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NOTE TO: Pamela Moseley

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SUBJECT: Document for AR226 (CONTAINS NO CBI)

Please file the attached correspondence in AR226 only:

- Fax dated June 10, 2002 from Robert Bilott to Mary Dominiak re C-8 Assessment of Toxicity Team Work Under November 14, 2001 Consent Order Between DuPont and State of West Virginia (Order No. GRW-2001-019)

Should you have any questions, or need additional information, please contact me at 564-8178 or Mary Dominiak at 564-8104.

Thanks.

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Re: C-8 Assessment Of Toxicity Team Work Under November 14, 2001 Consent Order Between DuPont And State Of West Virginia (Order No. GRW-2001-019)

Ladies and Gentlemen:

As indicated in our prior correspondence to the State and Federal agencies, our law firm and co-counsel in Charleston, West Virginia, have been certified by a State Court in West Virginia to serve as counsel for a class of all persons whose drinking water is or has been contaminated with ammonium perfluorooctanoate ("C-8") attributable to releases from E.I. duPont de Nemours and Company's ("DuPont's") Washington Works in Wood County, West Virginia. As class counsel, we seek clarification from the agencies with respect to a situation involving a threat to the health of the members of the class we represent. More specifically, we seek clarification of the manner in which the C-8 Assessment of Toxicity Team ("CAT Team") established under the referenced Consent Order selected 150 parts per billion (ppb) as a "screening level" for C-8 in drinking water in West Virginia, which members of the class are drinking on a daily basis. As explained below, the information that has been made available to us to date indicates that the CAT Team's analysis is fundamentally inconsistent with the facts and agency guidance for interpreting those facts with respect to the calculation of "screening levels" or "lifetime drinking water health advisories" ("DWHAs"). Based on the press releases and public meetings sponsored by the CAT Team regarding the 150 ppb number, the class members are being led to believe that drinking water with up to 150 ppb C-8 presents no risk of any kind to their long-term health. We do not believe that is correct. Available facts and guidance do not support either a "screening level" or DWHA above even 1 ppb, let alone 150 ppb.

Although we requested an opportunity to designate a representative of the class members to sit on the CAT Team for purposes of determining an appropriate screening level for C-8 in drinking water, that request was refused. We did not, therefore, have a representative present during the CAT Team's meeting on May 6-7, 2002, nor have we received any minutes or written reports clarifying the details of the analysis used by the CAT Team in selecting the C-8 screening level during that meeting. Although we understand that a formal report summarizing the CAT Team's screening level analysis most likely will not be available for another several months, the information that has been made available to date by the CAT Team through its public meetings in West Virginia and Ohio on May 15, and May 16, 2002, and during our deposition last Thursday and Friday of the CAT Team's Leader, Dr. Dee Ann Staats, is sufficient to raise serious concerns with respect to the manner in which the CAT Team performed its analysis. Because of the public health threat involved, we are compelled to raise these concerns with you now for prompt resolution.

Based upon the information made available to date, we understand that the CAT Team understood that its purpose was to derive a "screening level" for C-8 in water of the nature often used as simply the threshold for triggering a cleanup or remediation of a Superfund or other

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hazardous waste site, as opposed to a DWHA designed specifically to conservatively protect human health from exposure to C-8 in drinking water. We further understand that the CAT Team calculated its "screening level for C-8 in drinking water through use of the following basic five-step process: (1) Selection of "key" toxicity studies on C-8; (2) Identification of the "critical effect" from C-8 exposure indicated in each of the "key" studies; (3) Identification of the C-8 dosing level at which the "critical effect" occurred in each of the "key" studies (the "critical effect level"); (4) Calculation of a reference dose or "RfD/RfC" for each "key" study by dividing the "critical effect level" by the product of the Intraspecies Extrapolation Uncertainty Factor (UF_H), the Interspecies Extrapolation Uncertainty Factor (UF_A), the Subchronic-to-Chronic Exposure Extrapolation Factor (UF_S), the LOAEL-to-NOAEL Extrapolation Uncertainty Factor (UF_L), the Database Quality and Completeness Uncertainty Factor (UF_D); and (5) Multiplication of the RfD/RfC derived for each of the "key" studies by "USEPA Region IX Screening Levels" assumptions regarding adult body weight and drinking water consumption level to derive the proposed drinking water screening level. Even assuming solely for purposes of argument that the CAT Team identified the appropriate "key studies," the appropriate "critical effects" for each of the "key" studies, and the appropriate "critical effect levels" for each of the "key" studies, available information and guidance do not support the CAT Team's calculations of corresponding RfD/RfCs or the ultimate screening level selected for C-8 in human drinking water, let alone use of the 150 ppb number as a DHWA for C-8. The bases for our concerns are summarized below.

I. The CAT Team Did Not Assign Appropriate Uncertainty Factor Values.

In calculating the RfDs/RfCs for each of the studies identified as the "key studies" by the CAT Team, CAT Team representatives have stated that each Uncertainty Factor is typically assigned a "default" value of 10, which can only be reduced to a less conservative value of 3 or even less conservative value of 1, if there is sufficient information or data to confirm that the basis for the standard default value of 10 is not appropriate. Although the calculations provided by the CAT Team indicate that the standard, conservative default value of 10 was used by the CAT Team for the UF_A and UF_H factors in calculating RfDs/RfCs for each of the "key" studies, it appears that the CAT Team generally selected the least conservative values for each of the remaining Uncertainty Factors. As explained below, it is not clear how the CAT Team can justify the use of those less conservative Uncertainty Factors, given available information on C-8 and agency guidance. (See, e.g., Exhibit C (USEPA's 1/17/92 "Background Document 3: Office of Drinking Water Health Advisories").)

A. The CAT Team Did Not Apply The Correct "LOAEL-To-NOAEL Extrapolation Uncertainty Factor" (UF_L).

Available data and guidance does not support the LOAEL-to-NOAEL Extrapolation Uncertainty Factor (UF_L) values used by the CAT Team in developing its screening level for C-8 in drinking water. Available guidance confirms that the UF_L factor, which addresses the

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uncertainty inherent in extrapolating data from a Lowest Observable Adverse Effect Level ("LOAEL"), should be kept at the default value of 10, unless a No Observable Adverse Effect Level ("NOAEL") was actually identified for the study in question. USEPA has taken the position in several other risk assessments, such as USEPA's risk assessment for 1, 3-butadiene, that a benchmark dose level ("BMDL"), although not defined as being the equivalent of either the NOAEL or LOAEL, should be viewed as the equivalent of a LOAEL. If the BMDL is close to a LOAEL, it is particularly appropriate to render it the equivalent of the LOAEL, especially if a NOAEL is not identified for a study, since effects may then occur much below the LOAEL or BMDL. For the C-8 2-generation reproductive rat study, no NOAEL was identified by the CAT Team and the BMDL (0.42 mg/kg/day) identified by the CAT Team is close to the LOAEL (1 mg/kg/day). In addition, the CAT Team incorrectly viewed the 1.6 BMDL referenced as a critical effect level for the 3M 1983 two-year rat study as a NOAEL, even though 1.6 was identified by the CAT Team as a LOAEL for the study making it impossible to dispute that the BMDL calculated by the CAT Team was the same as the LOAEL. The CAT Team also erred in labeling the 0.47 critical effect level identified by the CAT Team for the 1993 Palazzolo 90-day study as a NOAEL, given that USEPA had just confirmed in its draft health assessment for C-8 that the 0.47 effect level was a LOAEL - not a NOAEL. (See Draft Hazard Assessment of Perfluorooctanoate Acid and its Salts (USEPA, OPPT (2/20/02) (as amended 4/15/02) ("USEPA Report"), at 47.) The existence of a 90-day LOAEL essentially at the chronic BMDL (0.47 versus 0.42 mg/kg/day) indicates that effects probably occur below the BMDL and a UF_L of 10 is appropriate. Nevertheless, it appears that the CAT Team inappropriately selected far less conservative UF_L values of 1 and 3 for studies in which LOAELS or BMDLs were used, instead of NOAELs.

Even if there were a dispute as to whether critical effect levels based on anything other than NOAELs justify use of a default value lower than 10 for the UF_L , the CAT Team has not explained why it did not choose to err on the side of being as conservative and as protective of human health as possible, which would have required selection of the default value of 10 as the appropriate UF_L value for any of the studies where the critical effect level was not based on the existence of an NOAEL. In other words, if there was any room for argument as to which UF_L value can be justified for any of the "key" studies, why did the CAT Team not err on the side of being the most protective of human health -- not the least protective? Moreover, it seems strange that the CAT Team (including members of governmental regulatory agencies charged with protecting human health and the environment) opted to select far less conservative (and thereby less protective) values for the UF_L factor than even the manufacturer of C-8 believed was appropriate. More specifically, in January of 2002, the manufacturer of C-8, the 3M Company ("3M"), submitted to USEPA a Lifetime Drinking Water Health Advisory for C-8 (the "3M Report") in which 3M stated that the UF_L factor for the 26-week monkey study reviewed by the CAT Team should be assigned a value of 6. (See 3M Report, at 8.) Yet, the CAT Team selected an even less conservative, less protective UF_L value of 3 for the exact same monkey study. This simply does not make sense, particularly when 3M's lead toxicologist for C-8 was at the CAT Team meeting.

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B. The CAT Team Did Not Apply The Correct "Subchronic-To-Chronic Exposure Extrapolation Factor" (UF_s).

Available data and guidance also does not support the Subchronic-to-Chronic Exposure Extrapolation Uncertainty Factor (UF_s) values selected by the CAT Team for the various "key studies" reviewed by the Team. According to CAT Team representatives, the UF_s factor is assigned a default value of 10, unless the study at issue is a "chronic" (lifetime) study. In a January 2002, report prepared by DuPont's consultant, ENVIRON (the "ENVIRON Report"), which was submitted by DuPont's attorneys to the WVDEP Leader of the CAT Team, Dr. Dee Ann Staats, ENVIRON stated that there had been only 2 chronic (lifetime) studies of C-8 -- the 2-year rat study conducted on behalf of 3M from 1983 (the "Sibinsky study") and a 2-year rat study from 2001 referenced as the "Biegel Study."^{1/} (ENVIRON Report, at 6 and 8.) ENVIRON also stated that the other studies that had been conducted with C-8 (including the 90-day rat study by Palazzolo from 1993 and the 26-week monkey study by Thomford from 2001) were all "subchronic" studies, requiring use of the default value of 10 for the UF_s value when calculating an RfD/RfC from such studies. (See ENVIRON Report, at 5 (referencing the 1993 Palazzolo study as a "subchronic feeding study") and at 7, 26 (referencing the 26-week monkey study co-sponsored by DuPont and 3M as a "subchronic toxicity study")). 3M also agreed that the default value of 10 is the appropriate UF_s factor for use in calculating an RfD/RfC from the 26-week monkey study, based on recognition that the study was "significantly less than chronic." (3M Report, at 7.) USEPA also recognized that the 1993 90-day rat study by Palazzolo was a "subchronic" study in the draft Hazard Assessment for C-8 that the agency released to the public in March of this year. (See USEPA Report, at 4, 41.) This is not surprising, given that USEPA defines chronic as lifetime or not substantially different from lifetime. (USEPA Office of Drinking Water Health Advisories Web site; USEPA Risk Assessment Guidelines, Part A (1989)). It is, therefore, not clear how the CAT Team, with representatives of DuPont, 3M, and USEPA present, assigned values less than 10, including the least conservative value of 1, to the exact same Palazzolo 90-day rat study and the Thomford 26-week monkey study that ENVIRON, 3M, and USEPA all previously agreed were subchronic.

It also is not clear how the CAT Team viewed the 2-generation rat study by York from 2002 as a "chronic" study, when the period from the first dosing of the parental generation to the sacrifice of the second generation of rat pups was only approximately 8 months -- considerably shorter than 2 years. In fact, each generation of the rats was dosed for only a period of approximately 4 months, which is only approximately 10% of the 2-3 year lifespan of a rat. USEPA specifically defines such exposures of approximately 10% of the experimental animal's lifespan as "subchronic." (See, e.g., Exh. C.) It is not clear, therefore, how the CAT Team justified selection of the least conservative value of 1 for the UF_s value, which is justified only when data from a chronic (lifetime) study is used.

^{1/} It is not clear at this point whether the Cat Team even reviewed the Biegel Study.

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C. The CAT Team Did Not Apply The Correct "Database Quality And Completeness Uncertainty Factor" (UF_D).

Currently-available data and agency guidance also do not support the CAT Team's selection of the least conservative value of 1 for the Database Quality and Completeness Uncertainty Factor (UF_D) in calculating an RfD/RfC. According to statements by CAT Team members, the UF_D factor is the value used to account for potential uncertainty arising from a less than complete database for the particular chemical at issue. DuPont's own consultant, ENVIRON, stated in its January, 2002, report submitted to the CAT Team's Leader, Dr. Staats, that a database is not considered "complete" for purposes of deviating from the standard default value of 10 for the UF_D, unless all of the following data exists: "(1) chronic toxicity studies in 2 species (1 non-rodent), (2) a multi-generation reproduction study, and (3) developmental toxicity studies in 2 species." (ENVIRON Report, at 25.) According to ENVIRON, the database for C-8 cannot be viewed as complete, even though "the available database for [C-8] includes developmental toxicity studies in 2 species (rat and rabbit)" and "[p]reliminary results of a 2-generation reproduction study are now available," because the available C-8 database "lacks at this time a non-rodent chronic study." (*Id.*) Thus, according to DuPont's own consultant, ENVIRON, the C-8 database, even with the existence of the 2-generation rat study, cannot be viewed as "complete." Consequently, it is, again, not clear how the CAT Team can justify use of the least conservative and least protective value of 1 for all of the available C-8 studies as the appropriate UF_D value, when even DuPont's consultant believes that the database for C-8 is not complete and could not justify a UF_D value of 1.

The "completeness" of the available C-8 database was discussed during a public meeting sponsored by WVDEP on May 15, 2002, in which the CAT Team representatives were not able to identify what actually caused the death of any of the monkeys at any of the dose levels during the 26-week monkey study, and seemed to suggest that some of the effects observed in the rat studies may not correlate with effects observed in primates or humans. Such apparent uncertainty would appear to raise serious concerns with respect to the "completeness" of the database on C-8 with respect to primate and human health. Such uncertainty would, in fact, appear to support multiplication of the sum of the five Uncertainty Factors by an additional "Modifying Factor (MF)" that, according to DuPont's consultant, ENVIRON, is justified for "expressing residual uncertainty associated with the study and database not explicitly treated by the standard UF_S (e.g., completeness of the overall database or the number of species examined)." (ENVIRON Report, at 21) "As with the UF_S, the value of the MF may be up to 10." (*Id.*) It would appear that use of a Modifying Factor would be particularly appropriate in evaluating C-8 studies, given indications from the recent 2-generation rat study that C-8 causes developmental effects. Yet, despite comments made by the CAT Team representatives themselves during the public meeting expressing uncertainty with extrapolation of the existing database to human health and again during the deposition of the CAT Team's leader, Dr. Staats, it does not appear that the CAT Team considered use of any Modifying Factor of any value in calculating its RfDs/RfCs.

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II. The CAT Team Ignored Potential C-8 Exposures From Non-Drinking Water Sources.

It is not clear from the information made available to date by the CAT Team how the CAT Team converted its RfDs/RfCs into its 150 ppb number for C-8 in drinking water, or exactly what the purpose of such a "screening level" is in this case. The CAT Team's Leader, Dr. Staats, has explained that the RfDs/RfCs were converted into a 150 ppb screening level by using "USEPA Region IX Screening Level" calculations. Although exactly what those calculations were has not yet been explained, it appears that the calculations incorporated the same standard USEPA default values for calculating a drinking water exposure limit ("DWEL") for use in calculating a DWHA, which assume a standard human body weight of 70 kg and standard human drinking water rate of 2 liters per day: $DWEL = (RfD/RfC \times 70) / 2$. After all, incorporation of the CAT Team's 0.0042 RfD/RfC into this same standard DWEL formula yields 147 ppb, which we understand was then rounded up by the CAT Team to 150 ppb ($0.0042 \times 70/2 = 147$ ppb). The CAT Team apparently used this DWEL as its "screening level" under the referenced Consent Order, instead of following the standard agency guidance for converting the 150 ppb DWEL into a DWHA. In fact, we understand that the CAT Team's leader, Dr. Staats did not view the task of the CAT Team as deriving a lifetime DWHA (as opposed to derivation of the type of "screening level" typically used to trigger cleanup obligations), and therefore did not consider the available agency guidance for deriving lifetime DHWAs. If this is the "screening level" approach actually used by the CAT Team, the CAT Team ignored the relative source contribution factor ("RSC") required under agency guidance for converting a DWEL into a lifetime DWHA, which both 3M and DuPont's consultant, ENVIRON, stated should be used in calculating any C-8 drinking water standard to account for the potential that community members could be exposed to C-8 from sources other than their drinking water.

As required under agency guidance for calculating lifetime DHWAs, Both 3M and ENVIRON have stated that a DWEL should be multiplied by the standard RSC default value of 0.2 (20%) to account for the "relative contribution of various potential pathways to total [C-8] exposure" such as "food and air." (3M Report, at 4. *See also* ENVIRON Report, at 26.) In other words, the more conservative DWHA process for identifying a "safe" level of a chemical in drinking water, requires use of the RSC to take into account the fact that community members typically may be exposed to a chemical from non-drinking water sources, such as air pollution containing the chemical, soils contaminated with the chemical, food contaminated with the chemical, *etc.*, which, if ignored when determining an exposure level for drinking water, could result in too high of a total daily dose of the chemical from all sources, combined. Conversion of the CAT Team's 150 ppb number into a more protective DWHA by using the standard RSC factor advocated by both 3M and DuPont's consultant, ENVIRON, would require the CAT Team to multiply its 150 ppb number by 0.2 (a reduction of the 150 ppb number by 80 %) to take into account the potential that members of the community may be exposed to C-8 from sources other than drinking water, such as air pollution. That step alone would reduce the CAT Team's number from 150 ppb to 30 ppb. Use of the DWHA RSC would appear to be particularly

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appropriate in this situation when DuPont is discharging C-8 directly into the air from stacks at its Washington Works plant.

In addition, when asked specifically why the CAT Team did not use the 0.2 (20%) RSC factor, the CAT Team members stated during the recent public meetings that the 0.2 (20%) RSC was "not applicable," because the CAT Team members allegedly had "unanimously" agreed that C-8 is not a "volatile" chemical and, therefore, could not possibly escape from the drinking water to create any inhalation risk from the drinking water itself. This seems strange, given USEPA's statements in its recent draft Hazard Assessment for C-8 that "quantitative conclusions regarding rates of volatilization from water or Henry's Law constant are not possible. However, APFO and PFOS are capable of transport out of water." (USEPA Report, at 11-12.) Moreover, even if the existing data proved that it is not possible for any C-8 to escape from drinking water to pose any inhalation risk, the CAT Team's rejection of the RSC based on the inhalation risk from the drinking water itself completely ignores the purpose for which the RSC factor is used -- namely, to take into account potential exposure to C-8 from sources other than drinking water, such as C-8 in air emissions from the DuPont's Washington Works. It is not, therefore, clear how the CAT Team can justify not using the RSC factor for purposes of calculating a drinking water standard for C-8, particularly when both 3M and DuPont's own consultant, ENVIRON, agree that the RSC should be used, and it is not clear that C-8 will not escape from drinking water.

III. The CAT Team Did Not Include Cancer Data In Its Screening Level Calculations.

It is not clear why the CAT Team did not perform a dose-response analysis for C-8 using cancer endpoints. Recognizing that C-8 exposure has been confirmed to cause Leydig cell tumors, hepatocellular tumors, and pancreatic acinar cell tumors in rodents, the most common animal model used to identify probable human carcinogens, DuPont's own consultant, ENVIRON, included a dose-response analysis for cancer endpoints in the original version of the report it submitted to the CAT Team's Leader, Dr. Staats, in January of 2002, that advocated a 10 ppb level for C-8 in drinking water. (See ENVIRON Report, at 26-30.) In addition, the Consent Order between DuPont and the State of West Virginia requires the CAT Team to perform a "determination of the potential carcinogenicity of C-8." (Consent Order, at C-4.) Yet, when asked how the CAT Team incorporated the C-8 cancer data into its calculations for a C-8 screening level for drinking water, CAT Team representatives have stated that the triad of cancers attributable to C-8 exposure had somehow been determined by the CAT Team to be totally "irrelevant" to humans. Any such conclusion would, however, be completely inconsistent with the conclusion recently reached by USEPA in its draft Hazard Assessment for C-8 released just 2 months ago, in which USEPA stated that "as the mechanisms of carcinogenic action of [C-8] have not been fully elucidated, it is assumed that the tumors induced in rats are relevant to humans." (USEPA Report, at 9 (emphasis added) (Report also refers to 1997 Clegg panel findings that Leydig cell tumors in rodents are a legitimate end point for cancer risk assessment when the mechanisms of action are not completely understood.)) It is, therefore, not clear how the CAT Team, with USEPA participants, could support a totally contradictory conclusion.

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The inherent inconsistencies between the CAT Team's analysis and available facts and guidance generate stunning differences between the "screening level"/cleanup numbers generated using the CAT Team analysis and the levels that would be generated using an analysis that is more consistent with available data and agency guidance interpreting that data in the conservative manner required to ensure adequate protection of human health from exposure to chemicals in drinking water. The nature of some of those differences is highlighted in the attached charts (Exhibits A and B) showing the numbers allegedly used by the CAT Team and the numbers that would appear to be more supported by available data and agency guidance, assuming for purposes of argument only that one does not dispute the "key" studies, "critical effects," and "critical effect levels" selected by the CAT Team and that no Modifying Factor is warranted. As indicated in those attached charts, use of available data and agency guidance would not support use of an exposure level for C-8 in drinking water above even 1 ppb, which also happens to be the "safe" level for C-8 in drinking water that DuPont has used internally since at least 1991. Thus, given the fact that available data and guidance does not support the CAT Team's 150 ppb level for C-8 in drinking water, we request that the State and Federal agencies take immediate steps to clarify how and why the CAT Team came up with a number that is more than 10-15 times higher than the numbers calculated just several months ago by both 3M and DuPont's consultant, and more than 150 times higher than any number that would be possible when viewing the available facts and available agency guidance in the light most protective of human health, particularly when the CAT Team did not review the results of any studies that had not also been reviewed by DuPont and 3M. We also request prompt clarification to the public that the "screening level" numbers being developed by the CAT Team are not the same thing as DWHAs. We also request that the State and Federal agencies immediately take those steps necessary to abate and remediate this on-going threat to public health. Thank you.

Very truly yours,



Robert A. Bilott

RAB/mdm

Attachments

cc: R. Edison Hill, Esq. (w/o attachments)
Larry A. Winter, Esq. (w/o attachments)
Gerald J. Rapien, Esq. (w/o attachments)

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EXHIBIT A - CAT TEAM REGION IX SCREENING LEVEL ANALYSIS

Alternative Derivations of the RfD and RfC Values for C8										
Reference	Critical Effect	Critical Effect Level ^a	UF _A	UF _J	UF _L	UF _S	UF _D	Composite UF ^b	RfD/RfC	Screening Level
Oral Studies										
Palazzolo et al. (1993) ^c 90-day rat study	Increased relative liver weight with histopathology in male rats	0.47 (NOAEL in males) 0.72 (BMDL)	10	10	1	1	1	100	0.005 0.0072	X
York et al. (2002) Two-Generation rat study	Increased liver weight in male rats, supported by histopathology at higher doses.	1 (LOAEL in males)	10	10	3	1	1	300	X	X
	Increased liver weight in male rats, supported by histopathology at higher doses (histopathology was not examined at the lowest dose, but incidence of hypertrophy was 100% at next highest dose).	0.42 (BMDL in males) ^d	10	10	1	1	1	100	0.004	150 ppb
3M (1983) Two-year rat study	Tubular hyperplasia of the ovarian stroma and clinical signs (ataxia) in female rats.	1.6 (LOAEL in females) 1.57 (BMDL)	10	10	1	1	1	100	0.0157	X
	Hepatic megalocytosis in male rats.	0.73 (BMDL in males)	10	10	1	1	1	100	0.0073	X
Thomford et al. (2001) ^e 26-week cynomolgus monkey study	Decreased thyroid hormone levels in male cynomolgus monkeys, and supported by a NOAEL at the same dose for clinical signs of toxicity in the co-critical rhesus monkey study (Goldenthal et al., 1978)	3 - 10 (LOAEL in males)	10	10	3	3	1	1000	0.003 - 0.01	X

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EXHIBIT B - LIFETIME DRINKING WATER ANALYSIS

Alternative Derivations of the RfD and RfC Values for C8											
Reference	Critical Effect	Critical Effect Level ^a	UF _A	UF _H	UF _L	UF _S	UF _D	Composite UF ^b	RfD/RfC	DWEL	DWHA
Oral Studies											
Palazzolo et al. (1993) ^c 90-day rat study	Increased relative liver weight with histopathology in male rats	0.47 (LOAEL in males)	10	10	10	10	10	100,000	0.000047	1.65 ppb	0.3 ppb
		0.72 (BMDL)	10	10	10	10	10	100,000	0.000007		
York et al. (2002) Two-Generation rat study	Increased liver weight in male rats, supported by histopathology at higher doses.	1 (LOAEL in males)	10	10	10	10	10	100,000	0.00001	0.35 ppb	0.07 ppb
		0.42 (BMDL in males) ^d	10	10	10	10	10	100,000	0.000042		
3M (1983) Two-year rat study	Tubular hyperplasia of the ovarian stroma and clinical signs (ataxia) in female rats.	1.6 (LOAEL in females)	10	10	10	1	10	10,000	0.00016	5.6 ppb	1 ppb
		1.57 (BMDL)	10	10	10	1	10	10,000	0.00016		
	Hepatic megalocytosis in male rats.	0.73 (BMDL in males)	10	10	10	1	10	10,000	0.00007	2.6 ppb	0.5 ppb
Thomford et al. (2001) ^e 26-week cynomolgus monkey study	Decreased thyroid hormone levels in male cynomolgus monkeys, and supported by a NOAEL at the same dose for clinical signs of toxicity in the co-critical rhesus monkey study (Goldenthal et al., 1978)	3 (LOAEL in males)	10	10	10	10	10	100,000	0.00003	1 ppb	0.2 ppb

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01/17/92**BACKGROUND DOCUMENT 3
OFFICE OF DRINKING WATER HEALTH ADVISORIES**

The U.S. EPA's Office of Drinking Water (ODW) develops Health Advisories (HAs) for individual contaminants representing less-than-lifetime exposures of One-day, Ten-day, Longer-term (an exposure of several months up to 7 years), and for Lifetime exposures. The HAs are developed from data describing noncarcinogenic endpoints of toxicity. HAs developed for Lifetime exposures are based on the chemical's oral Reference Dose (RfD) (described in Background Document 1A1). HAs serve as informal technical guidance levels to assist public health officials when emergency spills or contamination situations occur. They are not legally enforceable and are subject to change as new information becomes available.

The HAs represent guidance levels for drinking water exposures. The values for the One-day, Ten-day and Longer-term exposure periods do not consider other sources of exposure such as food or air. For each, the resulting value, in mg/L, assumes that 100% of an individual's exposure comes from drinking water. The lifetime HA, calculated only for an adult from a chronic study, does take into consideration other sources of exposure by applying a relative source contribution (RSC). In the absence of chemical-specific data, an RSC of 10 is used for inorganic contaminants and an RSC of 20 is used for organic contaminants (NAS, 1977).

The HAs are derived employing an approach similar to that used to derive RfDs in that a NOAEL (or LOAEL) is divided by an uncertainty factor (UF). This value is adjusted for the body weight of the protected individual and assumed daily water consumption

The study selected for deriving a HA ideally employs an oral route of exposure. Therefore, a study where the chemical exposure is by drinking water is ideal. Studies using dietary or gavage exposure are also acceptable. Inhalation data are only used in instances where oral data are not available and by applying specific assumptions used in route-to-route extrapolation.

The data used for HA derivations are generally from a study of comparable duration to the HA time period being calculated. For a One-day HA, the study time period should ideally be from a single exposure. However, longer study durations may be acceptable if the data base is limited. The Ten-day HA may be calculated from a study of less than or equal to 30 days. Developmental studies involving maternal exposure during part of the gestational period have also been used. Longer-term HAs are derived from subchronic studies where animals are exposed for approximately 10% of their lifetime

(for example, 90 days for rodents).

The NOAELs or LOAELs are identified from studies that provide information on the target organ affected. A study that demonstrates a dose-response relationship is preferred over a study where only a single dose has been tested. Lethality studies are not considered for HA derivation.

HAs are derived to protect sensitive members of the population. For the One-day and Ten-day HAs, the protected individual is assumed to be a child. The child is assumed to weigh 10 kg unless otherwise noted. It is also assumed that the child consumes 1 L of water/day. For a Longer-term exposure, HAs are calculated for both a child and an adult. It is assumed that an adult weighs 70 kg and consumes 2 L of water/day. For a Lifetime exposure, the HA is only calculated for an adult, since the child will not be in this exposure category for a lifetime.

HAs are calculated according to the equation:

$$HA = (\text{NOAEL or LOAEL}) (BW) / (UF) (\text{L/day}) = \text{mg/L}$$

where: NOAEL = No-Observed-Adverse-Effect Level
(the exposure in mg/kg bw/day)

or

LOAEL = Lowest-Observed-Adverse Effect Level
(the exposure dose in mg/kg bw/day)

BW = assumed body weight of protected individual
(10 kg child or 70 kg adult)

UF = uncertainty factors, based on quality and nature of data

L/day = assumed water consumption
(1 L/day for child or 2 L/day for adult)

The uncertainty factor accounts for the inherent variability within the human population and between the animal species. An uncertainty factor of 10 is used when good acute or chronic human data that identify a NOAEL are the basis for the HA. If the human data are of good quality, but identify a LOAEL rather than a NOAEL, then an uncertainty factor of 100 is used. An uncertainty factor of 100 is also used when a NOAEL from a well-conducted animal study serves as the basis of the HA. If an animal study that identifies a LOAEL, or an animal study of limited quality is the basis of the HA, then an uncertainty factor of 1000 is employed. Use of the uncertainty factor is largely judgmental, and may take into account the quality of the toxicological data base, the significance of the adverse effect or the counterbalancing of possible beneficial effects.

Lifetime HAs (noncarcinogens only) are calculated from the Drinking Water

Equivalent Level (DWEL) which, in turn, is based on the unrounded RfD. DWELs are calculated from the equation:

$$DWEL = (RfD) (BW) / (_ L/day)$$

where: RfD is the unrounded oral RfD derived in Section 1 of the chemical file, and, BW and $_ L/day$ are the adult reference values for body weight and water consumption, respectively. Lifetime HAs assume that only a given percentage of the total compound intake is by drinking water and are derived by the equation:

$$Lifetime\ HA = DWEL \times RSC$$

where: RSC = relative source contribution; the assumed exposure from drinking water.

Lifetime HAs are not derived for compounds potentially carcinogenic for humans because of the difference in assumptions concerning toxic thresholds for carcinogenic and noncarcinogenic effects.

In situations where data are not available to calculate Longer-term HAs, the DWEL may be recommended for the Longer-term HA. For the child Longer-term HA, the DWEL may be recalculated using the child's weight and water consumption.

For more information about Health Advisories, call the Office of Drinking Water at (202)382-7571 or FTS 382-7571.

Reference: NAS (National Academy of Sciences). 1977. Drinking Water and Health, Vol. 1. Washington, DC.



SEARCH IRIS



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