

to the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501, as it does not contain any information-collection requirements within the meaning of that Act.

List of Subjects in 29 CFR Part 102

Privacy, Reporting and recordkeeping requirements.

For the reasons stated above, 29 CFR part 102 is amended as follows:

PART 102—[AMENDED]

Subpart K—Records and Information

1. The authority citation for part 102 continues to read as follows:

Authority: Sec. 6, National Labor Relations Act, as amended (29 U.S.C. 151, 156). Section 102.117 also issued under section 552(a)(4)(A) of the Freedom of Information Act, as amended (5 U.S.C. 552(a)(4)(A)), and section 552a (j) and (k) of the Privacy Act (5 U.S.C. 552a (j) and (k)). Sections 102.143 through 102.155 also issued under sec. 504(c)(1) of the Equal Access to Justice Act, as amended (5 U.S.C. 504(c)(1)).

2. Section 102.117 is amended by adding paragraphs (p) and (q) as follows:

§ 102.117 [Amended]

* * * * *

(p) Pursuant to 5 U.S.C. 552a(k)(2), the system of records maintained by the NLRB containing Agency Disciplinary Case Files (Nonemployees) shall be exempted from the provisions of 5 U.S.C. 552a (c)(3), (d), (e)(1), (e)(4) (G), (H), and (I), and (f) insofar as the system contains investigatory material compiled for law enforcement purposes other than material within the scope of 5 U.S.C. 552a(j)(2).

(q) The Privacy Act exemption set forth in paragraph (p) of this section is claimed on the ground that the requirements of subsections (c)(3), (d), (e)(1), (e)(4) (G), (H), and (I), and (f) of the Privacy Act, if applied to Agency Disciplinary Case Files, would seriously impair the ability of the NLRB to conduct investigations of alleged or suspected violations of the NLRB's misconduct rules, as set forth in paragraphs (o) (1), (3), (4), (7), (8), and (11) of this section.

Dated, Washington, DC, December 5, 1996.

By direction of the Board.

John J. Toner,

Executive Secretary.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 131

[FRL-5663-5]

National Toxics Rule: Remand of Water Quality Criteria for Dioxin and Pentachlorophenol to EPA for Response to Comments

AGENCY: U.S. Environmental Protection Agency.

ACTION: Notice of availability of US EPA response to comments.

SUMMARY: In this document, the U.S. Environmental Protection Agency ("EPA") is publishing a document entitled "Response to Comments from American Forest and Paper Association ("AFPA") on Two of the Exposure Assumptions Used by EPA in Developing the Human Health Water Quality Criteria for Dioxin and Pentachlorophenol". AFPA challenged EPA's promulgation of human health water quality criteria for dioxin and pentachlorophenol. The District Court remanded these criteria to EPA for an adequate response to AFPA's comments regarding two exposure assumptions used by EPA in developing those criteria: an assumption that daily water consumption is 2 liters, and an assumption that all consumed fish are contaminated at criteria levels. EPA has prepared a response in accordance with the court's order, and is publishing that response in this document.

FOR FURTHER INFORMATION CONTACT: Denis R. Borum, Office of Science and Technology, Office of Water (4304), USEPA, 401 M Street, SW., Washington, D.C. 20460, (202) 260-8996.

SUPPLEMENTARY INFORMATION: In November 1991, EPA proposed chemical-specific, numeric criteria for priority toxic pollutants, including dioxin and pentachlorophenol, necessary to bring all States into compliance with the requirements of section 303(c)(2)(B) of the Clean Water Act. (The "National Toxics Rule" or "NTR", 56 FR 58420; codified at 40 CFR 131.36.) AFPA commented on a number of aspects of the proposal, including the exposure assumptions used in EPA's water quality criteria methodology. The NTR was promulgated in December 1992 (57 FR 60848; codified at 40 CFR 131.36). AFPA challenged the rule as arbitrary and capricious in violation of the Administrative Procedure Act, 5 U.S.C. 551 *et seq.* (Civil Action No. 93-CV-0694 (RMU), DCDC.) On September 4, 1996, the court issued an order remanding the human health criteria for

dioxin and pentachlorophenol to EPA for "an adequate response to AFPA's comments" regarding two of the exposure assumptions used by EPA in developing the criteria. These assumptions are that daily water consumption is 2 liters, and that all consumed fish are contaminated at the criteria levels.

The court directed EPA to respond to AFPA's comments on these two issues by December 13, 1996, or the human health criteria for dioxin and pentachlorophenol will be vacated automatically. This notice publishes EPA's response to AFPA's comments. Under the order, AFPA has 60 days from the publication of EPA's response to re-open the litigation; upon expiration of the 60 days, the action will stand dismissed with prejudice.

In accordance with section 553 of the Administrative Procedure Act, EPA has determined that there is good cause not to solicit public comment on this notice. In this notice, the Agency is simply responding to comments on the proposed NTR and such responses are not subject to further public comment. Moreover, the public has had ample opportunity to comment on the exposure assumptions addressed in this notice since the assumptions have been reflected in a number of Agency regulatory actions. For these reasons, EPA finds further public comment to be unnecessary.

Dated: December 5, 1996.

Robert Perciasepe,

Assistant Administrator for Water.

Response to Comments From the American Forest and Paper Association on Two Exposure Assumptions Used by EPA To Develop Human Health Water Quality Criteria for Dioxin and Pentachlorophenol

Background

The purpose of the Clean Water Act ("CWA") is to protect the nations waters, on which public health and the environment depend. Toward this end, the CWA requires those discharging into surface waters of the United States to have permits that limit the amount of pollutants discharged. To set such limits, "criteria" are established for each pollutant at a level necessary to preserve or achieve the uses designated for particular waterbodies by the States. In other words, for waterbodies designated as drinking water supplies, the criteria should assure that people can safely drink the water. Where waterbodies are to be used for fishing, swimming or recreation, the criteria should assure that people can safely eat fish that are taken from those waters, and safely use

the waters for other designated purposes. These criteria, intended to protect public health, are referred to as "human health criteria".

Human health criteria are derived to establish quantitative estimates of chemicals which, if not exceeded, will protect the general population from adverse health impacts from exposure to contaminated surface water. There are two routes of human exposure: water consumption and fish consumption. In order to develop the criteria, EPA needed to determine appropriate exposure assumptions for these pathways. In 1980, EPA announced its methodology for establishing human health criteria. 45 FR 79318 (Nov. 28, 1980). To predict the effects of low doses of the pollutant on a hypothetical person over a 70-year lifetime, EPA assumed the exposed individual is a male who weighs 70-kilograms and who on a daily basis consumes an average of 6.5 grams of fish and shellfish and 2 liters of water. *Id.* at 79323–24. EPA also assumed for purposes of the methodology that the consumed water and fish are contaminated at the criteria levels. *Id.*, at 79323.

Issue 1: EPA's Estimate of Water Intake as 2 Liters per Day

As noted above, in order to derive human health criteria, EPA needed to make assumptions concerning daily exposure to pollutants in surface water from two primary routes: water consumption and fish consumption. EPA has assumed an average daily water consumption of 2 liters. The Agency recognizes that a number of other drinking water consumption rates have been suggested. Having reviewed those studies, EPA's policy judgment continues to be that an assumed daily consumption of 2 liters is reasonable to provide the margin of safety needed to protect most people and thereby meet the objectives of the CWA. EPA is not required, by the CWA or regulation, to base its assumed water consumption on "average ingestion" in statistical terms. Rather, as EPA explained in the proposed NTR, the assumed water consumption rate is based on an "approximate" national average. (56 FR 58436), *i.e.*, the approximate national average may be a starting point not an end point. Also, both the Agency and the National Academy of Sciences ("NAS") have indicated that policy reasons are appropriate considerations in adopting "average" drinking water consumption rates. Since 1980, EPA has on several occasions reviewed and publicly addressed the rationale for its water consumption value, but to the extent that questions remain as to the

basis for the assumption, EPA here further explains that rationale.

The Agency's 1980 methodology for deriving human health criteria assumed a water consumption of 2 liters per day. EPA cited a study done by the NAS in support of this assumption. The NAS study was undertaken to meet the needs expressed in the 1974 Safe Drinking Water Act ("SDWA"). Under the SDWA, EPA was required to establish federal standards for protection from harmful contaminants in the drinking water supplies of the nation. Congress directed EPA to arrange with the NAS to study the adverse effects on health attributable to contaminants in drinking water. In 1977, NAS produced a multi-volume study entitled *Drinking Water and Health*, National Academy of Sciences, Washington, D.C. 1977. In this study, NAS considered 2 liters to be the average amount of water consumed per day. While noting that the average per capita water consumption of the U.S. population, as calculated from a survey of nine different literature sources, was 1.63 liters per day, NAS adopted 2 liters per day as representing the "intake of the majority of water consumers". *Id.* at 11. EPA adopted 2 liters per day as the drinking water exposure for its human health criteria methodology, understanding that it included a margin of safety that would ensure that most of the population would be protected.

In its comments on the proposed NTR, AFPA argued that the assumed 2 liters per day water consumption rate was overly conservative:

In a paper recently accepted for publication in *Risk Analysis* (Exhibit 9) * * * (the) analysis demonstrated that the 50th percentile intake of "tap water" * * * was slightly less than one liter per day. * * * ChemRisk recently analyzed similar water consumption data and came up with a similar figure for "tap water" consumption—1.2 liters per day. (Exhibit 2) Since an individual exposed to contaminated surface water would at most only be exposed to that contamination in the "tap water" he consumes, and not in the moisture content inherent in foods that he purchases. * * * the two liter per day assumption EPA has used overstates by a factor of 2 the potentially contaminated water that an average individual might consume. AFPA Comments on Proposed Rule, Dec. 19, 1991, pp. 59–60.

The ChemRisk analysis states that EPA's 2.0 liters per day value is based on the daily ration of water required by US Army field personnel; ChemRisk questions whether this value is appropriate for a general population with access to other beverages and that does not engage in as much physical exertion and is not as exposed to the outdoors. ChemRisk reviewed several

studies that show the average adult consumption rate for liquids ranges from 0.4 to 2.2 L/day. Based on a study showing that approximately 60% of the total dietary fluid intake is water, ChemRisk concludes that if a total fluid consumption rate of 2 liters per day is reasonable, then 60% of that consumption rate or 1.2 liters per day is water. (pp. 5–1 to 5–2)

EPA is familiar with the studies, including those cited by AFPA, that estimate average consumption of water to be less than 2 liters per day. Indeed, in 1990, EPA conducted its own analysis of data that suggested that the average water consumption rate across the U.S. adult population is 1.4 liters per day. "Exposure Factors Handbook", EPA 600/8–89/043, at 2–6 (AR VA–103). However, while noting that the scientific literature suggests a daily rate of 1.4 liters, EPA made clear that "[p]olicy or precedent reasons may support the continued use of the 2.0 L/day [figure] as the average adult drinking water consumption rate." This analysis further indicates that consumption of 2 liters per day covers about 90 percent of the population; the remaining 10 percent of the population consumes more than a daily average of 2 liters. In this analysis, 2 liters per day is characterized as a reasonable worst-case water consumption rate for adults. Since EPA's purpose in selecting 2 liters as an average daily water consumption rate was to provide a margin of safety sufficient to protect most people—to the extent that 2 liters per day is protective of approximately 90 percent of the population—using 2 liters per day as the assumed water consumption rate for the NTR is consistent with EPA's approach in setting human health criteria.

In a 1992 SDWA rulemaking that established health-based contaminant levels for numerous pollutants in drinking water (57 FR 31,776), the issue of water consumption estimates was re-examined yet again. In the SDWA rulemaking, the Chemical Manufacturers Association ("CMA") submitted comments (which mirror those submitted by AFPA in the contemporaneous NTR rulemaking) objecting to EPA's use of 2 liters per day to set drinking water standards. CMA recommended instead the 1.4 liters per day estimate in EPA's Exposure Factors Handbook. In response to CMA's comments, EPA acknowledged that the 1.4 liters per day estimate is "an overall average of a number of studies" but rejected using that value since some of the studies did not necessarily consider indirect water consumption (such as use in cooking) and therefore may not account for all exposures related to the

occurrence of contaminants in drinking water. EPA reiterated that the 2 liters per day assumption was a more appropriate value "in order to be conservative and allow for an adequate margin of safety." *Id.* at 31787. EPA further noted that the Exposure Factors Handbook considered 2 liters per day a reasonable worst case estimate.

The Agency's rationale and conclusion in the drinking water regulation is equally applicable to the NTR. Therefore, EPA included the Federal Register notice (*Id.* 31787–31788) containing EPA's response to CMA's comments on the 2 liters per day figure in the record for the NTR rulemaking. In the NTR, an assumption of water consumption of 2 liters per day provides a sufficient margin of safety to ensure that most people can safely drink from waterbodies designated as drinking water sources.

In sum, AFPA disagrees with EPA's choice of methodology and desired level of health protection in deriving an estimate of assumed water consumption. EPA is not required under the CWA to base its water consumption estimate on "average ingestion" in statistical terms. In order to meet the objectives of the CWA, EPA believes that its assumed water consumption must include a margin of safety so that the general population is protected. The NAS adopted a water consumption figure of 2 liters per day in its study of drinking water and public health as representing the consumption of the majority of water consumers. EPA has reviewed the subsequent studies of water consumption, but continues to believe that 2 liters per day is appropriate for ensuring protection of public health under the CWA.

Issue 2. EPA's Assumption That All of the Fish Consumed Is Contaminated at the Criteria Level

In developing a methodology for deriving human health criteria, EPA made assumptions about exposure to contamination from eating fish taken from surface waters. The purpose of the assumptions was to ensure that if the criteria were met in a waterbody designated for fishing, most people could safely eat fish from that waterbody. In addition to the assumption in the methodology that the hypothetical man has an average daily consumption of 6.5 grams of fish, EPA assumes that all of that fish is taken from water with pollutants present at the criteria level.

It is EPA's view that to ensure that people can safely eat fish from waters designated for fishing, it is necessary to assume that all of the consumed fish is

taken from waterbodies at the criteria level. EPA recognizes that there are differences in fishing patterns and the degree to which fish bioaccumulate contaminants from the water. However, it is EPA's judgment that this assumption regarding fish contamination is necessary to derive criteria that are sufficiently protective to meet the objectives of the CWA.

AFPA commented that this assumption overstates the actual expected exposure to a contaminant:

Another source of overestimation of exposure comes from the implicit assumption that each portion of freshwater fish consumed by an individual will have the maximum concentration of the subject contaminant * * * This assumption is obviously an overstatement, since not all fish (presumably very few of them, in fact) will have been exposed to ambient water which is just barely achieving the water quality standard. Likewise, if the water quality standards are being met, it would only be on rare occasions that the water consumed will have a concentration as high as the water quality standard allows. By definition, if the water quality standard is implemented, ambient concentrations of the pollutant will normally be less. In addition, depending on the dilution calculations (if any) used in implementing the water quality standard, there may be little or no portion of the stream where the concentration of the pollutant is ever as high as the water quality standard allows (due to dilution and the use of low stream flows * * * EPA has very recently made this point forcefully in briefs and argument in the Eastern District of Virginia in *NRDC, et al. v. U.S. EPA*, No. 3:91CV0058. [cite omitted]. EPA has noted that FDA's analysis of risk from eating dioxin-contaminated fish in the Great Lakes assumed that * * * 90 percent of the fish an individual consumed would show no measurable contamination or would be taken from uncontaminated areas. (cite omitted). AFPA Comments on Proposed National Toxics Rule, December 19, 1991, pp. 60–61.

Two exhibits to AFPA's comments were prepared for the National Council of the Paper Industry for Air and Stream Improvement. Exhibit 2 discusses studies of fish consumption of anglers in New York and Maine, and Exhibit 4 addresses exposure to dioxin from the consumption of fish caught in fresh waters impacted by certain pulp mills. Both reports conclude that it is unlikely that all of the fish consumed by sport anglers come from only one waterbody or from impacted waters. The dioxin report notes, however, that no data are available on the number of waterbodies fished by members of the general population or sport fishermen over a course of time.

In its methodology, EPA assumes that all fish consumed by the hypothetical exposed individual are contaminated at the maximum concentration level that is

"safe" (*i.e.*, the criteria level). This is the same assumption that EPA makes as to water consumption, and the Agency's rationale supporting that assumption is equally applicable to fish consumption.

AFPA offers examples of situations which, it contends, make it unlikely that individuals will be exposed at the criteria level. EPA is aware that levels of actual exposure to contamination from consuming fish will vary depending on a number of factors. Daily fish consumption may be both greater than and less than 6.5 grams. As EPA noted in the proposed NTR, the exposure assumptions are based on approximate national averages, but "considerably understate the exposure that would occur for certain segments of the population that have high fish consumption or depend on fish consumption for subsistence." *Id.* at 58,436.

AFPA's exhibits note that sport fishing patterns may differ among communities. Fishermen with access to a number of different waterbodies may very well fish in several places and the levels of contamination may differ among those waterbodies. Further, different species of fish bioaccumulate pollutants at different rates. There are many circumstances that may be relevant to fish consumption in different communities and the level of contamination of those fish. However, whether people fish from a number of locations, or whether some waterbodies are not as contaminated as others does not demonstrate that EPA's assumption is invalid. EPA must develop national criteria (that States may modify) that must be protective of the general population. Neither AFPA nor other commenters provided EPA with evidence sufficient to allow the Agency to use a less conservative assumption.

It continues to be EPA's view that in order to develop criteria that are sufficiently protective, it is necessary to assume that all consumed fish are taken from waters at the criteria level. By deriving criteria based on that assumption, EPA is better able to ensure that people can safely eat fish from waters designated for fishing.

The local circumstances that AFPA reports are best addressed by the States which have chief responsibility for implementing the CWA. States can modify or adapt EPA's recommended human health criteria to reflect just such local environmental conditions, and EPA encourages them to do so. (See 57 FR 60888, Dec. 22, 1992).

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