International POPs Elimination Network

INFORMATION RELEVANT TO THE BASEL CONVENTION'S HAZARDOUS CHARACTERISTIC H11 – TOXIC (DELAYED OR CHRONIC), i.e., *DE MINIMIS* CONCENTRATIONS IN WASTE, AND THE STOCKHOLM CONVENTION'S "LOW POPS CONTENT"

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This informational document is intended to inform and support development of criteria for the Basel Convention's Hazardous Characteristic H11 – Toxic (Delayed or Chronic) to be used in classifying wastes with regard to their chronic toxicity, giving particular consideration to the potential implications of these criteria and resulting *de minimis* levels with regard to the "low POPs content" levels to be developed in cooperation with the Conference of Parties of the Stockholm Convention on Persistent Organic Pollutants.

SUMMARY

The Stockholm Convention specifies that persistent organic pollutants (POPs), upon becoming wastes, must be *"destroyed or irreversibly transformed so that they do not exhibit the characteristics of persistent organic pollutant or otherwise disposed of in an environmentally sound manner when destruction or irreversible transformation does not represent the environmentally preferable option or the persistent organic pollutant content is low ...."*[1] The Convention also requires the Conference of the Parties (COP) to work with the *"appropriate bodies of the Basel Convention"* to *"[e]stablish levels of destruction and irreversible transformation necessary to ensure that the characteristics of persistent organic pollutants as specified in paragraph 1 of Annex D are not exhibited*".[2] The POPs characteristics listed in Annex D paragraph 1 are persistence, bio-accumulation, potential for long-range environmental transport, and adverse effects. Each molecule of a given POP possesses these characteristics. Consequently, destruction or irreversible transformation must be carried out to the extent that POPs cannot be detected. I.e., effectively 100 percent destruction or irreversible transformation must be achieved.

The Stockholm COP must also work cooperatively with the Basel Convention "*to establish, as appropriate, the concentration levels of the chemicals listed in Annexes A, B and C in order to define the low persistent organic pollutant content referred to in*

[1] Stockholm Convention on Persistent Organic Pollutants Article 6.1(d).
[2] Stockholm Convention at Article 6.2(a).

paragraph 1(d)(ii)".[3] As described in the first paragraph, this "low POPs content" is the threshold concentration above which POPs wastes must undergo destruction or irreversible transformation unless this is not the environmentally preferable option. In the latter circumstance or when the POPs concentration is below this "low POPs content", the wastes must be otherwise disposed of in an environmentally sound manner.

Any discussions of *de minimis* levels, presumably those levels of chemicals of concern below which unacceptably high human health impacts are not expected to occur, and "low POPs content" must be grounded in considerations of the overriding purpose of the Stockholm Convention, which is *"to protect human health and the environment"*[4] with awareness of *"health concerns,* ***especially in developing countries****"*[5] and taking into account particular requirements of developing countries, and the need to transfer technology and to provide financial and technical assistance.[6] Therefore, it is unreasonable, unjust and contrary to the purpose of the treaty to set acceptable levels of "low POPs content" based on a lowest common denominator of what countries with lesser capacity can attain. Global, regional and national interests are best served by establishing health-based levels for *de minimis* concentrations and for low POPs content in conjunction with appropriate support for capacity-building to enable developing countries to achieve those levels.

Furthermore, *de minimis* concentrations that vary depending on the use of contaminated sites, such those set by the United States and Germany for soil contaminated with PCBs and dioxin,[7] are short sighted in that they assume that a given site will always maintain its current use. Over time uses can change, and records can be lost or destroyed. The better approach is to set the limits at the most strict level for all sites and so avoid long-term problems.

These considerations make it imperative that, for each of the POPs, the *de minimis* concentration and "low POP content" are health-based limits that stem from an evaluation of each chemical's long-term potential for adversely affecting human health. Such an evaluation should include analysis of ecological pathways each POP can follow, long-term bioaccumulation factors, all exposure pathways (including prenatal exposure and postnatal exposures via breastmilk), human health data for each POP, and related information. Once health-based limits have been set, sampling and analytical technologies may be addressed to ensure that levels are determined by universal methods of appropriate precision and accuracy. With this approach, establishing both *de minimis* concentrations and "low POPs content" is a two-step process involving (1) agreement on health-based levels and (2) determination of universal sampling and analytical standards based on technical feasibility. Once the standards are established, capacity building within developing countries to develop sampling and analytical capabilities as well as waste treatment capabilities must be supported.

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[3] Stockholm Convention at Article 6.2(c).
[4] Stockholm Convention on POPs, Art. 1.
[5] Stockholm POPs Convention, Preamble (emphasis added).
[6] Id.
[7] See Part III below and Appendix I.

Step 1: Health-Based Standards

The United States Environmental Protection Agency (USEPA) has determined that aldrin, chlordane, DDT, dieldrin, dioxin, heptachlor, hexachlorobenzene, PCBs and toxaphene are probable human carcinogens.[8] It is USEPA policy to assume that no level of exposure to probable human carcinogens is safe.[9] Following this policy, the health-based *de minimis* concentrations and "low POPs content" levels of these chemicals should be set at zero. For the remaining two chemicals, endrin and mirex, carcinogenicity has not yet been conclusively determined. USEPA has estimated levels of daily exposure to toxic non-carcinogens that do not result in appreciable threat of deleterious effects during a lifetime. These levels are 0.0003 mg/kg-day for endrin and 0.0002 mg/kg-day for mirex.[10]

USEPA's numbers are not directly applicable to hazardous waste in all cases because they assume chronic exposure and do not take into account bioaccumulation. These considerations present no additional concerns for those chemicals for which the *de minimis* concentration has been set at zero—the majority of the POPs chemicals—because the acceptable level of exposure remains zero after these considerations have been taken into account. Determining appropriate health-based *de minimis* levels for endrin and mirex poses a greater problem. USEPA has conducted complex analyses focused on treated hazardous wastes and considering exposure pathways and human health, among other things. These studies have resulted in proposed levels of hazardous chemicals acceptable in the wastewater and nonwastewater resulting from the treatment of hazardous waste. These so-called "exit levels" are, for endrin, 0.073 mg/L for waste water and 0.26 mg/kg for nonwastewater[11] and for mirex/kepone, 0.0000264 mg/L for wastewater 0.000277 mg/kg for non-wastewater.[12] While these exit levels have been criticized and have not been adopted, they represent the results of USEPA's most comprehensive study of the situation to date.

Step 2: Limits of Detection and/or Quantitation

USEPA has defined a quantity called the Exemption Quantitation Criteria (EQC), which is equal to the *"lowest limit [of a chemical] that can be reliably measured within acceptable limits of precision and accuracy during routine laboratory operating conditions using appropriate methods*."[13] This is a reasonable level at which to set both *de minimis* concentrations and "low POPs content" levels. Those that have been

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[8] See Table 5.
[9] See the discussion of the Safe Drinking Water Act in Section I.C.1. below on p. 13. The two chemicals not identified as probable human carcinogens are endrin and mirex.
[10] See Table 5: Oral RfDs for endrin and mirex.
[11] See Table 4: Health-Based Proposed Exit Levels.
[12] 60 FR 66344, 66435, Table C-2. Summary of Constituent-Specific Exit Level Development Using MCL-Based Numbers and 66430, Table C-1. Summary of Constituent-Specific Exit Level Development Using Toxicity Benchmarks. The limits for kepone determined by these two methods are the same.
[13] 60 FR 66344, 66377, Dec. 21, 1995. See section 2.1.2 below and Table 4, column 3: Health- Based Proposed Exit Levels.

determined by USEPA are given in Table A below. EQCs need to be determined for the spaces left blank.

In its proposal for setting "exit levels" for hazardous pollutants described above, USEPA proposed setting the exit levels at the EQC in those cases when *"quantitative measurement of the ... risk-based level cannot reliably be achieved*,"[14] with the caveat that the chemical would also have to meet the Universal Treatment Standards (UTS). The only one of the Stockholm-listed POPs chemicals for which the EQC is greater than the UTS is mirex/kepone. Thus for mirex/kepone, the UTS standard is included in Table A.

Table A. Proposed *de minimis* Concentrations and "Low POPs Content" Levels

POP	Health-Based POPs Content Goal	*de minimis* Concentrations and "Low POPs Content"[15]	
		Wastewater mg/L	Nonwastewater mg/kg
Aldrin	zero	EQC = 0.000034	EQC = 0.0006
Chlordane	zero	EQC = 0.00004	
DDT	zero	EQC = 0.000081	
Dieldrin	zero		
Dioxins/Furans	zero	EQC = 1.000 x 10-8	
Endrin	0.073 mg/L for wastewater 0.26 mg/kg for non-wastewater		
Heptachlor	zero	EQC = 0.00004	
Hexachlorobenzene	zero	EQC = 0.0016	EQC = 0.072
Mirex/Kepone	0.0000264 mg/L for wastewater 0.000277 mg/kg for non-wastewater	EQC = 0.016 UTS = 0.0011	EQC = 0.097
PCBs	zero	EQC = 0.0005	EQC = 0.04
Toxaphene	zero	EQC = 0.0013	EQC = 0.03

EQC = Exemption Quantitation Criteria
UTS = Universal Treatment Standards

[14] 60 FR 66344, 66378.
[15] See Section 2.1.2 and Table 4 for a more complete discussion of these limits.

Table B: Comparison of Technology-Based and Health-Based Hazardous Waste Standards (see Table 4 for a more complete presentation of values and their derivations)

POP	Health-Based Residue Concentration Limits (currently stayed), mg/kg	Health-Based Proposed Exit Levels (proposed rule)			Technology-Based Standards (in effect): Treatment Standards for Hazardous wastes 40 CFR 268.40 and Universal Treatment Standards 40 CFR 268.48	
		Waste water mg/L	Nonwastewater		Waste water mg/L	Non-waste-water mg/kg
			Totals mg/kg	Leach** mg/L		
Aldrin	0.00002	0.000034*	0.0006*	0.000034*	0.021	0.066
Chlordane	0.0003	0.00004*	0.098	0.036/ 0.00016	0.0033	0.26
DDT	0.001	0.000081*	0.0032	0.0054	0.0039	0.087
Dieldrin	0.00002	0.000059	0.0018	0.54	0.017	0.13
Dioxins & Furans	6 x 10-8	1.000x10-8*	8.000x10-9	5.400x10-7/ 1.000x10-8	0.000063	0.001
Endrin	0.0002	0.073	0.26	24/32	0.0028	0.13
Heptachlor	0.00008	0.00004*	8		0.0012	0.066
Hexachloro-benzene	0.0002	0.0016*	0.072*	0.018/ 0.0016*	0.055	10
Mirex/Kepone #	N/A	0.016*	0.097*	0.016*	0.0011	0.13
PCBs	0.00005	0.0005*	0.04*	0.009/ 0.0005*	0.10	10
Toxaphene	0.005	0.0013*	0.03*	6/0.11	0.0095	2.6

Draft scoping paper on H11 as submitted by the United States

The values presented in Tables A and B above stand in stark contrast to those presented in Appendix A of UNEP/CHW/OEWG/1/INF/8, the draft scoping paper on H11:

UNEP/CHW/OEWG/1/INF/8

Appendix A

Basel H-11 Waste Constituent Categories and *De Minimis* Concentrations in Waste

Waste Constituent Hazard Category		*De Minimis* Waste Concentration (Waste is not H-11 hazardous below this value)
Category A:	Unit cancer risk of greater than 1 per mg/kg-d Chronic toxicity RfD less than 10^{-3} mg/kg-d	100 ppm
(Note: Arsenic, with unit cancer risk of 1.5 per mg/kg-d would fit in Category A)		
Category B:	Unit cancer risk of 10^{-1} to 1 per mg/kg-d Chronic toxicity RfD between 10^{-3} and 10^{-2} mg/kg-d	1000 ppm (0.10%)
Category C:	Unit cancer risk of 10^{-2} to 10^{-1} per mg/kg-d Chronic toxicity RfD between 10^{-2} and 10^{-1} mg/kg-d	1.0%
(Note: Benzene, with unit cancer risk of 5.5×10^{-2} per mg/kg/d would fit in Category C)		
Category D:	Unit cancer risk less than 10^{-2} per mg/kg-d Chronic toxicity RfD greater than 10^{-1} mg/kg-d	10%

Based on the unit cancer risks presented in Table 5, the listed POPs would be categorized as follows in the proposed scheme:

Waste Constituent Hazard Category	*De Minimis* Waste Concentration	Listed POPs
Category A	100 ppm	Aldrin, dieldrin, dioxins and furans, heptachlor, hexachlorobenzene, toxaphene
Category B	1,000 ppm (0.10%)	Chlordane, DDT
Category C	10,000 ppm (1.0%)	PCBs
Category D	100,000 ppm (10%)	
Unclassifiable		Endrin, mirex

As shown by this categorization of the listed POPs, the *de minimis* concentrations proposed in the draft scoping paper are far in excess of any such concentrations that might be regarded as compatible with the goals and obligations of the Stockholm Convention. Moreover, no known national or regional regulatory scheme presents 100 ppm as a *de minimis* level for dioxins or 10,000 ppm as a *de minimis* level for PCBs.

It is also apparent that more than four categories are necessary if the full range of toxic potencies of the listed POPs is to be appropriately encompassed. For example, in this proposed system, dioxins and aldrin fall into the same category, Category A, even though dioxins, which are the most potent of the listed POPs, have a unit cancer risk for oral

intake that is some 365 times greater than that of aldrin, the POP which has the second highest unit cancer risk, as shown in Table 5.

Crafting an appropriate categorization scheme for hazardous wastes is a very complex undertaking and the draft scoping paper is a first step in that direction. However, as exemplified by placement of the listed POPs within the proposed scheme, the task of selecting suitable categories and *de minimis* levels requires much more consideration.

1.0 STOCKHOLM CONVENTION

Article 6.1(d)(ii) of the Stockholm Convention on Persistent Organic Pollutants states that each Party shall take appropriate measures to ensure that stockpiles and wastes consisting of or containing POPs are *"disposed of in such a way that the persistent organic pollutant content is destroyed or irreversibly transformed so that they do not exhibit the characteristics of persistent organic pollutants"* unless this is not *"the environmentally preferable option"* or the *"persistent organic pollutant content is low*."[1] Article 6.2 requires Parties to *"cooperate closely with the appropriate bodies of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal*"[2] to, *inter alia*, (a) establish levels of destruction and irreversible transformation of POPs, and (c) establish what concentration levels constitute the low POPs content referred to in Art. 6.1.

The purpose of this document is to inform the Basel convention OEWG discussion of *de minimis* concentrations as well as "low POPs content" by specifying the levels deemed acceptable under US law for each of the currently listed POPs chemicals and examining how these levels are justified.

2.0 USEPA REGULATIONS

USEPA regulates POPs substances under a number of federal acts, including the Clean Air Act, the Clean Water Act, the Safe Drinking Water Act, and the Solid Waste Disposal Act, assigning different limits in different contexts.[3] The standards most directly analogous to the establishment of "low POPs content" for the purposes of the Stockholm Convention are those dealing with the fate of materials remaining after the treatment of hazardous wastes. These are discussed below and given in Table 1. Additional information regarding PCBs can be found in Appendix 1.

2.1 Hazardous Waste Regulations

2.1.1 Current Hazardous Waste Regulations: Technology-Based Standards

Treatment Standards for Hazardous Wastes (40 CFR 268.40) and the Universal Treatment Standards (40 CFR 268.48) are technology-based standards (best demonstrated available technology, BDAT),[4] and for the chemicals under consideration, acceptable levels are the same for both standards (see Table 1). The Treatment Standards for

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[1] Stockholm Convention on Persistent Organic Pollutants, Art. 6.1(d).
[2] *Id*. at Art 6.2.
[3] One of the POPs, mirex is a pesticide that was used in the United States to control fire ants. Its use has been banned since 1978. The USEPA has identified Mirex as a hazardous waste but has not set any limits for its treatment and disposal or for its allowability in drinking water. USEPA has set treatment standards for hazardous wastes containing kepone, a decomposition product of Mirex, which has also been used as a pesticide. Agency for Toxic Substances and Disease Registry.
[4] Treatment Standards for Hazardous Wastes: 51 FR 40572-01, 40578; proposed rule; 55 FR 22520-01, 22524, final rule. Universal Treatment Standards: 59 FR 49782, 47986; final rule.

Hazardous Wastes specify the amount of each chemical allowed in waste that is to be "land disposed." Land disposal is defined to include *"any placement of such hazardous waste in a landfill, surface impoundment, waste pile, injection well, land treatment facility, salt dome formation, salt bed formation, or underground mine or cave*."[5] Universal Treatment Standards are invoked in the treatment of contaminated soils;[6] the cleanup of spills at hazardous waste treatment, storage, and disposal facilities (TSDs); and the treatment of "characteristic wastes."[7]

USEPA has also promulgated regulations limiting the amounts of undestroyed chemicals of concern that hazardous waste combustors can emit into the air. Combustors of wastes containing dioxin must achieve a destruction and removal efficiency (DRE)[8] of at least 99.9999%.[9] In addition, these combustors may not emit more than 0.20 ng TEQ/dscm of dioxin into the air.[10] Both the DRE standard and the emissions limit are based on Maximum Achievable Control Technology (MACT).[11] Combustors of wastes containing other POPs must achieve a DRE of at least 99.99%, based on analysis of a chosen principal organic hazardous constituent (POHC).[12]

2.1.2 USEPA Attempts at Setting Health-Based Hazardous Waste Standards

USEPA has tried on at least two occasions to establish health-based standards for acceptable levels of hazardous chemicals in treated hazardous wastes. The first try, promulgated on Feb. 21, 1991 as 40 CFR 266.112, listed health-based standards for determining whether residues from Bevill devices (cement kilns, light-weight aggregate kilns, primary smelters, coal-fired boilers) co-processing hazardous waste and raw materials are hazardous wastes. These health-based limits are given in Table 2. They were derived by

> *"convert[ing] drinking water limits (i.e., maximum concentration limits (MCLs), and limits based on reference doses (RfDs) for noncarcinogens and unit risk values for carcinogens assuming the exposed individual drank two liters of water per day for a lifetime) to total concentrations simply by mathematically converting the milligram per liter drinking water limits to milligram per*

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[5] Solid Waste Disposal Act 42 USC 6924(k) "Land disposal" defined.
[6] 40 CFR 268.49: Alternative LDR treatment standards for contaminated soil.
[7] 40 CFR 268.40: Treatment Standards for Hazardous Wastes:
[8] USEPA's performance standard for hazardous waste incinerators, destruction and removal efficiency (DRE), takes into account only those quantities of undestroyed chemicals of concern that are released to the air in stack gases. The more comprehensive performance standard – and the appropriate standard in the context of the Stockholm Convention -- is destruction efficiency (DE), which takes into account releases in all outputs (gaseous, liquid and solid) of incinerators and other treatment processes.
[9] 40 CFR 63.1203 (c)(2). DRE compares the amount of a toxic chemical going into the combustor with the amount of that toxic chemical emitted into the air after combustion. It does not look at the amount of the toxic chemical present in the solid and liquid products of combustion.
[10] 40 CFR 63.1203 (a)(1)(i).
[11] 64 FR 52828, 52861, Dec. 30, 1999 (emissions standard is a MACT standard); id. at 52849 (DRE standards are part of the MACT standard).
[12] 40 CFR 63.1203(c)(1).

kilogram units."[13]

More than two years after the rule was finalized, USEPA placed an administrative stay on the health-based limits, requiring that instead affected owners and operators of Bevill devices "comply with land disposal restriction [LDR] standards [for nonwastewaters] for the hazardous constituents that are reasonably expected to be present in their residues."[14] As of Sept. 8, 2003, that stay is still in effect, and the affected entities are still operating under the Nov. 1993 interim rule. The reason given for the stay was that the health-based limits are "mistaken" because

> *"[i]n the rush to promulgate the [ ] rules under a stringent court-ordered deadline, the Agency failed to note that this approach continues to assume that the hypothetical exposed individual is ingesting two liters (two kilograms) per day of the media--that is, two kilograms or 4.4 pounds of residue. Clearly, this was not the Agency's intent. In previous risk assessments, the Agency has often assumed that an individual ingests 0.2 grams of soil per day. If a residue ingestion rate of 0.2 grams per day was assumed, then the [health-based] nonmetal limits may be orders of magnitude too stringent*."[15]

USEPA justified the use of the technology-based LDR levels in place of the health-based limits by stating that (1) use of these levels was to be on an interim basis pending rulemaking to establish health-based levels;[16] and (2) most of the LDR standards are based on the level of detection of the chemical in combustion residues, so even if the true health-based standard for a chemical is lower than the LDR standard, it would have no practical significance.[17]

The next try, proposed in 1995, is known as the "Hazardous Waste Identification Rule."[18] This proposed rule was intended to determine "exit levels" for hazardous wastes: the concentrations of hazardous chemicals in treated hazardous wastes below which treated hazardous wastes are no longer considered hazardous. The exit levels were developed after extensive analysis that took into account pathways of exposure, human health benchmarks (both carcinogenic and noncarcinogenic), ecological benchmarks, risk assessment, and ground water risk analysis, among other things.[19]

USEPA proposed two alternative bases for exit levels and asked for comments on each: (1) exit levels derived by using an MCL benchmark for drinking water ingestion and using toxicity benchmarks for all other routes of exposure, and (2) exit levels derived by using toxicity benchmarks for all routes of exposure. The Agency's proposed option for establishing exit values is based on risk modeling to a hazard quotient of 1 and a 1×10^{-6}

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[13] 58 FR 59598-01, 59599, Nov. 9, 1993.
[14] *Id*. at 59598.
[15] *Id*. at 59599.
[16] *Id*. at 59600.
[17] *Id*.
[18] 60 FR 66344, Dec. 21, 1995
[19] *Id* at 66344.

cancer risk.[20] Because the proposed rule generated extensive comments that led USEPA to conclude that *"considerable work needed to be done to resolve complex scientific and technical issues raised,"*[21] the rule has yet to be finalized.

USEPA proposed exit levels for the Stockholm listed POPs chemicals are given in Table 3. As can be seen from the table, many exit levels are set at the Exemption Quantitation Criteria, (EQC) which USEPA has declared to be the *"lowest limit that can be reliably measured within acceptable limits of precision and accuracy during routing laboratory operating conditions using appropriate methods.*"[22] USEPA describes EQC by saying:

> *"A regulatory action level (e.g., exit levels) must provide a clear distinction between those wastes subject to the regulation and those excluded. Action levels based on analytical determinations within a methods quantitative range can be used to determine regulatory status with a high degree of confidence. On the other hand, when an analyte is present at a concentration equal to the detection limit (DL) it will be detected only half the time. In other words there is a 50% risk of a false negative result when the analyte is present at the DL concentration. There is, however, a less than 1% risk of false positive results at this level. Therefore, regulations set at the detection limit would not identify non-compliance reliably*."[23]

Given that the purpose of using EQC rather than detection limits is to increase the probability that a substance present at that concentration will indeed be detectable, the EQC level must be higher than the detection limit.

2.1.3 Comparison of Technology-Based and Health-Based Standards

Table 4 summarizes the current technology-based Treatment Standards for Hazardous Wastes, the proposed health-based exit levels and the stayed health-based concentration limits for Bevill devices. It can be seen from the table that, except for endrin, the health-based limits are considerably lower than the technology-based standards. The table also shows that the proposed exit levels for wastewater for nine out of the eleven POPs chemicals are at the level of the Exemption Quantitation Criteria. USEPA justified using the LDR tech-based standards in place of the health-based standards by saying that the technology-based standards are in many cases set at the level of detection. It can be seen from the table, however, that for the Stockholm POPs, most of the technology-based standards are considerably higher than the EQC.

3.0 POPs Limits Under Other USEPA Regulations

USEPA limits on POPs under the Safe Drinking Water Act and the Clean Water Act are given in Table 6.

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[20] *Id* at 66353.
[21] 64 FR 63382, 63389, Nov. 19, 1999
[22] 60 FR 66344, 66377.
[23] 60 FR 66344, 66377, Dec 21, 1995.

3.1 Safe Drinking Water Act

The Safe Drinking Water Act requires USEPA to develop two parameters in relation to toxic substances in drinking water: maximum contaminant level goals (MCLGs) and maximum contaminant levels (MCLs). MCLGs are health-based parameters set at *"concentration levels at which no known or anticipated adverse health effects would occur, allowing for an adequate margin of safety*."[24] MCLs are then set *"as close to the MCLG as is feasible*"[25] taking into account *"availability and performance of technologies for removing the contaminant, the costs of applying those technologies*" and the *"laboratory ability to measure the contaminant reliably*."[26] In addition, USEPA ensures that each MCL is set at a level below the "maximum reference risk range" of 10-4 to 10-6 excess individual risk of cancer from a particular carcinogen at lifetime exposure.[27]

USEPA classifies six of the POP chemicals for which MCLGs have been developed (chlordane, heptachlor, PCBs, dioxin, toxaphene, and hexachlorobenzene) as Group B2 carcinogens.[28] Group B2 carcinogens are substances that are *"Probable human carcinogen[s] based on a combination of sufficient evidence in animals and inadequate data in humans.*"[29] USEPA policy is to set the MCLGs for all substances that are at least probable human carcinogens, including Group B2 carcinogens, at zero, assuming there is no threshold value below which exposure has no adverse effect. Thus, as shown in Table 6, the MCLGs for chlordane, heptachlor, PCBs, dioxin, toxaphene, and hexachlorobenzene are set at zero.

Because there have been conflicting reports about whether or not endrin is carcinogenic, USEPA has classified it as a Group D carcinogen– *"Not classifiable based on lack of data or inadequate evidence of carcinogenicity from animal data*."[30] Therefore, in determining an MCLG for endrin, USEPA relied on reference dose (RfD) data for endrin's noncarcinogenic adverse effects on health.[31] USEPA derived a drinking water equivalent level (DWEL) of 0.009 mg/L by multiplying the RfD by an assumed adult body weight of70 kg, then dividing by an average daily water consumption of 2 L/day. The DWEL assumes total daily exposure to a chemical is from drinking water. Multiplying the DWEL by the relative source contribution[32] translates into an MCLG for endrin of 0.002 mg/L.[33]

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[24] 56 FR 3526, 3531, Jan. 30, 1991.
[25] 56 FR 3526, 3547, Jan. 30, 1991.
[26] Id.
[27] Id.
[28] chlordane: 56 FR 3526, 3544; heptachlor: 56 FR 3526, 3545; PCBs: 56 FR 3526, 3546; dioxin: 57 FR 31776, 31795; toxaphene: 54 FR 22062, 22092; hexachlorobenzene: 55 FR 30370, 30393.
[29] 56 FR 3526, 3532.
[30] 55 FR 30370, 30392.
[31] Id at 30391. The study USEPA relied on was a chronic oral dog bioassay conducted by Jolley et al. and published in 1969 (CBI MRID 00030198). Id.
[32] 56 FR 3526, 3532
[33] 55 FR 30370, 30391.

3.2 Clean Water Act

3.2.1 Ambient Water Criteria

Section 129 of Title 40 of the Code of Federal Regulations sets effluent limitations on manufacturers and formulators of various toxic chemicals, including six of the POPs included in the Stockholm convention—aldrin, DDT, dieldrin, endrin, PCBs, and toxaphene. These regulations include for each toxic chemical an "ambient water criterion," which is defined as

> *"that concentration of a toxic pollutant in a navigable water that, based upon available data, will not result in adverse impact on important aquatic life, or on consumers of such aquatic life, after exposure of that aquatic life for periods of time exceeding 96 hours and continuing at least through one reproductive cycle; and will not result in a significant risk of adverse health effects in a large human population based on available information such as mammalian laboratory toxicity data, epidemiological studies of human occupational exposures, or human exposure data, or any other relevant data."*[34]

Ambient water criteria set for POPs chemicals are given in Table 6. Although section 307(a) of the CWA does not expressly require the USEPA to set ambient water criteria, the agency did so because it found the criteria to be *"an important ingredient in carrying out the mandate of that section to provide an 'ample margin of safety'* for organisms which might be affected by discharges of [toxics] in the aquatic environment."[35] Moreover, the criteria *"provide a most helpful intermediate in establishing levels of effects to be avoided ... They also provide a triggering mechanism for the 'tightening variance clause' established in section 129.7 for water bodies to which a discharge at the levels in the standards still would not provide an ample margin of safety owing to site-specific peculiarities.*"[36]

Ambient water criteria are set at the level necessary to protect aquatic organisms (including the food chain supporting them) and consumers of aquatic life (including humans) from the effects of a pollutant with an adequate margin of safety assuming continued or chronic presence of the pollutant at that level in the water.[37] Generally, the only data available on the effects of POPs is acute toxicity data rather than chronic toxicity data. Because the ambient water criteria assume chronic exposure, it is necessary to translate the acute toxicity levels into chronic toxicity levels. This is done by multiplying the acute toxicity level for the most sensitive species to be protected from a

[34] 40 CFR 129.2(g).
[35] 41 FR 6532, 6548, Feb. 2, 1977.
[36] 41 FR 2588, 2610, Jan. 12, 1977.
[37] *Id* at 2588 and 2593.

given chemical (usually the 96-hour LC/50) by a so-called "application factor."[38] The resulting ambient water concentration is expected to "protect all species from chronic toxicity."[39] The National Academy of Sciences has recommended an application factor of 0.01 for organochlorine pesticides unless an application factor has been experimentally determined.

Setting ambient water criteria for POPs chemicals at a level that protects aquatic organisms from chronic exposure to the chemicals in the water is not protective enough because these chemicals bioaccumulate in aquatic organisms. That is, aquatic organisms absorb these chemicals, both from the surrounding water and from the food they eat, and store them in their tissues at levels much higher than that found in the ambient water. Initial absorption of a chemical is rapid, and then the rate of absorption decreases until a steady state is approached. It may take as little as one day or as long as several months for the level of the chemical in the organism to reach the steady-state level. Once this level has been reached, however, the concentration of the chemical in the organism is generally proportional to the ambient water concentration (although hot spots, sediments and other local factors may affect proportionality), and can be expressed as a "bioaccumulation factor:" the ratio between the concentration of the steady-state level of the chemical in the organism and the concentration of the chemical in the ambient water.[40] The bioaccumulation factor is independent of the concentration of the chemical in the ambient water.[41]

Thus, the ambient water criterion for PCBs was set at a level that takes into account a (conservative) bioaccumulation factor for PCB's of 274,000. As explained by the USEPA, *"[t]he ... criterion [for PCBs] of 0.001 ug/l multiplied by 274,000 produces a tissue level of 0.274 parts per million (ppm). This is below any of the reported effects levels relied on by the Agency in developing the criterion*."[42]

3.2.2 Toxics Criteria for States Not Complying with the Clean Water Act Section 303(c)(2)(B)

Section 303(c)(2)(B) of the Clean Water Act requires states to adopt specific numerical criteria for toxic pollutants. USEPA has developed default criteria to use in states that have not yet developed their own.[43] These criteria are designed to ensure that the water in a given water body is clean enough to protect all designated uses of that water body. Designated uses of water bodies usually include such things as providing habitat for fish and shellfish and providing a supply of fish and shellfish that is safe for human and wildlife consumption. USEPA's default criteria that have been set for Stockholm listed POPs are given in Table 6.

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[38] *Id* at 2598. The use of application factors for deriving chronic toxicity levels from acute toxicity levels is a "recognized and sound scientific practice" recommended by the National Academy of Sciences. 41 FR 6532, 6548.
[39] 41 FR 2588, 2593.
[40] 41 FR 6532, 6539. Feb. 2, 1977.
[41] *Id*.
[42] *Id* at 6548.
[43] 40 CFR 131.36

The criteria for fresh and saltwater organisms *"might be thought of as an estimate of the highest concentration of a substance in water which does not present a significant risk to the aquatic organisms in the water and their uses."*[44] The criteria were developed using toxicity data from eight specified families of organisms representing a wide spectrum of aquatic life.[45] USEPA admits that the criteria may be underprotective because toxic effects were considered for one chemical at a time, with *"no consideration of additive or synergistic effects."*[46] USEPA also states that the criteria may in some circumstances be overprotective as they do not take into account variations in receiving water characteristics such as pH and hardness.[47]

The criteria for human health were developed from carcinogenicity data and systemic toxicity data.[48] USEPA's default assumption is that humans are exposed to the toxic chemical only via ingestion of water and contaminated fish and shellfish.[49] USEPA assumes consumption of *"2 liters per day of water and 6.5 g per day of fish/shellfish contaminated at a level equal to the criteria concentration but multiplied by a bioconcentration factor"* by a person having a mass of 70 kg.[50] As was the case for aquatic species, there is no consideration of additive, synergistic or antagonistic effects in mixtures.[51]

USEPA has found all of the POPs chemicals except endrin and mirex/kepone to be at least probable carcinogens, and therefore assumes that for these chemicals there is no threshold value below which exposure is safe.

4.0 POPs Limits Under CERCLA

The Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) describes the extent to which a hazardous waste site must be cleaned up in order to be considered clean.[52] According to this law, any hazardous substance that will remain onsite must at least comply with any legally applicable standard or any standard that is relevant and appropriate under the circumstances including any limitation under such laws as TSCA, SDWA, CAA, CWA, Marine Protection, Research and Sanctuaries Act, or SWDA; and any limitation under a State environmental law that is more stringent than any Federal standard. In addition, *"[r]emedial actions shall require a level or*

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[44] 57 FR 60848, 60861, Dec. 22, 1992 (quoting 45 FR 79341).
[45] 57 FR 60848, 60861, Dec. 22, 1992).
[46] Id.
[47] Id.
[48] 57 FR 60848, 60862. The discussion in this section of the Federal Register is as clear a presentation of the assumptions behind USEPA's human health guidelines as I have seen. KS
[49] Id. at 60862-60863.
[50] Id. USEPA has in a separate discussion acknowledged that bioaccumulation factors (which assess uptake of a toxic from water, food and sediments) are probably a better measure than bioconcentration factors (which assess uptake of the toxic from water only). 64 FR 61182, 61184, Nov. 9, 1999.
[51] 57 FR 60848, 60863.
[52] 42 USC 9621(d). Degree of Cleanup.

standard of control which at least attains the Maximum Contaminant Level Goals established under the Safe Drinking Water Act and water quality criteria established under section 304 or 303 of the CWA, where such goals or criteria are relevant and appropriate under the circumstances of the release or threatened release."[53]

Thus, CERCLA invokes the USEPA limits given above in Sections II and III as well as any more stringent relevant state laws.

[53] 42 USC 9621(d)(2)(A).

Table 1: Persistent Organic Pollutants –USEPA Technology-Based Hazardous Waste Standards Currently in Effect

POP	Treatment Standards for Hazardous Wastes[1] 40 CFR 268.40		Universal Treatment Standards[2] 40 CFR 268.48		Standards for Emissions into the air from combustion of Hazardous Wastes[3]
	Wastewater[4] mg/L	Nonwastewater[5] mg/kg	Wastewater[4] mg/L	Nonwastewater[5] mg/kg	
Aldrin	0.021	0.066	0.021	0.066	DRE 99.99% as shown by POHC
Chlordane	0.0033	0.26	0.0033	0.26	DRE 99.99% as shown by POHC
DDT	0.0039	0.087	0.0039	0.087	DRE 99.99% as shown by POHC
Dieldrin	0.017	0.13	0.017	0.13	DRE 99.99% as shown by POHC
Dioxins & Furans	0.000063	0.001	0.000063	0.001	DRE= 99.9999% 0.20 ng TEQ/dscm (7% O2)[7]
Endrin	0.0028	0.13	0.0028	0.13	DRE 99.99% as shown by POHC
Heptachlor	0.0012	0.066	0.0012	0.066	DRE 99.99% as shown by POHC
Hexachloro-benzene	0.055	10	0.055	10	DRE 99.99% as shown by POHC
Mirex/ Kepone[6]	0.0011	0.13	0.0011	0.13	DRE 99.99% as shown by POHC
PCBs[8]	0.10	10	0.10	10	****[8]
Toxaphene	0.0095	2.6	0.0095	2.6	DRE 99.99% as shown by POHC

[1]**§ 268.40 Applicability of treatment standards.**
(a) A prohibited waste identified in the table "Treatment Standards for Hazardous Wastes" may be land disposed only if it meets the requirements found in the

table. For each waste, the table identifies one of three types of treatment standard requirements:
(1) All hazardous constituents in the waste or in the treatment residue must be at or below the values found in the table for that waste ("total waste standards"); or
(2) The hazardous constituents in the extract of the waste or in the extract of the treatment residue must be at or below the values found in the table ("waste extract standards"); or
(3) The waste must be treated using the technology specified in the table ("technology standard"), which are described in detail in § 268.42, Table 1--Technology Codes and Description of Technology-Based Standards.
(b) For wastewaters, compliance with concentration level standards is based on maximums for any one day, except for D004 through D011 wastes for which the previously promulgated treatment standards based on grab samples remain in effect. For all nonwastewaters, compliance with concentration level standards is based on grab sampling. For wastes covered by the waste extract standards, the test Method 1311, the Toxicity Characteristic Leaching Procedure found in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods", USEPA Publication SW-846, as incorporated by reference in § 260.11, must be used to measure compliance. An exception is made for D004 and D008, for which either of two test methods may be used: Method 1311, or Method 1310, the Extraction Procedure Toxicity Test. For wastes covered by a technology standard, the wastes may be land disposed after being treated using that specified technology or an equivalent treatment technology approved by the Administrator under the procedures set forth in § 268.42(b).
[2]**§ 268.48 Universal treatment standards.**
(a) Table UTS identifies the hazardous constituents, along with the nonwastewater and wastewater treatment standard levels, that are used to regulate most prohibited hazardous wastes with numerical limits. For determining compliance with treatment standards for underlying hazardous constituents as defined in § 268.2(i), these treatment standards may not be exceeded. Compliance with these treatment standards is measured by an analysis of grab samples, unless otherwise noted in the Table UTS.
[3] 40 CFR 63.1203 sets these limits (DREs and dioxin TEQ emission limit) under the Clean Air Act for "Hazardous Waste Combustors;" 40 CFR 266.104 sets these DREs under the Solid Waste Disposal Act for "Hazardous Waste Burned in Boilers and Industrial Furnaces;" 40 CFR 264.343 sets these DREs under the Resource Conservation and Recovery Act for owners and operators of incinerators used for the treatment of hazardous waste. It is important to note that USEPA's performance standard for hazardous waste incinerators, destruction and removal efficiency (DRE), takes into account only those quantities of undestroyed chemicals of concern that are released to the air in stack gases. The more comprehensive performance standard – and the appropriate standard in the context of the Stockholm Convention -- is destruction efficiency (DE), which takes into account releases in all outputs (gaseous, liquid and solid) of incinerators and other treatment processes.
[4]40 CFR 268.2(f) Wastewaters are wastes that contain less than 1% by weight total organic carbon (TOC) and less than 1% by weight total suspended solids (TSS). Concentration standards for wastewaters are expressed in mg/1 and are based on analysis of composite samples.
Except for Metals (EP or TCLP) and Cyanides (Total and Amenable) the nonwastewater treatment standards expressed as a concentration were established, in part, based upon incineration in units operated in accordance with the technical requirements of 40 CFR part 264, subpart O or 40 CFR part 265, subpart O, or based upon combustion in fuel substitution units operating in accordance with applicable technical requirements. A facility may comply with these treatment standards according to provisions in 40 CFR 268.40(d). All concentration standards for nonwastewaters are based on analysis of grab samples.
[5]40 CFR 268.2(d) Nonwastewaters are wastes that do not meet the criteria for wastewaters in paragraph (f) of this section.
[6] Mirex is a pesticide that was used in the United States to control fire ants. Its use has been banned since 1978. The USEPA has identified Mirex as a hazardous waste but has not set any limits for its treatment and disposal or for its allowability in drinking water. Kepone is a decomposition product of Mirex. Agency for Toxic Substances and Disease Registry. USEPA has set treatment standards for hazardous wastes containing kepone, and these are the values in the table. Agency for Toxic Substances and Disease Registry.

[7]TEQ = toxicity equivalence, the international method of relating the toxicity of various dioxin/furan congeners to the toxicity of 2,3,7,8-tetrachlorodibenzo-p-dioxin ; dscm = dry standard cubic meter; POHC = principal organic hazardous constituent

[8] If liquid PCBs are incinerated, the combustion efficiency must be at least 99.9%.40 CFR 761.70(a)(2). If nonliquid PCBs are incinerated, the mass air emission from the incinerator must be no greater than 0.001 g PCB/kg of PCB introduced into the incinerator. 40 CFR 761.70(b)(1). The Solid Waste Disposal Act (SWDA) prohibits land disposal of "Liquid hazardous waste containing polychlorinated biphenyls at concentrations greater than or equal to 50 ppm." 42 USC 6924(d)(2)(D).

Table 2: Health-Based Hazardous Waste Residue Concentration Limits – Stayed by Administrative Order, 40 CFR Pt. 266 App. VII

POPs substance	Concentration limits for residues (mg/kg) = ppm		
Aldrin	2x10-5	=	0.00002
Chlordane	3x10-4	=	0.0003
DDT	1x10-3	=	0.001
Dieldrin	2x10-5	=	0.00002
Dioxins	6x10-8	=	0.00000006
Endrin	2x10-4	=	0.02
Heptachlor	8x10-5	=	0.00008
Hexachlorobenzene	2x10-4	=	0.0002
Mirex/Kepone	N/A		
PCBs	5x10-5	=	0.00005
Toxaphene	5x10-3	=	0.005

Table 3: Health-Based Exit Levels Proposed in Hazardous Waste Identification Rule – Not in Effect
64 FR 66344

POP	Exit Levels from MCLs*			Exit Levels from Toxicity Benchmarks*		
	Waste water mg/L**	Nonwastewater mg/kg		Waste water mg/L**	Nonwastewater mg/kg	
		Totals mg/kg**	Leach mg/L**		Totals mg/kg**	Leach mg/L**
Aldrin	0.000034†	0.0006†	0.000034†	0.000034†	0.0006†	0.000034†
Chlordane	0.00004†	0.098	0.036	0.00004†	0.098	0.00016
DDT	0.000081†	0.0032	0.0054	0.000081†	0.0032	0.0054
Dieldrin	0.000059	0.0018	0.54	0.000059	0.0018	0.54
Dioxins & Furans	1.000x10-8†	8.000x10-9	5.400x10-7	1.000x10-8†	8.000x10-6	1.000x10-8†
Endrin	0.073	0.26	24	0.073	0.26	32
Heptachlor	0.00004†	8		0.00004†	8	
Hexachloro-benzene	0.0016†	0.072†	0.018	0.0016†	0.072†	0.0016†
Mirex/ Kepone#	0.016†	0.097†	0.016†	0.016†	0.097†	0.016†
PCBs	0.0005†	0.04†	0.009	0.0005†	0.04†	0.0005†
Toxaphene	0.0013†	0.03†	6	0.0013†	0.03†	0.11

*Columns 1, 2, and 3 represent the exit levels that were derived by using an MCL benchmark for drinking water ingestion & using toxicity benchmarks for all other routes of exposure. Columns 4, 5 and 6 represent the exit levels that were derived by using toxicity benchmarks for all routes of exposure.
**In order to qualify for exit from hazardous waste status, total constituent concentrations in both wastewaters and nonwastewaters must be at or below the exemption levels given in this table. In addition, all leachable constituents must be below the levels given in the "Leach" column.

†EQC = Exemption Quantitation Criteria: lowest limit that can be reliably measured within acceptable limits of precision and accuracy during routine laboratory operating conditions using appropriate methods. 60 FR 66344, 66377, Dec. 21, 1995.
Mirex is a pesticide that was used in the United States to control fire ants. Its use has been banned since 1978. The USEPA has identified Mirex as a hazardous waste but has not set any limits for its treatment and disposal or for its allowability in drinking water. Kepone is a decomposition product of Mirex. Agency for Toxic Substances and Disease Registry. USEPA has set treatment standards for hazardous wastes containing kepone, and these are the values in the table. Agency for Toxic Substances and Disease Registry.

Table 4: Comparison of Technology-Based and Health-Based Hazardous Waste Standards

POP	Health-Based Residue Concentration Limits (currently stayed), mg/kg	Health-Based Proposed Exit Levels (proposed rule)			Technology-Based Standards (in effect): Treatment Standards for Hazardous wastes 40 CFR 268.40 and Universal Treatment Standards 40 CFR 268.48	
		Waste water mg/L	Nonwastewater		Waste water mg/L	Non-waste-water mg/kg
			Totals mg/kg	Leach** mg/L		
Aldrin	0.00002	0.000034*	0.0006*	0.000034*	0.021	0.066
Chlordane	0.0003	0.00004*	0.098	0.036/ 0.00016	0.0033	0.26
DDT	0.001	0.000081*	0.0032	0.0054	0.0039	0.087
Dieldrin	0.00002	0.000059	0.0018	0.54	0.017	0.13
Dioxins & Furans	6 x 10-8	1.000x10-8*	8.000x10-9	5.400x10-7/ 1.000x10-8	0.000063	0.001
Endrin	0.0002	0.073	0.26	24/32	0.0028	0.13
Heptachlor	0.00008	0.00004*	8		0.0012	0.066
Hexachloro-benzene	0.0002	0.0016*	0.072*	0.018/ 0.0016*	0.055	10
Mirex/Kepone #	N/A	0.016*	0.097*	0.016*	0.0011	0.13
PCBs	0.00005	0.0005*	0.04*	0.009/ 0.0005*	0.10	10
Toxaphene	0.005	0.0013*	0.03*	6/0.11	0.0095	2.6

*EQC = lowest limit that can be reliably measured within acceptable limits of precision and accuracy during routine laboratory operating conditions using appropriate methods. 60 FR 66377, Dec. 21, 1995.

**When two numbers are given separated by a "/", the first number was derived using an MCL benchmark for drinking water ingestion and toxicity benchmarks for all other routes of exposure, and the second number was derived using toxicity benchmarks for all routes of exposure.
Mirex is a pesticide that was used in the United States to control fire ants. Its use has been banned since 1978. The USEPA has identified Mirex as a hazardous waste but has not set any limits for its treatment and disposal or for its allowability in drinking water. Kepone is a decomposition product of Mirex. Agency for Toxic Substances and Disease Registry. USEPA has set treatment standards for hazardous wastes containing kepone, and these are the values in the table. Agency for Toxic Substances and Disease Registry.

Table 5: POPs Risk Data from IRIS*

POP	Cancer risks					Non-cancer risks	
	Oral Slope factor = unit cancer risk[1] per mg/kg-day	Drinking water unit risk[2] per mg/L	Drinking water concentration at 10-6 risk mg/L	Air Unit Risk per mg/m^3	Air concentration at 10-6 risk mg/m^3	Oral RfD[3] mg/kg-day	Inhalation RfC[4] mg/m^3
Aldrin	1.7 x 10	4.9 x 10-1	2 x 10-6	4.9	2 x 10-7	3 x 10-5	no data
Chlordane	3.5 x 10-1	1x 10-2	1 x 10-4	1 x 10-1	1.0 x 10-5	5 x 10-4	7 x 10-4
DDT[5]	3.4 x 10-1	9.7 x 10-3	1 x 10-4	9.7 x 10-2	1 x 10-5	5 x 10-4	no data
Dieldrin	1.6 x 10	4.6 x 10-1	2 x 10-6	4.6	2 x 10-7	5 x 10-5	no data
Dioxin[6]	6.2 x 10+3	1.8 x 10+2	6 x 10-9	1.3 x 10+3	8 x 10-10	[1 x 10-9] [7,8]	no data
Endrin	Inconclusive[9]	inconclusive	inconclusive	inconclusive	inconclusive	3 x 10-4	no data
Heptachlor	4.5	1.3 x 10-1	8 x 10-6	1.3	8 x 10-7	5 x 10-4	no data
Hexachloro-benzene	1.6	4.6 x 10-2	2 x 10-5	4.6 x 10-1	2 x 10-6	8 x 10-4	inadequate data
Mirex/ Kepone	no data	no data	no data	no data	no data	2 x 10-4	no data
PCBs[10]	4 x 10-2	1 x 10-2	1 x 10-4	1 x 10-1	1 x 10-5	inadequate data	no data
Toxaphene	1.1	3.2 x 10-2	3 x 10-5	3.2 x 10-1	3 x 10-6	no data	no data

*IRIS = Integrated Risk Information System – database maintained by USEPA. website: http://www.epa.gov/iris/

The USEPA table in Appendix A of Hazardous Characteristic H11 – Toxic (Delayed or Chronic) UNEP/CHW/OEWG/1/INF/8 uses the term "unit cancer risk" for the parameter that is labeled "oral slope factor" in the IRIS database. This was determined by comparing the unit cancer risk stated in the table for benzene (5.5 x 10-2 per mg/kg/d) with the oral slope factor for benzene given in IRIS (5.5 x 10-2 per mg/kg/d).

[1]**Slope Factor:** An upper bound, approximating a 95% confidence limit, on the increased cancer risk from a lifetime exposure to an agent. This estimate, usually expressed in units of proportion (of a population) affected per mg/kg/day, is generally reserved for use in the low-dose region of the dose-response relationship, that is, for exposures corresponding to risks less than 1 in 100. IRIS Glossary of terms.

[2] **Unit Risk:** The upper-bound excess lifetime cancer risk estimated to result from continuous exposure to an agent at a concentration of 1 µg/L in water, or 1 µg/m^3 in air. The interpretation of unit risk would be as follows: if unit risk = 1.5 x 10^{-6} µg/L, 1.5 excess tumors are expected to develop per 1,000,000 people if exposed daily for a lifetime to 1 µg of the chemical in 1 liter of drinking water. IRIS Glossary of terms.

[3] **Reference Dose (RfD):** An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a NOAEL, LOAEL, or benchmark dose, with uncertainty factors generally applied to reflect limitations of the data used. Generally used in USEPA's noncancer health assessments. IRIS Glossary of terms.

[4] **Reference Concentration (RfC):** An estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a NOAEL, LOAEL, or benchmark concentration, with uncertainty factors generally applied to reflect limitations of the data used. Generally used in USEPA's noncancer health assessments. IRIS Glossary of terms.

[5] DDT = p,p'-dichlorodiphenyltrichloroethane

[6] dioxin = hexachlorodibenzo-p-dioxin mixture

[7] Birnbaum, L., et al. "The US EPA's scientific reassessment of the risks of exposure to dioxin," Organohalogens 14:1-4, 1993: *"In the case of dioxin and related compounds, calculation of an RfD based on human and animal data and including standard uncertainty factors to account for species differences and sensitive subpopulations would result in reference intake levels on the order of 10-100 times below the current estimates of daily intake in the general population."*

[8] In 1987, USEPA derived a reference dose (RfD) for dioxin of 1 pg/kg bw/day despite recent assertions to the contrary, e.g., in the Agency's dioxin reassessment ["Chapter 9. Risk Characterization," (Draft, Do Not Quote or Cite, Revised May 2, 1994, Internal Review Draft) under cover letter from William H. Farland, Director, Ofice of Health and Environmental Assessment : "EPA Draft Chapter on Dioxin Risk Characterization, Dated May 2, 1994.]

[9] Endrin: "oral administration of endrin did not produce carcinogenic effects in either sex of two strains of rats and three strains of mice." Other studies have been less conclusive, so USEPA has classed endrin as Group D: not classifiable as to human carcinogenicity – IRIS website

[10] PCBs: IRIS gives two values for the oral slope factor: 4 x 10-2 per mg/kg-day = lowest risk and persistence; central-estimate slope factor; and 2.0 per mg/kg-day = high risk and persistence; upper bound slope factor.

Table 6 Persistent Organic Pollutants – USEPA limits other than hazardous waste limits

POP	Safe Drinking Water Act 40 CFR 141.61 MCLG (ug/L) mg/L	Safe Drinking Water Act 40 CFR 141.61 MCL (ug/L) mg/L	Clean Water Act 40 CFR 129* Ambient Water Criteria** ug/L (mg/L)	**Clean Water Act** Toxics criteria for states not complying w/CWA 303(c)(2)(B) -- 40 CFR 131.36 Freshwater Organisms Criterion Maximum Conc. ug/L (mg/L)	Freshwater Organisms Criterion Continuous Conc. ug/L (mg/L)	Saltwater Organisms Criterion Maximum Conc. ug/L (mg/L)	Saltwater Organisms Criterion Continuous Conc. ug/L (mg/L)	Human Health (10^{-6} risk for carcinogens) For consumption of: Water & Organisms ug/L (mg/L)	Human Health (10^{-6} risk for carcinogens) For consumption of: Organisms Only ug/L (mg/L)
Aldrin			0.003 (0.000003)	3 (0.003)		1.3 (0.0013)		0.00013 (0.00000013)	0.00014 (0.00000014)
Chlordane	zero	(2) 0.002		2.4 (0.0024)	0.0043 (0.0000043)	0.09 (0.00009)	0.004 (0.000004)	0.00057 (0.00000057)	0.00059 (0.00000059)
DDT			0.001 (0.000001)	1.1 (0.0011)	0.001 (0.000001)	0.13 (0.00013)	0.001 (0.000001)	0.00059 (0.00000059)	0.00059 (0.00000050)
Dieldrin			0.003 (0.000003)	2.5 (0.0025)	0.0019 (0.0000019)	0.71 (0.00071)	0.0019 (0.0000019)	0.00014 (0.00000014)	0.00014 (0.00000014)
Dioxins & Furans	zero	(3x10-5) 3x 10-8						0.000000013 (1.3 x 10-11)	0.000000014 (1.4 x 10-11)
Endrin	(2) 0.002	(2) 0.002	0.004 (0.000004)	0.13 (0.00013)	0.0023 (0.0000023)	0.037 (0.000037)	0.0023 (0.0000023)	0.76 (0.00076)	0.81* (0.00081)
Heptachlor	zero	(0.4) 0.0004		0.52 (0.00052)	0.0038 0.0000038)	0.053 (0.000053)	0.0036 (0.0000036)	0.00021 (0.00000021)	0.00021 (0.00000021)
Hexachloro-benzene	zero	(1) 0.001							
Mirex/Kepone									
PCBs***	zero	(0.5) 0.0005	0.001 (0.000001)					0.00017** (0/00000017)	0.00017** (0.00000017)
Toxaphene	zero	(3) 0.003	0.005 (0.000005)	0.73 (0.00073)	0.0002 0.0000002)	0.21 0.00021)	0.0002 (0.0000002)	0.00073 (0.00000073)	0.00075 (0.00000075)

MCLG = maximum contaminant level goal
MCL = maximum contaminant level

* 40 CFR 129 sets effluent limits for manufacturers and formulators of the listed toxic chemicals.
** Ambient Water Criteria: that concentration of a toxic pollutant in a navigable water that, based upon available data, will not result in adverse impact on important aquatic life, or on consumers of such aquatic life, after exposure of that aquatic life for periods of time exceeding 96 hours and continuing at least through one reproductive cycle; and will not result in a significant risk of adverse health effects in a large human population based on available information such as mammalian laboratory toxicity data, epidemiological studies of human occupational exposures, or human exposure data, or any other relevant data.

* Endrin: No criteria for protection of human health from consumption of aquatic organisms (excluding water) were presented in the 1980 criteria document or in the 1986 Quality Criteria for Water. Nevertheless, sufficient information was presented in the 1980 document to allow a calculation of a criterion, even though the results of such a calculation were not shown in the document.
** PCBs: This criterion applies to total PCBs (e.g., the sum of all congener or isomer or homolog or Aroclor analyses).

Aquatic life criteria for these compounds were issued in 1980 utilizing the 1980 Guidelines for criteria development. The acute values shown are final acute values (FAV), which by the 1980 Guidelines are instantaneous values as contrasted with a CMC, which is a one-hour average.

Criteria Maximum Concentration (CMC) = the highest concentration of a pollutant to which aquatic life can be exposed for a short period of time (1-hour average) without deleterious effects. Criteria Continuous Concentration (CCC) = the highest concentration of a pollutant to which aquatic life can be exposed for an extended period of time (4 days) without deleterious effects. ug/L = micrograms/Liter

Human **Health Risk Criteria** (except dioxin) revised to reflect current agency q_1* or **RfD**, as contained in the **Integrated Risk Information Sy**stem (IRIS). The fish tissue **bioconcentration factor (BCF) from the 1980 criteria documents** was retained in all cases.

Appendix I: Regulation of PCBs

Regulations promulgated pursuant to the Toxic Substances Control Act specify the following clean-up standards for high-concentration spills and low-concentration spill involving 1 pound or more PCBs by weight in unrestricted areas:

> Indoor solid surfaces and high-contact outdoor solid surfaces defined as high contact residential/commercial surfaces shall be cleaned to 10 ug/100 cm2 (as measured by standard wipe tests).[1]
>
> Indoor vault areas and low contact, outdoor, impervious solid surfaces shall be decontaminated to 10 ug/100 cm2.[2]
>
> Low-contact, outdoor, nonimpervious solid surfaces shall be either cleaned to 10 ug/100 cm2 or cleaned to 100 ug/100 cm2 and encapsulated.[3]
>
> Soil contaminated by the spill will be decontaminated to 10 ppm PCBs by weight provided that soil is excavated to a minimum depth of 10 inches. The excavated soil will be replaced with clean soil, i.e., containing less than 1 ppm PCBs, and the spill site will be restored (e.g., replacement of turf).[4]

The Solid Waste Disposal Act prohibits land disposal of "Liquid hazardous wastes containing polychlorinated biphenyls at concentrations greater than or equal to 50 ppm."[5]

PCB remediation waste, that is, soil, rags, and other debris generated as a result of any PCB spill cleanup,[6] must also be cleaned up. In general, bulk PCB remediation waste must be cleaned to <= 1 ppm in high occupancy areas and <= 25 ppm in low occupancy areas.[7]

If liquid PCBs are incinerated, the combustion efficiency must be at least 99.9%.[8] If nonliquid PCBs are incinerated, the mass air emission from the incinerator must be no greater than 0.001 g PCB/kg of PCB introduced into the incinerator.[9]

The decontamination standard for water containing PCBs is < 200 ug/L (< 200 ppb) for non-contact use in a closed system;[10] < 3 ug/L (3 ppb) for water discharged into a treatment works;[11] and <0.5 ug/L (0.5 ppb) for water for unrestricted use[12] (this equals the MCL set for water under the Safe Drinking Water Act).[13]

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[1] 40 CFR 761.125(c)(4)(ii).
[2] 40 CFR 761.125(c)(4)(iii).
[3] 40 CFR 761.125(c)(4)(iv).
[4] 40 CFR 761.125(c)(4)(v).
[5] Solid Waste Disposal Act (SWDA) 42 USC 2624(2)(C).
[6] 40 CFR 761.3: definitions
[7] 40 CFR 761.61(a)(4).
[8] 40 CFR 761.70(a)(2).
[9] 40 CFR 761.70(b)(1).
[10] 40 CFR 761.79(b)(i).
[11] 40 CFR 761.79(b)(ii).
[12] 40 CFR 761.79(b)(iii).
[13] 40 CFR 141.61.