfish consumption in U.S.);
- 13 g/day (FDA--estimated average consumption by sports fishers);
- 30 g/day (EPA--estimated typical consumption by sports fishers);
- 39 g/day (FDA--estimated 90th percentile consumption by sports fishers);
- 69 g/day (FDA--estimated average consumption by subsistence fishers);
- 116 g/day (FDA--estimated 90th percentile consumption by subsistence fishers); and
- 140 g/day (EPA--estiamted high consumption rate for subsistence fishers or other high-rate consumers).

A typical drinking water ingestion rate of 2 l/day was used to estimate human exposures through ingestion of contaminated drinking water. It was assumed that the water consumed is taken from the point of highest in-stream pollutant concentration after the effluent is fully mixed in the receiving stream and that the water is not treated to remove contaminants prior to ingestion.

2.6.3 Results and Discussion

Table 9 presents the estimated cancer risks associated with human consumption of contaminated fish. In terms of risks of non-cancer effects, the results of the EPA analysis indicate that discharges from 27 percent of mills could cause toxic liver effects upon ingestion of one 4-ounce fish serving, assuming an effective BCF of 50,000 for edible tissues compared to a 1-day health advisory dose of 100 pg/kg/day (estimated by EPA for the purpose of this assessment); assuming a BCF of 5,000, only 5 percent of the mills could cause liver effects. A higher percentage of mills discharge effluent that may cause reproductive effects from long-term, low-level exposure, based on a reference dose of 1 pg/kg/day estimated by EPA for the purpose of this assessment. Similarly, the FDA analysis indicated that subsistence fishers could be at risk for reproductive effects.

With regard to drinking water risks, use of the simple dilution method estimates that the cancer risks associated with the 69 mills evaluated range from 10^{-4} to 10^{-10}. The greatest percentage of these mills (23 mills or 33 percent) are associated with risk levels within the

Table 9. -- Estimated Cancer Risks Associated with Consumption of Contaminated Fish

Agency	Method	Consumer type	2,3,7,8-TCDD BCF[a]	Approach	Upper bound cancer risk[b] ($lifetime^{-1}$)
EPA	Site-specific	Average	5,000	Simple dilution EXAMS II	10^{-8} to 10^{-2} 10^{-8} to 10^{-3}
EPA	Site-specific	Sports	100,000	Simple dilution EXAMS II	10^{-6} to $\geq 10^{-1}$ 10^{-7} to $\geq 10^{-1}$
FDA	Generic	Sports	NA	NBS Data	10^{-5} to 10^{-3}
EPA	Site-specific	Subsistence	100,000	Simple dilution EXAMS II	10^{-6} to $\geq 10^{-1}$ 10^{-6} to $\geq 10^{-1}$
FDA	Generic	Subsistence	NA	NBS Data	10^{-4} to 10^{-3}

[a] The BCF of 5,000 for 2,3,7,8-TCDD is based on edible tissue residue levels. The BCF of 100,000 is based on whole body residue levels; to obtain estimates of levels in the edible portion of fish, this whole body BCF was divided by a factor of 2 resulting in an effective BCF of 50,000. Similarly, for 2,3,7,8-TCDF, a whole body residue BCF of 3,900 was adjusted by a factor of 2 to obtain an effective BCF of 1,950.

[b] EPA classifies 2,3,7,8-TCDD as a "B2" carcinogen. Risks presented were calculated using the TEF method; EPA estimates of risks are based on the carcinogenic slope factor estimate for 2,3,7,8-TCDD of 1.6×10^{-4} $(pg/kg/day)^{-1}$; FDA estimates are based on an estimated carcinogenic slope factor of 1.8×10^{-5} $(pg/kg/day)^{-1}$.

NA = Not applicable.

10^{-6} range. Use of the EXAMS II water column method estimates that the risk levels associated with the 64 mills evaluated using this method range from 10^{-5} to 10^{-9}. Fifty of these mills (78 percent) are associated with risk levels in the 10^{-6} (18 mills) to 10^{-7} (32 mills) range. These results are likely overestimates of human health risks because of the conservative assumptions made concerning no treatment of the water and ingestion of water at the point of highest in-stream concentration.

In evaluating the risks estimated in this assessment for ingestion of contaminated fish, it should be noted that BCFs are highly species specific. Using a single BCF does not take into account interspecies differences in the rate and degree of contaminant bioconcentration. For example, a study conducted by Cook et al. (1989) indicates that a BCF of 200,000 for whole body levels, which is higher than the upper limit used in this study (i.e., 100,000), may be applicable for 2,3,7,8-TCDD for some species of fish. EPA used two BCF values for whole body levels, 5,000 and 100,000 (50,000 for edible tissue), to put bounds on the probable range of bioconcentration by aquatic organisms.

The assumed fish tissue consumption rates also have an impact on results of this assessment. The fish tissue consumption rate of 6.5 g/day (or less than two 4-ounce meals per month) is considered an average level of fish and shellfish consumption by the general population in the United States. However, this consumption rate does not reflect the consumption rate of subsistence or sports fishers.

The predictions from the EPA assessment also do not take into consideration the mobility of fish in the receiving waters. Both resident and migrating species will move in and out of the discharge area. The first two EPA assessment approaches assume that the fish remain exposed to the predicted contaminant concentration up to the time they are caught, thus resulting in a conservative estimate of aquatic life impacts and human health risk. However, because there is strong agreement between monitored fish tissue levels (i.e., the National Bioaccumulation Study results) and modeled fish tissue levels, there is a high degree of confidence that fish downstream from pulp and paper mills are being contaminated and that humans consuming these fish at regular intervals are at risk.

It should also be noted that the assumptions made in this assessment regarding BCF, fish consumption rates, stream flow rates, and bioavailability may overestimate or underestimate risks compared to risks estimated in State risk assessments.

Taking into account the above assumptions, simplifications, and limitations, the results of this assessment indicate the potential exists for high levels of 2,3,7,8-TCDD and 2,3,7,8-TCDF contamination in the water column resulting from surface water effluent discharges from many of the chlorine-bleaching pulp and paper mills investigated. These predicted contaminant concentrations could represent significant implications for human health.

2.7 Summary of Risks Resulting from Pulp and Paper Mill Sludge Incineration

2.7.1 Introduction

The assessment of risks to humans from incineration of pulp and paper mill sludge is discussed in more detail in Chapter 7 of the Background Document to the Integrated Risk Assessment. The primary source document used for this chapter in the Background Document is as follows:

Dusetzina M. 1989. Human health exposure and risk assessment for dioxins-pulp/paper waste water sludge incineration-subtask 5. Washington, DC: U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards.

2.7.2 Methodology

Dusetzina (1989) used air dispersion modeling (i.e., HEM-Human Exposure Model) to predict potential inhalation exposures to CDDs/CDFs to populations surrounding each of the 21 pulp and paper mills that reported employing incineration as a wastewater sludge disposal method in the 104-Mill Study. The estimated exposures were used to predict both maximum exposed individual (MEI) cancer risks and aggregate (or population) risks.

Information used to estimate potential emissions (i.e., input to the air dispersion model) included the following:

(1) Combustor and flue gas characteristics of power boilers at 16 of the 21 pulp and paper mills incinerating wastewater sludges. Information used included flue gas temperature, flue gas volume, stack height, stack diameter, residence time above 1,800°F in the combustor, type of air pollution control device, air pollution control device operating temperature, and annual operating time of the combustor spent burning sludge.

(2) Dioxin and furan emission test results from a pulp and paper mill power boiler at Cloquet, Minnesota, which co-combusted wastewater sludge.

(3) Wastewater sludge characteristics as reported in the 104-Mill Study, such as sludge quantity and 2,3,7,8-TCDD and 2,3,7,8-TCDF concentrations, from facilities that disposed of their sludge by incineration.

Two methods were used to estimate emissions of CDDs/CDFs to air. The first method estimated emissions by assuming that the CDD/CDF concentrations in the stack flue gas of each power boiler were the same as the maximum measured stack gas concentrations from the one facility tested. Annual emissions were estimated by prorating the emissions based on the flue gas volumes and operating hours for each facility. The second method assumed that all 2,3,7,8-TCDD/TCDF contained in the wastewater sludge was emitted to the atmosphere. The use of the latter method to estimate emissions resulted in estimated emissions 700 to 700,000 times greater than the emission based on the stack gas monitoring data. The latter method does not consider the potential for CDD/CDF formation as products of incomplete combustion (PIC).

2.7.3 Results and Discussion

The estimate of the MEI risk using the first method (i.e., stack gas method) was 1.2×10^{-10}, which occurred at the Longview, Washington, facility. The second method (i.e., the sludge concentration method) estimated the MEI risk to be highest at the Pine Bluff, Arkansas, facility (9.3×10^{-7}). Estimated population risks were very low. The highest predicted annual incidence at any facility was 0.0002. Table 10 presents the predicted MEI and population risks for each facility.

These two methods were used to assess risks for several reasons. Relevant, although limited, data were used in each method. Although the stack gas concentration data were more limited (stack gas concentrations were available at only one stack) than the concentration data for 2,3,7,8-TCDD/TCDF in sludge, these were probably more relevant since destruction efficiency, partitioning to fly ash and bottom ash, and distribution of CDDs/CDFs in gaseous and particulate phases did not have to be characterized. Uncertainties regarding these parameters are important for the sludge concentration method. One major problem associated with the stack gas method was, of course, the limited data. Questions concerning secondary formation of CDDs and CDFs as products of incomplete combustion and effectiveness of control devices, particularly if a significant fraction of the CDDs/CDFs are in a gaseous phase, are important for the sludge concentration method.

The Office of Air Quality Planning and Standards (OAQPS) contends that the first method (i.e., the stack gas method) provides a better estimate of the performance of the boilers used at the 21 pulp and paper mill facilities that incinerate sludge than the worst-case estimates from the second method, which assumes no destruction of CDDs/CDFs in the sludge feed. The sludge charged to the power boiler for which stack gas concentration data are available uses a high sludge feed content (10 to 15 percent of feed) relative to the feed content used by the other facilities (2 to 17 percent) and therefore may represent an over-estimation of typical emissions. The second method (i.e., the sludge

Table 10. Combined Dioxin/Furan Risks and Annual Incidence[a]

Location	Maximum individual risk		Annual incidence	
	Sludge conc. method ($x10^{-7}$)	Stack gas method ($x10^{-7}$)	Sludge conc. method	Stack gas method
Pine Bluff, AR	9.3	0.000055	0.00015	<0.000001
Port Angeles, WA	3.1	0.00026	0.000013	<0.000001
Longview, WA	2.5	0.0012	0.000027	<0.000001
Texarkana, TX	1.8	0.000042	0.000098	<0.000001
Everett, WA	1.4	0.00029	0.000042	<0.000001
Lewiston, ID	1.4	0.000053	0.0000097	<0.000001
Houston, TX	1.2	0.000055	0.0002	<0.000001
Moss Point, MS	0.95	0.000049	0.000012	<0.000001
Westbrook, ME	0.16	0.000021	0.000014	<0.000001
Georgetown, SC	0.15	0.000044	0.0000016	<0.000001
Ketchikan, AK	0.15	0.000045	<0.000001	<0.000001
Roaring Springs, PA	0.12	0.00011	0.0000015	<0.000001
Tacoma, WA	0.11	0.000037	0.000034	<0.000001
West Point, VA	0.056	0.000029	<0.000001	<0.000001
Hinckley, ME	0.049	0.000011	0.0000027	<0.000001
Claiborne, AL	0.049	0.000012	<0.000001	<0.000001
Jackson, AL	0.039	0.000029	<0.000001	<0.000001
Cloquet, MN	0.038	0.0000035	<0.000001	<0.000001
Mobile, AL	0.025	0.000057	0.0000023	<0.000001
Hoquiam, WA	0.021	0.000056	<0.000001	<0.000001
Sitka, AK	0.012	0.0000091	<0.000001	<0.000001

[a] EPA classifies 2,3,7,8-TCDD as a "B2" carcinogen. Risks presented were calculated using the EPA unit risk estimate for 2,3,7,8-TCDD and the TEQ method. This unit risk estimate was derived using the EPA carcinogenic potency estimate for 2,3,7,8-TCDD (1.6×10^{-4} $(pg/kg/d)^{-1}$). Had risks been calculated using FDA's potency estimate (1.8×10^{-5} $(pg/kg/d)^{-1}$), then the risks and incidences would be a factor of 8.9 lower than those presented in the table. Had risks been calculated using CPSC's potency estimate (6.7×10^{-5} $(pg/kg/d)^{-1}$), then the risks would be "at least" a factor of 2.3 lower than those presented in the table. The term "at least" is used because, as discussed in Section 2.3 of this report, CPSC does not place the same emphasis on risks calculated by the TEQ method as it does for 2,3,7,8-TCDD itself when estimating carcinogenic potency.

concentration method), although more conservative since no destruction of CDDs/CDFs is assumed, does not account for secondary formation of CDDs/CDFs as products of incomplete combustion.

2.8 Summary of Risks Resulting from Use of and Consumer Body Contact with Paper Products Under CPSC Jurisdiction

2.8.1 Introduction

This section summarizes estimated human exposure and risks resulting from the use of consumer paper products containing 2,3,7,8-TCDD and 2,3,7,8-TCDF. The assessment of risks resulting from use of and consumer body contact with paper products is discussed in greater detail in Chapter 8 of the Background Document to the Integrated Risk Assessment. The major source document for this chapter in the Background Document is the following:

Babich MA. 1989. CPSC staff assessment of the risks to human health from exposure to chlorinated dioxins and dibenzofurans in paper products. Memorandum from Dr. Michael A. Babich (CPSC) to Lois Dicker (EPA/OTS). January 25, 1990.

2.8.2 Methodology

The paper products considered in Babich (1989) were limited to products under CPSC jurisdiction (see Table 11). They were divided into product categories, depending on the assumed exposure mechanism. Exposure was assumed to occur by means of either liquid mediated exposure or dry contact. Products involving liquid-mediated absorption included disposable infant diapers, paper towels, facial tissue, and toilet tissue. Paper towels were further divided into two scenarios, drying hands and household cleaning. Exposure by means of contact with dry paper included paper napkins and communication paper (i.e., uncoated sheets such as bond paper, books, magazines, and newsprint). Exposure to communication paper was assessed for exposures at home and in school.

Dermal exposure was treated as a two-step process: (1) migration or extraction of dioxin from paper or pulp into a liquid contacting the skin or to the surface of the skin itself, followed by (2) percutaneous absorption. The migration step may occur by either of two general mechanisms, liquid-mediated extraction or skin contact with dry paper (unmediated diffusion).

The industry average concentrations of 2,3,7,8-TCDD and 2,3,7,8-TCDF reported for pulp in the 104-Mill Study were used to estimate dermal exposures for all products except disposable diapers. For diapers, the average concentrations of 2,3,7,8-TCDD and 2,3,7,8-TCDF reported for pulp in the 104-Mill Study for those mills that produce pulp specifically for disposable diapers were used.

Table 11. Individual Lifetime and Population Cancer Risks from 2,3,7,8-TCDD and 2,3,7,8-TCDF in Consumer Paper Products

Product	2,3,7,8-TCDD LADD (pg/kg/d)	TEQ LADD (pg/kg/d)	Lifetime individual cancer risk[c]			Exposed population	Excess cancers per year		
			CPSC	EPA	FDA		CPSC	EPA	FDA
Superabsorbent Diapers	2.4×10^{-7}	6.8×10^{-7}	2.1×10^{-11} (100)	2.0×10^{-10} (35)	2.2×10^{-11} (35)	-	-	-	-
Conventional Diapers	1.7×10^{-6}	5.0×10^{-6}	1.5×10^{-10} (100)	1.4×10^{-9} (35)	1.6×10^{-10} (35)	1.0×10^{7}[d]	0.00002	0.0002	0.00002
Paper Towels (Hand Drying)	7.1×10^{-6}	1.1×10^{-5}	6.3×10^{-10} (100)	3.1×10^{-9} (64)	3.6×10^{-10} (64)	2.4×10^{8}	0.002	0.011	0.001
Paper Towels (Cleaning)	2.3×10^{-5}	5.1×10^{-5}	2.1×10^{-9} (100)	1.5×10^{-8} (45)	1.6×10^{-9} (45)	2.4×10^{8}	0.007	0.051	0.005
Facial Tissue (Normal Use)	1.3×10^{-7}	5.6×10^{-7}	1.2×10^{-11} (100)	1.6×10^{-10} (23)	1.8×10^{-11} (23)	1.2×10^{8}	0.00002	0.0003	0.00003
Facial Tissue (Makeup Removal)	7.2×10^{-6}	1.6×10^{-5}	6.4×10^{-10} (100)	4.6×10^{-9} (45)	5.2×10^{-10} (45)	1.2×10^{8}	0.001	0.008	0.0009
Toilet Tissue (Males)	3.0×10^{-6}	1.1×10^{-5}	2.7×10^{-10} (100)	3.1×10^{-9} (22)	3.6×10^{-10} (22)	1.2×10^{8}	0.0005	0.005	0.0006
Toilet Tissue (Females)	1.4×10^{-5}	5.2×10^{-5}	1.2×10^{-9} (100)	1.5×10^{-8} (22)	1.7×10^{-9} (22)	1.2×10^{8}	0.002	0.026	0.003
Communication Paper (Homes)	5.8×10^{-6}	1.3×10^{-5}	5.1×10^{-10} (100)	3.7×10^{-9} (45)	4.2×10^{-10} (45)	2.4×10^{8}	0.002	0.013	0.001
Communication Paper (School)	6.8×10^{-6}	1.5×10^{-5}	6.1×10^{-10} (100)	4.3×10^{-9} (45)	4.9×10^{-10} (45)	2.4×10^{8}	0.002	0.015	0.002
Paper Dinner Napkins	2.3×10^{-6}	5.1×10^{-6}	2.1×10^{-10} (100)	1.4×10^{-9} (45)	1.7×10^{-10} (45)	2.4×10^{8}	0.0007	0.005	0.0006

Table 11. (continued)

Product	2,3,7,8-TCDD LADD (pg/kg/d)	TEQ LADD (pg/kg/d)	Lifetime individual cancer risk[c]			Exposed population	Excess cancers per year		
			CPSC	EPA	FDA		CPSC	EPA	FDA
All Products (Male)[a]	5.0×10^{-5}	1.1×10^{-4}	4.5×10^{-9} (100)	3.2×10^{-8} (45)	3.5×10^{-9} (45)	1.2×10^{8}	0.008	0.055	0.006
All Products (Female)[b]	6.8×10^{-5}	1.6×10^{-4}	6.1×10^{-9} (100)	4.6×10^{-8} (45)	5.2×10^{-9} (45)	1.2×10^{8}	0.010	0.079	0.009

[a] Includes all products except superabsorbent diapers, facial tissues (makeup removal), and toilet tissue (females).
[b] Includes all products except superabsorbent diapers and toilet tissue (males).
[c] EPA classifies 2,3,7,8-TCDD as a "B2" carcinogen. Numbers in parentheses are the percent of estimated risk due to 2,3,7,8-TCDD.
[d] Assumes use only of conventional diapers. Resident population age 0 to 3 years.

2.8.3 Results and Discussion

The exposures and individual cancer risks estimated to result from 2,3,7,8-TCDD and 2,3,7,8-TCDD in consumer paper products under CPSC jurisdiction are summarized in Table 11. Estimates of individual cancer risk (using CPSC's cancer potency estimate) range from 1 x 10^{-11} (i.e., 10 per trillion) for facial tissues (normal use scenario) to 2 x 10^{-9} (i.e., 2 per billion) for paper towels. For all products combined, the individual risk is estimated to be 5 x 10^{-9} (i.e., 5 per billion). Use of the EPA cancer slope factor and TEQ method for assessing toxicity of 2,3,7,8-TCDF results in slightly greater risks. Use of the FDA cancer slope factor and TEQ method results in slightly lower risks.

Excess cancer risks per year in the U.S. population are also presented in Table 11. Less than one cancer case per year is expected to occur from 2,3,7,8-TCDD and 2,3,7,8-TCDF in consumer paper products. Additivity was assumed in combining risks from different products or different scenarios.

The average daily dose (ADD) values estimated for all products are well below the estimated health advisory level for protection against liver toxicity (10 days at 10 pg/kg/d) that was developed by EPA for the purposes of this assessment. Thus, the hazard index is much less than one, indicating that the risk for non-cancer effects is absent or, at most, trivial. ADD values and hazard index values are given in Table 12 for all products.

Numerous conservative but not unreasonable assumptions were used to perform this assessment. These included: (1) use of matrix/solution equilibrium partitioning coefficients for 2,3,7,8-TCDD/TCDF in assessing short-duration exposures even though equilibrium may not be reached in these short durations; (2) use of data on 2,3-dibromo-1-propanol phosphate (TRIS) transfer from cloth to skin to simulate transfer of 2,3,7,8-TCDD/TCDF from paper to skin; (3) use of correction factors to account for the effect of anatomic site, diseased/damaged skin, and individual age on percutaneous absorption; and (4) use of results of in vitro studies with human skin of percutaneous absorption of 2,3,7,8-TCDD. However, even with the use of conservative assumptions, the predicted cancer and non-cancer risks were negligible.

2.9 Summary of Risks Resulting from the Use of Pulp-Containing Medical Devices Under FDA Jurisdiction

2.9.1 Introduction

This section summarizes estimated human exposure and risk associated with the use of medical devices containing bleached wood pulp. Examples of medical devices believed to contain bleached wood pulp include scented and unscented menstrual pads and tampons, alcohol pads, surgical apparel,

Table 12. Risks of Non-Cancer Adverse Effects from 2,3,7,8-TCDD and 2,3,7,8-TCDF in Consumer Paper Products

Product	2,3,7,8-TCDD ADD[a] (pg/kg/d)	TEQ ADD[a] (pg/kg/d)	2,3,7,8-TCDD Hazard Index[b]	TEQ Hazard Index[b]
Superabsorbent Diapers	$5.3x10^{-6}$	$1.5x10^{-5}$	$5.3x10^{-7}$	$1.5x10^{-6}$
Conventional Diapers	$4.0x10^{-5}$	$1.2x10^{-4}$	$4.0x10^{-6}$	$1.2x10^{-5}$
Paper Towels (Hand Drying)	$7.1x10^{-6}$	$1.1x10^{-5}$	$7.1x10^{-7}$	$1.1x10^{-6}$
Paper Towels (Cleaning)	$2.3x10^{-5}$	$5.1x10^{-5}$	$2.3x10^{-6}$	$5.1x10^{-6}$
Facial Tissue (Normal Use)	$1.3x10^{-7}$	$5.6x10^{-7}$	$1.3x10^{-8}$	$5.6x10^{-8}$
Facial Tissue (Makeup Removal)	$1.0x10^{-5}$	$2.2x10^{-5}$	$1.0x10^{-6}$	$2.2x10^{-6}$
Toilet Tissue (Males)	$3.0x10^{-6}$	$1.1x10^{-5}$	$3.0x10^{-7}$	$1.1x10^{-6}$
Toilet Tissue (Females)	$1.4x10^{-5}$	$5.2x10^{-5}$	$1.4x10^{-6}$	$5.2x10^{-6}$
Communication Paper (Home)	$7.7x10^{-6}$	$1.7x10^{-5}$	$7.7x10^{-7}$	$1.7x10^{-6}$
Communication Paper (School)	$4.0x10^{-5}$	$8.8x10^{-5}$	$4.0x10^{-6}$	$8.8x10^{-6}$
Paper Dinner Napkins	$2.3x10^{-6}$	$5.1x10^{-6}$	$2.3x10^{-7}$	$5.1x10^{-7}$

[a] ADD is the average daily dose during the period of exposure.
[b] The hazard index is the ratio of ADD to the EPA 10-day health advisory of 10 pg/kg/d.

medical absorbent fiber, and examination gowns. The assessment of risks resulting from the use of pulp-containing medical devices under FDA jurisdiction is summarized in Chapter 9 of the Background Document to the Integrated Risk Assessment. The major source document used in the Background Document is the following:

USEPA. 1989. U.S. Environmental Protection Agency. Assessment of exposures and risks to the general population from the use of pulp-containing medical devices. Draft report. Washington, DC: U.S. Environmental Protection Agency, Office of Toxic Substances. Contract No. 68-02-4254.

2.9.2 Methodology

Medical devices believed to contain bleached wood pulp and the parameters used to estimate exposure are presented in Table 13. The industry average concentrations of 2,3,7,8-TCDD and 2,3,7,8-TCDF reported for pulp in the 104-Mill Study (data obtained from EPA's Office of Water Regulations and Standards in September 1989) were used to estimate dermal exposures, except those exposures due to products made from rayon. These concentrations were 8.5 pg/g for 2,3,7,8-TCDD and 84.4 pg/g for 2,3,7,8-TCDF. For the following specific devices, which are composed primarily of dissolved cellulose, the average concentrations in pulp for those mills producing dissolving cellulose were used; these concentrations were 0.8 pg/g for 2,3,7,8-TCDD and 3.0 pg/g for 2,3,7,8-TCDF:

Unscented menstrual tampon;
Scented menstrual tampon;
Wound dressings containing carboxymethyl cellulose;
Medical absorbent fiber; and
Hydroxypropymethyl Cellulose.

Methods and assumptions used to estimate dermal exposure were patterned after those used for assessing dermal exposures to consumer body contact products (see Section 2.8).

2.9.3 Results and Discussion

Table 14 presents estimates of risks to the general population from the use of pulp-containing medical devices. All predicted individual risks are less than 10^{-9}. Although population risks were not calculated, they are assumed to be very low, less than 0.005 cancers per year for any product.

The same assumptions regarding partitioning coefficients and percutaneous absorption rates that were used to assess dermal exposures to body contact papers in Section 2.8 were used here to assess dermal exposures to 2,3,7,8-TCDD and 2,3,7,8-TCDF in medical devices. As with

Table 13. Exposure/Risk Parameters for Medical Devices

Device name[a]	Contact type[a]	Device mass[a] (gm)	Pulp in product[a] (%)	Pulp mass in product[a] (gm)	Exposure duration[a] (days/ lifetime)	Volume of liquid on skin/ total volume[b] (%)	Wetting factor[b] (%)	Absorbtion rate through skin[c] (%)	Partition coefficient[c] TCDD	Partition coefficient[c] TCDF
Unscented Menstrual Pad	Skin	10	90	9	2,400	25	10	25	14,300	5,300
Scented Menstrual Pad	Skin	10	90	9	2,400	25	10	25	14,300	5,300
Unscented Menstrual Tampon	Intact Nat. Channel	3-5	90	3.6	2,400	100	100	100	14,300	5,300
Scented Mentrual Tampon	Intact Nat. Channel	3-5	90	3.6	2,400	100	100	100	14,300	5,300
Alcohol Pads	Skin	0.5-1	100	0.75	6	100	100	25	2,000	2,000
Skin Prep. Wipe for Dressing Wounds	External, Short Term	2			NA	50	10	25	14,300	5,300
Absorbable Hemostatic Agents	Internal, Short Term	3-5	100	4	NA	100	100	100	14,300	5,300
Wound Dressings Containing Carboxymethyl Cellulose	Compromised Tissue	4	100		NA	50	50	100	14,300	5,300
Surgical Apparel: Hood, Cap, Masks, Gowns, Foot Cov., Drapes	External	150 (GWNS) 7-10 (MSKS)	100	150 8.5	0.17	NA	NA	0.30	NA	NA
Adult Diapers	Skin	113.5	90	102.2	730	0.017	10	25	14,300	6,300
Medical Disposable Bedding	Skin	113.5	100	113.5	1	NA	NA	0.30	NA	NA
Medical Absorbent Fiber	Skin	<0.5	100	0.5	17.7	50	100	25	14,300	5,300
Absorbent Tipped Applicator	Skin	0.25	50	0.12	17.7	100	100	25	2,000	2,000
Examination Gown	Skin	113.5	100	113.5	0.6	NA	NA	0.30	NA	NA
Ophthalmic Sponges	Surgical Aids	0.5	100	0.5	0.08	100	100	100	14,300	5,300
Hydroxypropymethyl Cellulose	Intraocular Surg Aid	<1 ml	100	1	0.08	100	100	100	14,300	5,300
Cottonoid Paddie	Compromised Tissue	2	<1	0.002	0.5	100	100	100	2,000	2,000
Electro Conductive Media	Skin Surface(Intact)	1-5	<1	0.003	2	100	100	25	2,000	2,000
Cutaneous Electrode	Skin Surface(Intact)	1-5	<1	0.003	2	100	100	25	2,000	2,000
Anesthetic Conduction Filter	No Direct Contact	2-3	100	2.5						
Breathing Circuit Bacteria Filter	No Direct Contact	2-3	100	2.5						
Heat & Moisture Condensers	No Direct Contact	2-3	100	2.5						
Isolation Gowns	External	150	100	150	0.17	NA	NA	0.30	NA	NA

NA - Not applicable

[a] Data obtained from FDA/CDRH (Stratmeyer (1989) or telephone conversations between Versar and FDA).

[b] Assumptions by Versar and FDA based on best available data and expected use patterns.

[c] Based on data obtained from Babich (1989) and Babich et al. (1989) (Section 2.8 of this technical summary).

Table 14. Estimates of Cancer Risks to the General Population from the Use of Pulp-Containing Medical Devices

Device name	Lifetime average daily dose (LADD)[a] (pg/kg/day) 2,3,7,8-TCDD	Lifetime average daily dose (LADD)[a] (pg/kg/day) TEQ	Lifetime individual cancer risk[b,c,d] EPA	2,3,7,8-TCDD (%)	FDA	2,3,7,8-TCDD (%)	CPSC	2,3,7,8-TCDD (%)	Potentially exposed population
Unscented Menstrual Pad	4.49E-08	1.65E-07	4.68E-11	27	5.25E-12	27	4.01E-12	100	3.96E+07
Scented Menstrual Pad	4.49E-08	1.65E-07	4.68E-11	27	5.25E-12	27	4.01E-12	100	3.71E+07
Unscented Menstrual Tampon	2.70E-07	5.43E-07	1.54E-10	50	1.73E-11	50	2.41E-11	100	2.83E+07
Scented Menstrual Tampon	2.70E-07	5.43E-07	1.54E-10	50	1.73E-11	50	2.41E-11	100	5.20E+06
Alcohol Pad	2.67E-09	5.32E-09	1.51E-12	50	1.70E-13	50	2.39E-13	100	1.0E+06 - 1.0E+07
Skin Prep. Wipe for Dressing Wounds	2.08E-10	7.64E-10	2.17E-13	27	2.43E-14	27	1.86E-14	100	Millions
Absorbable Hemostatic Agent	1.66E-08	6.11E-08	1.73E-11	27	1.95E-12	27	1.48E-12	100	Millions
Wound Dressing Containing Carboxymethyl Cellulose	7.82E-12	1.57E-11	4.46E-15	50	5.01E-16	50	6.99E-16	100	Hundreds of Thousands
Surgical Apparel: Hood, Cap, Mask, Gown, Foot cov., Drape	3.64E-07	7.25E-07	2.06E-10	50	2.31E-11	50	3.25E-11	100	Millions (patients) Thousands (health care)
Adult Diaper	1.05E-10	3.43E-10	9.73E-14	31	1.09E-14	31	9.41E-15	100	1.0E+06 - 1.0E+07
Medical Disposable Bedding	1.62E-06	3.23E-06	9.15E-10	50	1.03E-10	50	1.45E-10	100	1.0E+06 - 1.0E+07
Medical Absorbent Fiber	3.46E-11	6.96E-11	1.97E-14	50	2.22E-15	50	3.09E-15	100	1.0E+06 - 1.0E+07
Absorbent-Tipped Applicator	1.26E-09	2.51E-09	7.13E-13	50	8.00E-14	50	1.13E-13	100	1.0E+06 - 1.0E+07
Examination Gown	9.71E-07	1.94E-07	5.49E-10	50	6.16E-11	50	8.67E-11	100	1.0E+06 - 1.0E+07
Ophthalmic Sponge	1.58E-11	5.15E-11	1.46E-14	31	1.64E-15	31	1.42E-15	100	
Hydroxypropymethyl Cellulose	2.50E-12	5.03E-12	1.43E-15	50	1.60E-16	50	2.24E-16	100	1.5 Million Cataract Oper./Year
Cottonoid Paddie	2.38E-12	4.74E-12	1.34E-15	50	1.51E-16	50	2.12E-16	100	Millions
Electro-Conductive Media	3.56E-12	7.10E-12	2.01E-15	50	2.26E-16	50	3.18E-16	100	Millions
Cutaneous Electrode	3.56E-12	7.10E-12	2.01E-15	50	2.26E-16	50	3.18E-16	100	Millions
Anesthetic Conduction Filter[e]									Millions
Breathing Circuit Bacteria Fltr.[e]									Millions
Heat and Moisture Condensers[e]									Millions
Isolation Gown	3.64E-07	7.25E-07	2.06E-10	50	2.31E-11	50	3.25E-11	100	Millions (patients) Thousands (health care)

Table 14. (continued)

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[a] LADDs were calculated as follows:

$$\frac{\left(\text{Concentration}\ \left(\frac{pg}{g}\right) \times \text{Pulp Mass}\ \left(\frac{g}{day}\right) \times \text{Exposure Duration (Days)} \times \text{Volume of Liquid on Skin/Total Volume} \times \text{Wetting Factor (unitless)} \times 1/\text{Partition Coefficient (unitless)} \times \text{Absorption Rate (\%)}\right)}{\text{Body Weight (Kg)} \times \text{Lifetime (70 years)} \times 365\ \text{days/year}}$$

There were two exceptions, however. The first exception was the method to estimate LADD for surgical apparel, medical disposable bedding, examination gowns, and isolation gowns. The other exception was for products where FDA already estimated the total mass of the product available for exposure (skin prep. wipe for dressing wounds, absorbable hemostatic agents, and wound dressings containing carboxymethyl cellulose). In this case, LADD was estimated as follows:

$$\frac{(\text{Concentration} \times \text{Total Mass Exposed} \times \text{Volume of Liquid on Skin/Total Volume} \times \text{Wetting Factor} \times 1/\text{Partition Coefficient} \times \text{Absorption Rate})}{\text{Body Weight} \times 70\ \text{years} \times 365\ \text{days/year}}$$

[b] The slope factors for 2,3,7,8-TCDD are as follows: EPA = 1.6×10^{-4} $(pg/kg\ day)^{-1}$; FDA = 1.8×10^{-5} $(pg/kg\ day)^{-1}$; CPSC = 6.7×10^{-5} $(pg/kg/day)^{-1}$.

[c] The slope factors for 2,3,7,8-TCDF are as follows: EPA = 1.6×10^{-5} $(pg/kg\ day)^{-1}$; FDA = 1.8×10^{-6} $(pg/kg\ day)^{-1}$; CPSC = 0.

[d] For EPA and FDA cancer slope factors, risk was estimated as follows: Risk = potency factor $(pg/kg\text{-}day)^{-1}$ x LADD (pg/kg-day)/0.55. However, for the CPSC cancer slope factor, risk was estimated as follows: Risk = potency factor $(pg/kg\text{-}day)^{-1}$ x LADD (pg/kg-day) / 0.75. The divisor is changed to 0.75 (from 0.55) because a different bioassay was used. The total risk is the sum of the risks from TCDD and TCDF.

[e] *There will be no direct contact for these products. The only potential exposure route is through inhalation of dioxin that leaves the filter or* condenser and enters the indoor air. Exposure through this pathway is expected to be negligible because only a very small amount of dioxin will leave these products and enter the air, and of the amount that does enter indoor air, very little will actually enter the lungs and be absorbed.

that assessment, this assessment required many other assumptions to compensate for lack of firm data characterizing product composition and the duration and frequency of product use. In general, conservative assumptions were made when reliable information was not available. However, even with the use of conservative assumptions, the predicted cancer risks are negligible (all less than 10^{-9}). Even though population risks were not estimated in the assessment, the results in Table 13 indicate that less than one excess cancer case per year would be expected from all products combined.

2.10 <u>Summary of Risks from Ingestion of Foods Contacting or Packaged in Bleached Paper Products</u>

2.10.1 Introduction

This risk assessment is discussed in more detail in Chapter 10 of the Background Document to the Integrated Risk Assessment. The primary source document used for this chapter in the Background Document is the following:

USFDA. 1990. U.S. Food and Drug Administration. Carcinogenic risk assessment for dioxins and furans in foods contacting bleached paper products. Report of the Quantitative Risk Assessment Committee. Washington, DC: U.S. Food and Drug Administration.

This assessment examined risks to (1) individuals in the U.S. population consuming average amounts of all foods that may have contacted bleached paper products (i.e., mean consumers - total sample basis) and (2) individuals who have been identified as "eaters" of various individual foods at mean and 90th percentile intake levels that contact specific bleached paper products (i.e., eaters only - food-by-food basis).

2.10.2 Methodology

Tables 15 and 16 list the bleached paper products and the associated foods for which exposures and risks were estimated for the "mean consumers - total sample basis" and "eaters only - food-by-food basis", respectively. Tables 15 and 16 also present the values used for two major parameters needed to estimate exposure: 2,3,7,8-TCDD TEQs in food and individual food intake rates. Data on TEQ levels in paper are also presented in Table 15. Concentrations of 2,3,7,8-TCDD TEQs assumed for the paper products were based on one of three data sets:

(1) Concentrations in milk, cream, and juice cartons were based on analytical data provided by the paper industry for the five manufacturers of all paperboard used for these cartons.

Table 15. Carcinogenic Risk for Consumers Resulting from Total Dioxin TEQ Intake from All Foods Contacting Bleached Paper ("mean consumer - total sample basis")

Food[a] (paper article)	Paper TEQ[b] levels (ppt)	TEQ levels in food (ppq)	Food intake per eating event (g)	Avg. daily food intake per person (grams/day)	Daily TEQ intake per person (pg/day)
1. Milk (cartons)	2	5	191	124	0.62
2. Coffee (filters)	8.8	3.2	332	136	0.44
3. Cream (cartons)	2	5	23.8	1.4	0.007
4. Juice (cartons)	2	15	190	36	0.54
5. Coffee (cups)	10.1	0.8	332	136	0.11
6. Soup (cups)	10.1	23	292	56	1.3
7. Meals-seasoned meat, vegs. (dual-oven trays)	10.6	35	215	61	2.1
8. Meals-seasoned meat (paper plates)	7.9	140	340[c]	37	5.2
9. Popcorn (microwave bags)	5.9	45	d	1.6	0.072
10. Donuts, sweet rolls (bakery cartons)	13.8	50	67.8	7.7	0.39
11. Frozen dairy desserts (ice cream cartons)	13.8	50	110	23	1.2
12. Tea (bags)	17	8	301	22	0.12
13. Margarine (wrap)	17	82	10.8	7.3	0.60
			Upper bound		12.7
			Lower bound[e]		5.5
			Best estimate[f]		9.1**

**The corresponding upper bound lifetime risks were estimated to be 2.4×10^{-6} based on FDA's slope factor, 2.1×10^{-5} based on EPA's slope factor, and 6.7×10^{-6} based on CPSC's slope factor.

[a]Food intake reported by Market Research Corporation of America (MRCA) obtained by multiplying the MRCA mean frequency of eating occasions (1982-87 5-year Menu Census) by the mean grams/eating occasions from USDA/NFCS, 1977-78 (Pao et al. 1982). Data are for the 2+ years age group, males and females, total sample population.

[b]104-mill average for producers (except updated for milk, cream, and juice carton producers) (API 1990). The value for items 10-13 is the total 104-Mill Study average for bleached wood pulp.

[c]Food intakes based on NCASI production of 20 billion plates/yr and assumptions of 80 plates/person/year, 2 plates per eating occasion, and 340 g food per eating occasion.

[d]NCASI per capita consumption estimate based on 1.4 billion bags sold in the U.S. in 1989. No survey data available for microwaveable popcorn.

[e]Estimate based on industry production figures for paper products.

[f]Midrange of lower and upper bound estimates.

Table 16. Upper Bound Carcinogenic Risk for Consumers of Foods Contacting Bleached Paper Contaminated with Dioxin ("eaters only - food-by-food basis")

Food[a,b] (paper article)	TEQ levels in food (ppq)	Food intake[c] (g/p/d) mean/90th %tile	Upper bound lifetime risk[d,e]					
			Mean intake			90th percentile intake		
			FDA	EPA	CPSC	FDA	EPA	CPSC
Milk (cartons)	5	170/408	2.2×10^{-7}	2.0×10^{-6}	6.2×10^{-7}	5.5×10^{-7}	4.9×10^{-6}	1.5×10^{-6}
Coffee (filters)	3.2	278/641	2.4×10^{-7}	2.1×10^{-6}	6.7×10^{-7}	5.3×10^{-7}	4.7×10^{-6}	1.5×10^{-6}
Cream (cartons)	5	7.3/18.7	1.0×10^{-8}	8.9×10^{-8}	2.8×10^{-8}	2.6×10^{-8}	2.3×10^{-7}	7.3×10^{-8}
Juice (cartons)	15	72/179	2.9×10^{-7}	2.6×10^{-6}	8.1×10^{-7}	6.0×10^{-7}	5.3×10^{-6}	1.7×10^{-6}
Coffee (cups)	0.8	278/641	5.9×10^{-8}	5.2×10^{-7}	1.6×10^{-7}	1.4×10^{-7}	1.2×10^{-6}	3.9×10^{-7}
Soup (cups)	23	74/148	4.5×10^{-7}	4.0×10^{-6}	1.3×10^{-6}	9.1×10^{-7}	8.1×10^{-6}	2.5×10^{-6}
Meals-seasoned meat, vegs. (dual-oven trays)	35	64/108	5.9×10^{-7}	5.2×10^{-6}	1.6×10^{-6}	9.9×10^{-7}	8.8×10^{-6}	2.8×10^{-6}
Meals-seasoned meat (paper plates)	140	37/74[f]	1.4×10^{-6}	1.2×10^{-5}	3.9×10^{-6}	2.7×10^{-6}	2.4×10^{-5}	7.5×10^{-6}
Popcorn (microwave bags)	45	16/32[g]	1.9×10^{-7}	1.7×10^{-6}	5.3×10^{-7}	3.7×10^{-7}	3.3×10^{-6}	1.0×10^{-6}
Donuts, sweet rolls (bakery cartons)	50	15/29	2.1×10^{-7}	1.9×10^{-6}	5.9×10^{-7}	4.0×10^{-7}	3.6×10^{-6}	1.1×10^{-6}
Frozen dairy desserts (ice cream cartons)	50	32/63	4.3×10^{-7}	3.8×10^{-6}	1.2×10^{-6}	8.5×10^{-7}	7.6×10^{-6}	2.4×10^{-6}

Table 16. (continued)

Food[a,b] (paper article)	TEQ levels in food (ppq)	Food intake[c] (g/p/d) mean/90th %tile	Upper bound lifetime risk[d,e]					
			Mean intake			90th percentile intake		
			FDA	EPA	CPSC	FDA	EPA	CPSC
Tea (bags)	8	120/284	2.6×10^{-7}	2.3×10^{-6}	7.3×10^{-7}	6.1×10^{-7}	5.4×10^{-6}	1.7×10^{-6}
Margarine (wrap)	82	9/19	2.0×10^{-7}	1.8×10^{-6}	5.6×10^{-7}	4.3×10^{-7}	3.8×10^{-6}	1.2×10^{-6}

[a]Food intake obtained by multiplying the MRCA mean and 90th percentile frequencies of eating occasions (14-day average, 1982-87 5-year Menu Census) (MRCA 1988) by the mean grams/eating occasion from USDA/NFCS, 1977-78 (Pao et al. 1982). Data are for the 2+ years age group, males and females, eaters-only population.

[b]See Table 15, footnote [b] for TEQ levels in the paper article.

[c]Mean/90th percentile values.

[d]Assumes a typical body weight of 60 kg for an adult.

[e]EPA classifies 2,3,7,8-TCDD as a "B2" carcinogen.

[f]See Table 15, footnote [c]. Because of the conservatism of the per capita estimate, FDA selected 37 g/p/d to represent the mean food intake eaters-only value as well. The 90th percentile value was assumed to be 2 times the mean. This is reasonably consistent with the relationship between the mean and 90th percentile figures for the other entries in the table.

[g]NCASI estimated per capita consumption of 1.6 g/person/day based on 1.4 billion bags sold in the U.S. in 1989. To obtain the eaters-only mean intake, FDA assumed that all microwaveable popcorn is consumed by only 10% of the U.S. population. The 90th percentile value was assumed to be 2 times the mean.

(2) Concentrations in coffee filters, cup stock, dual-ovenable trays, paper plates, bakery cartons, ice cream cartons, and microwave popcorn bags were based on the average of the 104-Mill Study results for those pulp mills known to produce pulp for these specific products.

(3) Concentrations in tea bags and margarine wraps were based on the average TEQ concentrations for all pulps analyzed in the 104-Mill Study.

For the "mean consumer - total sample basis" assessment, food intake rates for individual foods were calculated by multiplying the mean frequency of eating occasions by the mean intake rate per eating occasion for the total sample population based on the Market Research Corporation of America's (MRCA) 1982-87 5-Year Menu Census. The "mean consumer - total sample basis" food intake rates include data for all individuals sampled and, therefore, consider individuals that do not eat the food item of concern as well as those individuals that do. Consequently, the mean food intake rates for the "mean consumer - total sample basis" are somewhat lower than those for the "eaters only - food-by-food basis." For the "eaters only - food-by-food basis" assessment, food intake rates for individual foods were calculated by multiplying the MRCA mean and 90th percentile frequency of eating occasions by the mean intake rate per eating occasion for "eaters only" reported in the USDA's 1977-78 National Food Consumption Survey.

The paper industry conducted a series of migration tests on paper food-contact products identified by FDA as high-priority products. These studies were performed under conditions intended to closely simulate actual food-contact applications. The results of these tests form the basis for FDA's estimates of rates of dioxin migration from paper into food. Migration studies were performed on coffee filters, milk cartons, cream cartons, orange juice cartons, cup stock and paper stock for hot foods, dual-ovenable trays, and microwave popcorn bags. For those paper product/food combinations not tested (i.e., bakery cartons, frozen dairy cartons, tea bags, and margarine wraps), migration rates developed for a similar type of paper product were used as surrogate values.

2.10.3 Results and Discussion

Table 15 presents the results of the cancer risk assessment for the "mean consumer - total sample basis." The estimates of lifetime upper bound individual lifetime cancer risk range from 2.4×10^{-6} (using FDA's cancer slope factor) to 2.1×10^{-5} (using EPA's cancer slope factor).

Table 16 presents the results of the cancer risk assessment for the "eaters only - food-by-food basis." The maximum estimated risks for mean consumers (eaters only) of any of the food products is less than 1.4 x

10^{-6} using FDA's cancer slope factor and less than 1.2 x 10^{-5} using EPA's cancer slope factor. The risks for 90th percentile (eaters-only) consumers of individual foods are approximately two times greater than risks for the mean (eaters-only) consumer.

FDA used an ADI of 1-10 pg/kg/day to assess non-cancer risks of potential exposures. This is the most sensitive non-cancer toxicological endpoint associated with dioxin exposure in animal studies. Although the estimated daily exposures in units of pg/kg/body weight/day are not shown in Tables 15 and 16, the calculated exposures were all less than the ADI.

The major uncertainties inherent in this assessment concern assumptions regarding food intake rates and dioxin migration rates. The estimation of exposure to TCDD and TCDF from consumption of all foods contacting paper articles requires consideration of appropriate food intake information. Available nationally representative food consumption data bases, however, do not provide information on whether foods are sold, held, heated, cooked, or served in contact with different types of materials. Therefore, for estimating the total dioxin TEQ intake from all foods that may contact bleached paper, available food consumption data for average consumers of each of the foods were used in conjunction with the assumption that all such foods have indeed been in contact with bleached paper prior to being consumed. This necessary assumption leads to an overestimate of consumption of food that has been in contact with paper and, hence, to an overestimate of total dioxin TEQ exposure.

This upper bound estimate of total dioxin TEQ exposure (12.7 pg/p/day) was adjusted through a comparison with a lower bound estimate of dioxin TEQ exposure, specifically, a per capita exposure obtained using industry-provided production figures and estimates of the amount of food that might contact the paper. Recognizing that a reasonable estimate should fall between the upper and lower bound estimates, FDA derived a "best estimate" of mean total dioxin TEQ exposure of 9.1 pg/person/day. This value is the mid-point between the upper and lower bound estimates.

For the "eaters only - food-by-food basis" assessment, it was also assumed that all foods consumed have indeed been in contact with bleached paper prior to being consumed. The other assumptions used for the total population exposure analysis also apply to the "eaters-only" analysis. Therefore, the dioxin TEQ intakes in Table 16 may also be considered as upper bound estimates of mean and 90th percentile for "eaters" of each of the foods. The dioxin TEQ exposures in Table 16 must not be summed because the population of eaters is not the same for each food category.

All of the migration studies demonstrated detectable levels of transfer of the dioxin congeners to the test foods. The temperature of foods, their composition, the nature of the paper article, and the dioxin congener levels in the paper articles were all found to influence the extent of transfer to test foods. Recent production lots of paper and paperboard used in food applications have been shown to have significantly lower levels of dioxin congeners than the levels used for this assessment. Therefore, the risks from these articles should be expected to be lower. However, FDA has not used these recently submitted figures to try to estimate lower risks because the quality and the completeness of these reports have not been assessed and migration studies that might show the extent of reduced exposure (and risk) have not been conducted.

Even considering these uncertainties, the results of the assessment of individual lifetime cancer risks indicate a potentially significant risk is posed by "current" (i.e., as used in this assessment) levels of dioxin in paper food contact product. Although individual risks are not high, the potentially exposed population is much larger than any other exposed population group addressed in the Integrated Assessment.

2.11 Summary of Risks from Use of Food, Drug, and Cosmetic Products Containing Cellulose Derivatives

2.11.1 Introduction

This section summarizes human exposures and risks estimated from use of food, drug, and cosmetic products containing cellulose derivatives. The assessment of risks resulting from use of food, drug, and cosmetic products containing cellulose derivatives is discussed in greater detail in Chapter 11 of the Background Document to the Integrated Risk Assessment. Exposure pathways examined were dermal exposures to cosmetic products and ingestion of food additives and drugs. Products analyzed included cosmetic products; all foods, including high-fiber breads; and drugs such as tablet binders and laxatives. The major source documents for this chapter in the Background Document are the following:

USFDA. 1990. U.S. Food and Drug Administration. Carcinogenic risk assessment for dioxins and furans in cosmetic products containing cellulose derivatives produced from bleached wood pulp. Report of the Quantitative Risk Assessment Committee. Washington, DC: U.S. Food and Drug Administration.

USFDA. 1990. U.S. Food and Drug Administration. Carcinogenic risk assessment for dioxins and furans in cellulose derivatives used in foods and ingested drug products. Report of the Quantitative Risk Assessment Committee. Washington, DC: U.S. Food and Drug Administration.

2.11.2 Methodology

(1) Cosmetic products. Powdered cellulose and various cellulose ethers are used in a wide range of leave-on type cosmetic products (e.g., lotions, creams, and powders) and wash-off type products (e.g., shampoos, conditioners, and dentifrices). The leave-on products are reported to contain less than 2 percent cellulose derivatives, while the wash-off products are reported to contain less than 1 percent. It was assumed that all cosmetic products are likely to contain the derivatives, and it was assumed that the derivatives are present at the maximum levels discussed above.

To account for the high amount of cosmetics used by some individuals, 90th percentile daily use rates for various products were derived by combining information on the average amount of cosmetic product used per application with 90th percentile frequency of use data. Standard factors used by FDA to account for the extent to which wiping, wearing off, or washing remove the products from the skin were combined with the usage data to identify those products that present the greatest potential for dioxin exposure. Three generic products (dentifrices, body lotions, and hair shampoos) were identified that dominate the potential for exposure.

The data available on 2,3,7,8-TCDD/TCDF concentrations in pulp from which cellulose-derived products are prepared indicate nondetectable levels. For this assessment, it was assumed that the cellulose derivatives contain 0.3 ppt of dioxin TEQ. This value represents approximately one-half the detection limit of the method used for analysis of dioxins in pulp.

As discussed in Sections 2.8 and 2.9, evaluation of the limited data available on percutaneous absorption of 2,3,7,8-TCDD indicates that an assumption of 25 percent absorption over a 24-hour period is not unreasonable. Therefore, this value was used in the assessment.

(2) Cosmetic wet wipes. Cosmetic wet wipes used to wipe hands and used in diaper changes are manufactured using either synthetic fibers or bleached pulp. Industry-supplied data indicate that wipes dispensed from pop-up containers do not contain any pulp; however, those that are dispensed from tubs in which the wipes lie flat in a stack are composed of bleached pulp (75 to 85 percent of dry weight) with the remaining material being binders and synthetic fibers. Potential exposure to dioxin congeners in the wet wipes made from bleached pulp can occur as a result of migration from the web into the lotion during extended storage, transfer of the lotion to the skin during wet wipe usage, and dermal uptake during the time between wet wipe usage and subsequent washing of the skin.

The following assumptions were used to estimate exposures:

- The dioxin TEQ in wet wipes was assumed to be 17 ppt, based on the average pulp level in 104-Mill Study;

- The dioxin TEQ/wet wipe lotion partition coefficient was assumed to be 300, based on empirical data from ongoing industry studies;

- The percent of lotion transferred from wipes to skin equals 20 percent for infants and 2 percent for adults;

- 25 percent of the dioxin TEQ is absorbed by the skin;

- 8 wet wipes are used daily.

(3) <u>Food additives and drugs</u>. Cellulose and cellulose-derived esters and ethers are used in food and drug formulations to produce certain effects such as anticaking, thickening, and stabilizing. Foods such as baked goods (e.g., bread, cookies, rolls, pie fillings, icings), dairy products (e.g., ice cream, whipped toppings, milkshakes), pasta, sausage casings, diet beverages, candy, dried fruits, and flavorings are foods identified by the paper industry that may contain powdered cellulose. Cellulose derivatives are also widely used in the formulation of drug tablets, suspensions, and creams.

The following assumptions and data were used to estimate the upper bound carcinogenic risk of exposure to dioxins and furans by ingestion of food and drugs containing cellulose and cellulose derivatives:

- As previously stated, the data available on 2,3,7,8-TCDD/TCDF concentrations in pulp from which cellulose-derived products are prepared indicate nondetectable levels. Dioxin and related furan were assumed to be present in pulps at one-half the average detection limit (i.e., about 0.3 ppt), based on the 104-Mill Study.

- It was assumed that the chemical and mechanical processing steps used to prepare the cellulose derivatives do not increase the residual levels of dioxins and furans above the levels assumed to be present in the bleached wood pulp used to manufacture these derivatives.

- It was assumed that 100 percent of the U.S. population eat at least one food containing a cellulose derivative.

- Estimates of food intake for the foods of interest were obtained from a 5-year (1982-87) Menu Census data base that contains 14 consecutive days of data and is likely to be representative of a typical diet for all age groups (MRCA 1987). The intake values for each food item were multiplied by the use levels of the appropriate cellulose derivative to obtain the intake estimate for the cellulose derivative. The intake estimate for each cellulose derivative was multiplied by its dioxin TEQ concentration to obtain the set of dioxin TEQ intakes that could be summed to provide an upper bound total population mean dioxin TEQ intake.

- Daily ingestion of cellulose derivatives resulting from chronic consumption of tablets was assumed to be less than 1 g/person/day (based on FDA data).

- The use of either methyl cellulose or sodium carboxymethyl cellulose in laxatives can result in daily doses of either of these derivatives as high as 6 g/person/day (Handbook of Nonprescription Drugs, 7th ed., 1982).

2.11.3 Results and Discussion

Table 17 summarizes the estimated exposures and risks for the cosmetic products, wet wipes, and food and drug additives.

As discussed in the methods section (Section 2.11.2), numerous conservative but reasonable assumptions were used to estimate exposures and risks. However, even with the use of conservative assumptions, the predicted individual cancer risks are very low, particularly for the cosmetic products containing cellulose derivatives and the cosmetic wet wipes. However, the potentially exposed population could be quite large, numbering in the millions. Also, although non-cancer risks were not assessed in the source documents, comparison of the daily exposure estimates in Table 17 with the estimated RFD of 1 pg/kg/day and the estimated health advisories of 10 to 300 pg/kg/day that were developed by EPA for this assessment indicates that the exposures pose minimal risk of non-cancer effects.

2.12 Summary of Risks to Wildlife from Land Application of Pulp and Paper Mill Sludge and to Aquatic Life from Discharge of Effluents

2.12.1 Introduction

This section summarizes risks to wildlife from land application of sludge and to aquatic life from discharge of effluents containing 2,3,7,8-TCDD and 2,3,7,8-TCDF. The assessment of these risks is described in greater detail in Chapter 13 of the Background Document to

Table 17. Upper Bound Carcinogenic Risk for Users of Food, Drug, and Cosmetic Products Containing Cellulose Derivatives

User	Lifetime average dioxin TEQ exposure (pg/kg/day)	Upper bound lifetime risk[c]		
		FDA	EPA	CPSC
<u>Cosmetic Products</u>				
Dentifrice user	8×10^{-6}	1.3×10^{-10}	1.2×10^{-9}	3.6×10^{-10}
Lotion user	8×10^{-5}	2.4×10^{-9}	2.1×10^{-8}	6.7×10^{-9}
Shampoo user	1.6×10^{-6}	4.7×10^{-11}	4.2×10^{-10}	1.3×10^{-10}
<u>Cosmetic Wet Wipes</u>				
Wet wipe (adult)	1.8×10^{-5} (2.2×10^{-4})[a]	5.8×10^{-10}	5.2×10^{-9}	1.6×10^{-9}
Wet wipe (infant)	5.6×10^{-4} (1.3×10^{-2})[a]	1.6×10^{-8}	1.4×10^{-7}	4.5×10^{-8}
<u>Food and Drugs</u>				
All foods	2.3×10^{-2}	4×10^{-7}	3.6×10^{-6}	1.1×10^{-6}
High-fiber bread	1.5×10^{-2} (2.7×10^{-2})[b]	2×10^{-7} (4×10^{-7})[b]	1.8×10^{-6} (3.6×10^{-6})[b]	5.6×10^{-7} (1.1×10^{-6})[b]
Tablet binders	5×10^{-3}	8×10^{-8}	7.1×10^{-7}	2.2×10^{-7}
Laxatives	3×10^{-2}	5×10^{-7}	4.4×10^{-6}	1.4×10^{-6}

[a]Value in parenthesis denotes the daily dose during the period of exposure (i.e., 3 years for infant and 6 years for adult).
[b]Value in parenthesis denotes exposure and risk for 90th percentile consumption rate.
[c]EPA has classified 2,3,7,8-TCDD as a "B2" carcinogen.

the Integrated Risk Assessment. The major source documents for this chapter in the Background Document are the following:

NYDEC. 1987. New York Department of Environmental Conservation. Niagara River biota contamination project: fish flesh criteria for piscivorous wildlife. Technical Report 87-3. Division of Fish and Wildlife, Bureau of Environmental Protection.

Rabert WS. 1990. An update on the environmental effects of TCDD and TCDF releases from pulp and paper mills on aquatic and terrestrial animals. U.S. Environmental Protection Agency, Office of Toxic Substances, Health and Environmental Review Division. Memorandum to P. Jennings, EPA, Exposure Assessment Branch. June 26, 1990.

USEPA. 1990a. U.S. Environmental Protection Agency. Risk assessment for 2,3,7,8-TCDD and 2,3,7,8-TCDF contaminated receiving waters from U.S. chlorine-bleaching pulp and paper mills. Washington, DC: Office of Water Regulations and Standards, U.S. Environmental Protection Agency. August 1990.

USEPA. 1990b. U.S. Environmental Protection Agency. Assessment of risks from exposure of humans, terrestrial and avian wildlife, and aquatic life to dioxins and furans from disposal and use of sludge from bleached kraft and sulfite pulp and paper mills. Washington, DC: Office of Toxic Substances and Office of Solid Waste. EPA 560/5-90-13.

2.12.2 Methodology

(1) Methodology for assessment of risks to wildlife. Exposure of wildlife to dioxins and furans occurs as a result of ingestion of prey items that have bioconcentrated 2,3,7,8-TCDD and 2,3,7,8-TCDF and also as a result of direct ingestion of soil to which pulp and paper mill sludge has been land-applied. Species selected for evaluation were obtained from lists maintained by Natural Heritage Programs in the seven states where land application of pulp and paper mill sludge currently occurs. These species represent common species as well as some threatened and endangered species believed to inhabit regions of the state where land application is practiced.

Soil concentrations of 2,3,7,8-TCDD and 2,3,7,8-TCDF were modeled for sludge-amended soil in each of the seven states where pulp and paper mill sludge is land-applied. The modeled concentrations were the average concentrations over a 1-year period after sludge is applied to soil. Wildlife exposures were then estimated for three ingestion and uptake levels: "low," "best," and "high" estimates. These three estimates were based on several variables including: uptake rates for vegetation eaten by wildlife; bioconcentration factors (BCF) for earthworms, insects, and small mammals; BCF for fish from sediment; whole-body elimination rate from birds, small mammals, and large mammals; percent of dioxin absorbed from food; total food consumption for birds and mammals; percent of diet that is soil; and fraction of food sources from sludge-applied land. The risk assessment was performed by computing the resultant exposure levels for each type of animal for each state and for each scenario (low, best, and high), and then comparing these exposure estimates with the NOAELs or LOAELs for the same or similar species. The following values for NOAEL and LOAEL were determined and compared with estimated exposures:

	2,3,7,8-TCDD (ppt)	2,3,7,8-TCDF (ppt)
LOAEL for bird eggs	65	650
NOAEL for migratory birds	11	110
NOAEL for nonmigratory birds	6	60
LOAEL for small mammals	10	100
LOAEL for large mammals	1.7	17

For estimated exposures, it was assumed that each species examined, with the exception of the river otter, obtained all of its food from the land application area. Because of their large range, river otters are assumed to obtain less than 10 percent of their diet from land application sites abutting waterways. Risks to raptors, such as owls feeding on mice or other small wildlife in treated areas, and risks to piscivorous birds, such as the bald eagle and osprey, were not addressed in this assessment because their home ranges were determined to be considerably larger than the land application areas. If, in the future, the concentrations of 2,3,7,8-TCDD/TCDF in sludge in the sizes of the application areas increased, then the risks to these and other wildlife species would need to be reevaluated.

(2) Methodology for assessment of risks to aquatic life from effluents. Currently, sufficient data are not available concerning the chronic effects of 2,3,7,8-TCDD and 2,3,7,8-TCDF on aquatic life to derive national water quality or sediment criteria for these contaminants. However, several studies have been conducted that provide some information concerning the long-term effects of 2,3,7,8-TCDD and 2,3,7,8-TCDF on aquatic life from subacute exposures. Sub-acute studies involve much longer exposure durations than acute studies but are not full-life-cycle exposures assessed in chronic studies. These studies were used to develop estimated chronic toxicity values for 2,3,7,8-TCDD and 2,3,7,8-TCDF. Potential aquatic life impacts were determined by comparing estimated in-stream concentrations of 2,3,7,8-TCDD and 2,3,7,8-TCDF to these estimated chronic toxicity values: 0.038 pg/l for 2,3,7,8-TCDD and 0.41 pg/l for 2,3,7,8-TCDF. Site-specific water column contaminant concentrations were calculated by USEPA (1990a) using the

simple dilution exposure assessment approach and low (7Q10) receiving stream flow conditions.

The effects on birds and mammals resulting from ingestion of contaminated fish were also considered. The measured levels of dioxins in fish downstream from the 104 mills were compared with maximum dietary levels of dioxins and furans recommended for birds and mammals by the New York Department of Environmental Conservation (NYDEC 1987).

2.12.3 Results and Discussion

(1) Assessment of risks to wildlife. Tables 18 and 19 summarize the estimated risks to mammals and to birds and bird eggs, respectively, from exposure to 2,3,7,8-TCDD as a result of land application of sludge. For the states with the lowest estimated exposures, adverse effects were predicted to be low for most of the species examined. For the states with the highest estimated exposures, adverse effects were predicted to be high for some of the species examined; for example, the shrew, bat, mole, robin, and woodcock. These species at greatest risk are those species whose diets consist of a high proportion of prey that bioconcentrate dioxins (e.g., earthworms and insects). Of those species examined, the avian species at greatest risk is the American woodcock; the mammalian species at greatest risk is the least shrew. For both birds and mammals, the risk levels appear to be highest for exposures to animals in Georgia. Adverse effects on individuals may be important if the individuals are members of species that are endangered or threatened. Table 20 presents results of a preliminary search for endangered and threatened species in seven counties where the eight pulp and paper mills that apply pulp and paper mill sludge to land are located. However, no direct evidence was found to indicate exposure of endangered or threatened species to dioxins from pulp and paper mills.

As a check on the methodology and results of this assessment, modeled estimates of 2,3,7,8-TCDD and 2,3,7,8-TCDF in soil and 2,3,7,8-TCDD in bird eggs were compared with measured concentrations collected as part of field studies of the impact of pulp and paper mill sludge application to a red pine plantation (NCASI 1987, Thiel et al. 1988). The comparison indicated the modeled estimates for the Wisconsin site were very similar to the measured concentrations at the Red Pine Plantation application site in Wisconsin. The modeled soil concentrations (Table 18) and the average measured soil concentrations (NCASI 1987) for 2,3,7,8-TCDD were 9 ppt and 10.8 ppt, respectively, and for 2,3,7,8-TCDF the values were identical, 106 ppt. Thiel et al. (1988) also conducted studies at the same Wisconsin sludge application site, but during the next year when 2,3,7,8-TCDD concentrations in the sludge were higher. Levels of 2,3,7,8-TCDD in bluebird and robin eggs were measured, and the reported levels in bluebird eggs ranged from 6 to 11 ppt (Thiel et al. 1988). The values predicted for the "best estimate" model (Table 19) were 27 ppt for the bluebird, a factor of 4.5 to 2.5 higher than the measured data.

Table 18. Estimates of Risks to Mammals from Exposure to 2,3,7,8-TCDD as a Result of Land Application of Pulp and Paper Mill Sludge

Species/state	Sludge conc. (ppt)	Soil conc. (ppt)	Adult risks[a] (times LOAEL) Low	Best	High
Least Shrew					
Georgia	220	181	2.99	44.80	114.48
Maine	13	1	0.02	0.25	0.63
Maryland	80	80	1.32	19.80	50.60
Mississippi	681	14	0.24	3.54	9.04
Ohio	145	145	2.39	35.89	91.71
Pennsylvania	34	0.2	0	0.06	0.14
Wisconsin	109	9	0.15	2.23	5.69
Grey Bat[b]					
Georgia	220	181	3.62	18.10	27.15
Maine	13	1	0.02	0.10	0.15
Maryland	80	80	1.60	8.00	12.00
Mississippi	681	14	0.29	1.43	2.15
Ohio	145	145	2.90	14.50	21.75
Pennsylvania	34	0.2	0	0.02	0.03
Wisconsin	109	9	0.18	0.90	1.35
Eastern Mole					
Georgia	220	181	1.22	15.40	38.50
Maine	13	1	0.01	0.09	0.21
Maryland	80	80	0.54	6.81	17.02
Mississippi	681	14	0.10	1.22	3.04
Ohio	145	145	0.98	12.34	30.85
Pennsylvania	34	0.2	0	0.02	0.05
Wisconsin	109	9	0.06	0.77	1.91
Virginia Opossum					
Georgia	220	181	0.72	2.88	4.69
Maine	13	1	0	0.02	0.03
Maryland	80	80	0.32	1.27	2.07
Mississippi	681	14	0.06	0.23	0.37
Ohio	145	145	0.58	2.31	3.76
Pennsylvania	34	0.2	0	0	0.01
Wisconsin	109	9	0.04	0.14	0.23
Striped Skunk					
Georgia	220	181	0.38	1.92	2.89
Maine	13	1	0	0.01	0.02
Maryland	80	80	0.17	0.85	1.28
Mississippi	681	14	0.03	0.15	0.23
Ohio	145	145	0.31	1.54	2.32
Pennsylvania	34	0.2	0	0	0
Wisconsin	109	9	0.02	0.10	0.14

Table 18. (Continued)

Species/state	Sludge conc. (ppt)	Soil conc. (ppt)	Adult risks[a] (times LOAEL) Low	Best	High
Nine-Banded Armadillo					
Mississippi	681	14	0.11	0.31	0.37
River Otter					
Georgia	220	181	0	0	0.06
Maine	13	1	0	0	0
Maryland	80	80	0	0	0.03
Mississippi	681	14	0	0	0
Ohio	145	145	0	0	0.05
Pennsylvania	34	0.2	0	0	0
Wisconsin	109	9	0	0	0

a These factors represent the comparison factor between the estimated exposure to mammals and the LOAEL for 2,3,7,8-TCDD of 10 ppt for small mammals and the LOAEL of 1.7 ppt for large mammals. For example, the best estimate of exposure of the Least Shrew to 2,3,7,8-TCDD from sludge applied to land in Georgia is 44.8 times greater than the LOAEL for small mammals (i.e., 10 ppt).

b The Grey Bat is considered to be an endangered species in the State of Georgia.

Table 19. Estimates of Risks to Adult and Hatching Birds from Exposure to 2,3,7,8-TCDD as a Result of Land Application of Pulp and Paper Mill Sludge

Species/state	Sludge conc. (ppt)	Exposure conc. (ppt)	Adult risks[a] (times NOAEL) Low	Best	High	Embryo risks[b] (times LOAEL) Low	Best	High
American Robin								
Georgia	220	181	0.67	4.13	6.57	1.36	10.59	30.16
Maine	13	1	0	0.02	0.04	0.01	0.06	0.17
Maryland	80	80	0.30	1.83	2.90	0.60	4.68	13.33
Mississippi	681	14	0.05	0.33	0.52	0.11	0.84	2.38
Ohio	145	145	0.53	3.31	5.26	1.09	8.49	24.16
Pennsylvania	34	0.2	0	0.01	0.01	0	0.01	0.04
Wisconsin	109	9	0.03	0.21	0.33	0.07	0.53	1.50
Woodcock								
Georgia	220	181	0.68	27.61	78.89	1.36	62.37	358.32
Maine	13	1	0	0.15	0.44	0.01	0.34	1.98
Maryland	80	80	0.30	12.20	34.87	0.60	27.57	158.37
Wisconsin	109	9	0.03	1.37	3.92	0.07	3.10	17.82
Eastern Bluebird								
Maine	13	1	0	0.02	0.03	0	0.05	0.13
Maryland	80	80	0.29	1.70	2.61	0.27	3.72	10.19
Ohio	145	145	0.53	3.09	4.72	0.49	6.75	18.47
Pennsylvania	34	0.2	0	0	0.01	0	0.01	0.03
Wisconsin	109	9	0.03	0.19	0.29	0.03	0.42	1.15
Great Crested Flycatcher								
Georgia	220	181	0.56	3.28	4.93	1.36	6.24	16.80
Maryland	80	80	0.25	1.45	2.18	0.38	2.76	7.43
Mississippi	681	14	0.04	0.26	0.39	0.07	0.49	1.33
Ohio	145	145	0.45	2.63	3.95	0.68	5.00	13.46
Pennsylvania	34	0.2	0	0	0.01	0	0.01	0.02
Loggerhead Shrike[c]								
Maryland	80	80	0.70	2.87	3.78	0.90	3.97	7.88
Mississippi	681	14	0.13	0.51	0.68	0.16	0.71	1.41
Ohio	145	145	1.28	5.20	6.85	1.63	7.20	14.29
Pennsylvania	34	0.2	0	0.01	0.01	0	0.01	0.02
Eastern Meadowlark								
Maryland	80	80	0.15	0.88	1.33	0.29	2.11	5.71
Mississippi	681	14	0.03	0.16	0.24	0.05	0.38	1.02
Ohio	145	145	0.28	1.60	2.42	0.53	3.82	10.34
Pennsylvania	34	0.2	0	0	0	0	0.01	0.02

Table 19. (Continued)

Species/state	Sludge conc. (ppt)	Exposure conc. (ppt)	Adult risks[a] (times NOAEL) Low	Best	High	Embryo risks[b] (times LOAEL) Low	Best	High
Tree Swallow								
Georgia	220	181	0.57	3.34	5.05	1.12	8.18	22.19
Maine	13	1	0	0.02	0.03	0.01	0.05	0.12
Maryland	80	80	0.25	1.47	2.23	0.49	3.62	9.81
Ohio	145	145	0.46	2.67	4.05	0.89	6.55	17.77
Wisconsin	109	9	0.03	0.17	0.25	0.06	0.41	1.10
Pine Warbler								
Georgia	220	181	0.82	4.76	7.15	0.92	6.79	18.26
Maine	13	1	0	0.03	0.04	0.01	0.04	0.10
Maryland	80	80	0.36	2.10	3.16	0.41	3.00	8.07
Ohio	145	145	0.65	3.81	5.73	0.74	5.44	14.63
Wisconsin	109	9	0.04	0.24	0.36	0.05	0.34	0.91
Wood Thrush								
Georgia	220	181	0.33	1.94	2.98	0.55	4.05	11.15
Maine	13	1	0	0.01	0.02	0	0.02	0.06
Maryland	80	80	0.15	0.86	1.32	0.24	1.79	4.93
Ohio	145	145	0.27	1.55	2.39	0.44	3.25	8.93
Wisconsin	109	9	0.02	0.10	0.15	0.03	0.20	0.55

a These factors represent the comparison factor between the estimated exposure to birds and the NOAEL for 2,3,7,8-TCDD of 11 ppt for migratory birds and 6 ppt for nonmigratory birds.

b These factors represent the comparison facator between the estimated exposure to bird eggs and the LOAEL for bird eggs for 2,3,7,8-TCDD of 65 ppt.

c The Loggerhead Shrike is considered to be a threatened species in the State of Maryland.

Table 20. Results of Preliminary Search[a] for Endangered (E) and Threatened (T) Species Found in the Counties[b] Where Pulp and Paper Mills Are Located that Apply Dioxin- and Furan-Contaminated Pulp and Paper Mill Sludge to Land

Endangered and threatened species	States with soil application						
	GA	ME	MD	MS	OH	PA	WI
Mammals							
Indiana bat (E)			P		P	P	
West Indian Manatee (E)	K						
Birds							
Bald Eagle (E)	K	K					K
Piping Plover (E)	K	K					
Wood Stork (E)	K						
Red-Cockaded Woodpecker (E)				K			
Reptiles							
Eastern Indigo Snake (T)				P			
Gopher Tortoise (T)				K			
Kemp's Ridley Sea Turtle (E)	K						
Leatherback Sea Turtle (E)	P						
Loggerhead Sea Turtle (T)	K						
Fish							
Shortnose Sturgeon		K					
Invertebrates							
Iowa Pleistocene Snail (terrestrial) (E)							
Plants							
Harperalla (E)			K				
Small Whorled Pogonia (E)		K					

[a]Based on information dated October 26, 1989.

[b]Pulp mill sites:
- Camden County, Georgia
- Cumberland County, Maine
- Alleghany County, Maryland
- Perry County, Mississippi
- Ross County, Ohio
- Wyoming County, Pennsylvania
- Wood County, Wisconsin

P - Possibly present in county
K - Known to be present in county

Levels of 2,3,7,8-TCDD measured in robin eggs ranged from 120 to 162 ppt (Thiel et al. 1988). The value predicted for the "best estimate" scenario was 34 ppt (Table 19), a factor of 3.5 to 4.8 lower than the measured data. Considering the wide range in biological variability in natural systems, the wildlife risk assessment model compares well with measured values, at least for 2,3,7,8-TCDD levels in bluebird and robin eggs.

Based on the results of the assessment and the assumption that wild species are at least as sensitive as the laboratory species on which the adverse effects levels are based, EPA is confident that, on land with high dioxin levels, adverse effects to wildlife are likely to occur. The size of the exposed populations is believed to be small at some sites because, at present, only limited land areas are being utilized for land application of pulp and paper mill sludge. However, only the otter consistently showed low risk estimates, and some wildlife species showed high risk estimates in some states. For some of these common species with large ubiquitous populations, the local impacts might be small, but any effects on local wildlife populations are nevertheless an adverse impact on the local ecosystem. Moreover, sufficient toxicity data are not available for avian reproduction tests and the adult bird toxicity endpoint is based on a LOAEL rather than a NOAEL. Consequently, it is impossible to conclude from these risk estimates that any of these exposure levels or scenarios are "safe" to wildlife.

(2) **Assessment of risks to aquatic life.** Water column concentrations of 2,3,7,8-TCDD immediately downstream from at least 80 out of 90 mills evaluated (89 percent) were estimated to exceed the lowest reported chronic effects level of 0.038 pg/l for 2,3,7,8-TCDD. The 2,3,7,8-TCDF concentrations in the water column below at least 74 mills (82 percent) exceeded the lowest reported chronic effects level of 0.41 pg/l for 2,3,7,8-TCDF.

The 7Q10 is used as a design flow for stressed aquatic systems; however, use of 7Q10 receiving water flow rates does not necessarily result in the extreme worst-case scenario for aquatic life acute impacts. 7Q10 is defined as the lowest consecutive 7-day average flow over a 10-year period. Streamflows less than or equal to the 7Q10 flow (expressed as a daily flow) can occur multiple times within a given year (for periods of 1 day to several days). It is possible that even brief exposures (i.e., less than 7 days) to high concentrations of 2,3,7,8-TCDD and 2,3,7,8-TCDF can result in toxic effects to aquatic organisms, and such effects may occur after an appreciable delay following only brief exposures.

Upon comparing the measured levels of dioxins for fish collected downstream from the 104 mills with the maximum daily dietary level of dioxin (i.e., 3 ppt) recommended by the New York Department of

Environmental Conservation (NYDEC 1987) for mammals and birds feeding on fish, it was determined that 66 percent of the fish, based on samples from the National Bioaccumulation Study (USEPA 1989), exceeded this NYDEC recommended value. Over 38 percent of the fish sampled showed measured levels which exceeded the NYDEC recommended value by twofold. EPA has not evaluated the technical basis for the dietary levels of dioxin recommended by NYDEC.

Taking into account the above assumptions, simplifications, and limitations concerning the risks to aquatic life from effluent discharges of 2,3,7,8-TCDD and 2,3,7,8-TCDF, the results of this assessment indicate that the levels of 2,3,7,8-TCDD and 2,3,7,8-TCDF contamination in the water column resulting from surface water effluent discharges from many chlorine-bleaching pulp and paper mills could be exerting significant adverse effects on aquatic life and on avian and mammalian predators feeding upon aquatic life.

2.13 Summary of Toxicity, Environmental Releases, and Effluent Concentrations of Other Chlorinated Organics

Risks from exposure to 2,3,7,8-TCDD and 2,3,7,8-TCDF are the primary focus of the Integrated Assessment. Many other chlorinated organic compounds (OCOs), however, are produced during pulp and paper mill bleaching and processing operations.

A screening-level analysis of OCOs found in pulp and paper mill effluent was performed. This analysis was intended to provide a qualitative assessment of the types and amounts of OCOs present in pulp mill effluents. Although much information on OCOs in pulp mill effluent was available, no data were available on concentrations of OCOs in sludge or pulp. Also, the information available is inadequate to permit the assessment of risks to humans or wildlife. Based on the OCO data that are available, some general observations can be made:

(1) Some OCOs are quite toxic to aquatic life. Of the OCO's identified in pulp and paper mill effluents for which toxicity data are available, the most toxic are the chlorinated phenols. These chemicals have been found in treated effluents at concentrations from 4 to 15 $\mu g/l$. Under conditions of 7Q10 low streamflow, in-stream concentrations might approach an order of magnitude of the LC_{50} levels.

(2) Because of time constraints, the potential impacts of the OCOs on terrestrial organisms were only briefly evaluated. Again, based on the available data, chlorinated phenols were shown to be most toxic. Therefore, application of pulp and paper mill sludge onto forests and agricultural lands may be of concern. At present, there are no data available on OCO concentrations in pulp and paper mill sludge.

(3) Chlorine bleaching at pulp and paper mills can be a major source of chloroform. During a search of the Toxic Release Inventory (TRI) data base for information on releases of OCOs, it was discovered that large quantities of chloroform (classified by EPA as a "B2" carcinogen) are released to water, land, and air by pulp and paper mills. Releases to air are reported to be as high as 1,700,000 pounds per year from one site.

(4) Concentrations of OCOs in treated effluents are generally much higher than concentrations of 2,3,7,8-TCDD and 2,3,7,8-TCDF. Concentrations of OCOs in treated effluents are typically two to three orders of magnitude higher than concentrations of 2,3,7,8-TCDD and 2,3,7,8-TCDF. However, the CDDs and CDFs are considered to be much more toxic than OCOs and are presumed to have the most significant potential for human hazard.

(5) Canada, West Germany, Finland, and Sweden have regulated or announced intentions to regulate the pulp and paper industry on the basis of TOX (Total Organic Halogens) or AOX (Adsorbable Organic Halogens).

3. REFERENCES

ADL. 1987. Arthur D. Little, Inc. Exposure and risk assessment of dioxin in bleached kraft products. Draft report. Washington, DC: U.S. Environmental Protection Agency, Office of Water Regulations and Standards. Contract No. 68-01-6951.

API. 1990. American Paper Institute, Inc. Letter dated March 15, 1990, from R. Cavaney to F. Shank.

Bonazountas M, JM Wagner. 1984. "SESOIL" a seasonal soil compartment model. Arthur D. Little, Inc., and DIS/ADLPIPE Inc. for the U.S. Environmental Protection Agency, Office of Toxic Substances. EPA Contract No. 68-01-5271.

Bowers JF et al. 1980. Industrial source complex (ISC) dispersion model user's guide. Volume I. Research Triangle Park, NC: U.S. Environmental Protection Agency. PB-80-133044.

Bowman RE, SL Schantz, NCA Weerasinghe, et al. 1989. Chronic dietary intake of 2,3,7,8-tetrachlorodibenzo-p-dioxin (2378-TCDD) at 5 or 25 ppt in the monkey: TCDD kinetics and dose effect estimates of reproduction toxicity. Chemosphere 18(1-6):243-252.

Cook PM. 1989 (Dec. 26). Environmental Research Laboratory-Duluth, MN, Office of Research and Development, U.S. Environmental Protection Agency. Review of draft risk assessment from paper mill discharges. Memorandum to GH Grubbs, Office of Water Regulations and Standards, U.S. Environmental Protection Agency, Washington, D.C.

Helms J. 1989 (Aug. 11). Office of Water Regulations and Standards, U.S. Environmental Protection Agency. U.S. EPA/paper industry cooperative dioxin study full congener analyses. Memorandum to G. Schweer, Office of Toxic Substances, U.S. Environmental Protection Agency, Washington, D.C.

MRCA. 1988. Market Research Corporation of America. Report to the Food and Drug Administration. Frequency distributions of the total number of eating occasions in an average 14-day period, by eaters only produced from the five menu census studies of July 1982 through June 1987 in partial fulfillment of Contract No. 223-87-2088, Task II, Section C.1.D(2) and Sections F.1.2(5-6). December 1988.

Nabholz JV. 1989. Bioconcentration factors for 2,3,7,8-chlorinated dibenzodioxins and 2,3,7,8-chlorinated dibenzofurans. Unpublished. Washington, DC: U.S. Environmental Protection Agency, Office of Toxic Substances.

NCASI. 1987. National Council of the Paper Industry for Air and Stream Improvement. Land treatment effects on wildlife populations in red pine plantations. Technical Bulletin No. 526. June 1987.

NYDEC. 1987. New York Department of Environmental Conservation. Niagara river biota contamination project: fish flesh criteria for piscivorous wildlife. Technical report 87-3, Division of Fish and Wildlife, Bureau of Environmental Protection.

Pao EM, Flemin KH, Guenther PM, Mickle SJ. 1982. Foods commonly eaten by individuals: amount eaten per day and per eating occasion. Home Economics Research Report No. 44. Washington, DC: U.S. Department of Agriculture.

Thiel DA, Martin SG, Duncan JW, Lemke MJ, Lance WR, Peterson R. 1988. Evluation of the effects of dioxin-contaminated sludges on wild birds. In: Proceedings of the 1988 TAPPI Enviornmental Conference.

USEPA. 1987. U.S. Environmental Protection Agency. National dioxin tudy. Report to Congress. Washington, DC: U.S. Environmental 'rotection Agency. EPA 530/SW-87-025.

ISEPA. 1988. U.S. Environmental Protection Agency. U.S. EPA/paper ndustry cooperative dioxin screening study. Washington, DC: Office of later Regulations and Standards. EPA 440/1-88-025.

ISEPA. 1989a. U.S. Environmental Protection Agency. Interim procedures 'or estimating risks associated with exposures to mixtures of chlorinated Jibenzo-p-dioxins and dibenzofurans (CDDs and CDFs) and 1989 update. Washington, DC: Risk Assessment Forum, March 1989. EPA 625/3-89-016.

USEPA. 1989b. U.S. Environmental Protection Agency. Bioaccumulative pollutants in fish - a national study. Volume D study report and appendices A and B. Draft report. Washington, DC: Office of Water Regulations and Standards. December 1989.

USEPA. 1989c. U.S. Environmental Protection Agency. 104-mill study data base. July 17, 1989, version. Washington, DC: Office of Water Regulations and Standards.

USEPA. 1990. U.S. Environmental Protection Agency. Assessment of risks from exposure of humans, terrestrial and avian wildlife, and aquatic life to dioxins and furans from disposal and use of sludge from bleached kraft and sulfite pulp and paper mills. Washington, DC: Office of Toxic Substances and Office of Solid Waste. EPA 560/5-90-013.

Yeh GT. 1981. AT123D: Analytical transport one-, two-, three-dimensional simulation of waste transport in the aquifer system. Oak Ridge National Laboratory, Environmental Sciences Division, Publication No. 1439.

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16. Abstract (Limit: 200 words)
This report presents the key findings, assumptions, and uncertainties of an assessment of risks from exposure of humans, terrestrial and avian wildlife, and aquatic life to dioxins and furans formed during chlorine bleaching at kraft and sulfite pulp and paper mills. This report contains condensed versions of eight major exposure/risk assessments and other support documents prepared by program offices within the U.S. Environmental Protection Agency (EPA), the U.S. Food and Drug Administration (FDA), and the U.S. Consumer Product Safety Commission (CPSC). Risks were evaluated from roughly 120 potential pathways to exposure to pulp and paper products, pulp and paper mill sludges, and pulp and paper mill effluents. The development of this assessment and the individual Agency exposure/risk assessments was coordinated by the Federal Interagency Working Group on Dioxin-in-Paper. The Background Document to this Integrated Assessment contains detailed summaries of the individual exposure/risk assessments.

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