

Definitions of Criteria for Identification of Persistent Pollutants

A. GENERAL

1. Chemical Substance - An element, mixture, or group of organic and inorganic compounds that is produced by or used in a chemical process;
 - a. Includes parent chemical substances whose transformation products exhibit persistent pollutant characteristics.
2. Log Octanol-Water Partition Coefficient (LogK_{ow})¹ - The ratio of a chemical substance's concentration in the octanol phase to its concentration in the aqueous phase of a two-phase octanol:water system, expressed in a logarithmic (base 10) format.²
3. Persistent Pollutant (per SB 737) - A [chemical] substance that is toxic and that either persists in the environment or³ accumulates in the tissue of humans, fish, wildlife⁴, or plants.

B. PERSISTENCE

1. The length of time a chemical substance remains in the aquatic environment until transformed by irreversible degradation processes into another chemical species.⁵
2. Half-life - A characteristic of a chemical substance which indicates the length of time it takes for the concentration of that substance to be reduced, through any degradation process, in an environmental medium by one-half (50%) relative to its initial level, assuming first-order decay kinetics.⁶
 - a. Physical, chemical and biological processes that degrade a substance are considered in determining its half-life.
 - b. Dilution or transportation (i.e., dissipation) to other locations or environmental media are not considered when determining a chemical substance's half-life.

C. ACCUMULATION

1. Bioaccumulation - The net amount (after absorption (uptake), distribution, metabolism, and elimination processes) of a chemical substance in an organism received via all exposure routes (i.e., air, water, sediment, soil, ingestion).
 - a. Typically includes accumulation directly from an environmental medium and indirectly through consumption of food items containing the chemical substance.
2. Bioaccumulation Factor (BAF) - Ratio of the concentration of a chemical substance in an organism to its concentration in water, based on uptake from the surrounding

¹ The workgroup also discussed whether definitions were needed for the octanol-air partition coefficient (K_{OA}), the organic carbon-water partition coefficient (K_{OC}), and the soil-water partition (or distribution) coefficient (K_{d}). They concluded these would not be necessary since none of these were used as criteria in PBT identification schemes.

² Most applicable to non-polar (neutral) organic chemical substances.

³ The workgroup discussed the consequences, in terms of list manageability, of an "or" versus "and" construction for this definition. For example, Environment Canada listed 343 chemical substances with an "and" (P+B+T) construction but 811 with B or T and 2047 with P or T.

⁴ Includes fish-eating birds.

⁵ "Aquatic" was added before "environment" to reflect the fact that SB 737 requires a focus on aquatic systems.

⁶ It was noted that half-life, although used to estimate degradation in environmental media under field conditions, is typically determined under laboratory conditions. It was also noted that after 2.5 or more half-lives there will still be some amount of chemical substance remaining.

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medium (e.g., water, sediment) and ingestion (reported as L/kg, dry weight not lipid normalized).⁷

3. Bioconcentration - The net amount (after absorption (uptake), distribution, metabolism, and elimination processes) of a chemical substance in an organism received via exposure to water only.
 - a. Differs from bioaccumulation because it refers to the uptake of substances into the organism from water alone.
4. Bioconcentration Factor (BCF) - Ratio of the concentration of a chemical substance in an organism to its concentration in water, based only on uptake from water (reported as L/kg, dry weight not lipid normalized).
5. Biomagnification - A process whereby chemical substances become increasingly concentrated at successively higher trophic levels of a food chain or food web.
6. Biomagnification Factor (BMF) - Ratio of the concentration of a chemical substance measured in the tissues of organisms in one trophic level to its concentration in the tissues of organisms in the next lower trophic level.

D. TOXICITY

1. Toxicity - A relative property of a chemical substance that refers to its potential to have an adverse effect on an individual organism.⁸
2. Noncarcinogen - A chemical substance with no known or suspected ability to induce cancer. There is also a known or assumed threshold of exposure below which there are no adverse health effects.
 - a. Criteria for Noncarcinogens
 - (i) Human: Oral reference dose (RfD_o, mg/kg/d)
 - (ii) Aquatic species (fish, crustacea, or algae/other aquatic plants)
 - Median lethal concentration (LC₅₀) - A statistically or graphically estimated concentration that is expected to be lethal to 50 percent of a group of organisms under specified conditions.
 - Median effective concentration (EC₅₀) - A statistically or graphically estimated concentration that is expected to cause one or more specified effects in 50 percent of a group of organisms under specified conditions.
 - No observed effect concentration (NOEC) - The highest concentration to which organisms are exposed in a full life-cycle or partial life-cycle (short-term) test that has no statistically significant observable adverse effect on the test organisms (i.e., the highest concentration at which values for observed responses are not statistically significantly different from the controls).
 - Lowest observed effect concentration (LOEC) - The lowest concentration to which organisms are exposed in a full life-cycle or partial life-cycle

⁷ The workgroup discussed the biota-sediment accumulation factor (BSAF) but concluded it would not be necessary since it was not used a criterion.

⁸ The workgroup discussed the level of biological organization (suborganismal to population) that would be most relevant to SB 737 and concluded that it was the organism (individual) level.

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(short-term) test that causes a statistically significant observable adverse effects on the test organisms (i.e., the lowest concentration at which values for observed responses are statistically significantly different from the controls).

3. Carcinogen - A chemical substance with the known or suspected ability to induce cancer.

a. Criteria for Carcinogens

(i) U.S. EPA 1986 Carcinogenicity Guidelines⁹

- A: Human Carcinogen - There is enough evidence to conclude that it can cause cancer in humans.
- B1: Probable Human Carcinogen - There is limited evidence that it can cause cancer in humans, but at present it is not conclusive.
- B2: Probable Human Carcinogen - There is inadequate evidence that it can cause cancer in humans but at present it is far from conclusive.
- C: Possible Human Carcinogen - There is limited evidence that it can cause cancer in animals in the absence of human data, but at present it is not conclusive.

(ii) U.S. EPA 2005 Carcinogenicity Guidelines¹⁰

- Carcinogenic to Humans
- Likely to Be Carcinogenic to Humans
- Suggestive Evidence of Carcinogenic Potential
- Inadequate Information to Assess Carcinogenic Potential

(iii) UN/Globally Harmonized System (GHS)

- 1A: Known to have carcinogenic potential for humans, based largely on human evidence.
- 1B: Presumed to have carcinogenic potential for humans, based largely on animal evidence.
- 2: Suspected human carcinogen.

(iv) International Agency for Research on Cancer (IARC)

- 1: Carcinogenic to humans
- 2A: Probably carcinogenic to humans
- 2B: Possibly carcinogenic to humans

(v) National Toxicology Program, Report on Carcinogens, 11th Edition

- Known to be a human carcinogen
- Reasonably anticipated to be a human carcinogen

4. Mutagen - A chemical substance with the known or suspected ability to induce inheritable mutations in the germ cells of humans or other organisms.

a. Criteria for Mutagens

⁹ The 1986 guidelines were retained because the narrative statements recommended in later U.S. EPA guidance (1999, 2005) do not easily lend themselves to setting criteria for determining whether a chemical substance is or is not a carcinogen. In addition, many existing classifications of chemical substances still use the 1986 descriptors.

¹⁰ The 2005 final guidelines emphasize that users should consider the full range of information in the narratives and not focus exclusively on the descriptors. Again, such narratives do not lend themselves to criteria development.

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- (i) UN/Globally Harmonized System (GHS)
 - 1A: Chemical substances known to induce inheritable mutations in germs cells of humans.
 - 1B: Chemical substances which should be regarded as if they induce inheritable mutations in germs cells of humans.
 - 2: Chemical substances which cause concern for humans owing to the possibility that they may induce inheritable mutations in germs cells of humans.
5. Reproductive Toxin - A chemical substance with the known or suspected ability to adversely affect sexual function and fertility in adult humans or other organisms.
 - a. Criteria for Reproductive Toxin
 - (i) UN/Globally Harmonized System (GHS)
 - 1A: Known human reproductive toxin, based primarily on human data.
 - 1B: Presumed human reproductive toxin, based primarily on animal data.
 - 2: Suspected human reproductive toxin.
6. Developmental Toxin - A chemical substance with the known or suspected ability to induce adverse effects in offspring during pregnancy or as a result of parental exposure; effects that may be manifested at any point in the lifespan of the organism.¹¹
7. Endocrine disruptor - An exogenous agent that interferes with the production, release, transport, metabolism, binding, action or elimination of natural hormones in the body responsible for the maintenance of homeostasis and the regulation of developmental processes.¹²

¹¹ Includes teratogenicity.

¹² The workgroup is aware of concerns about chemical substances apparently capable of interfering with human and wildlife endocrine systems. At present, however, there is no generally recognize scheme to identify or categorize chemical substances in this regard.
