

RATIONALE FOR THE PROPOSED REVISIONS TO DEPARTMENT OF HEALTH
WATER QUALITY STANDARDS

STATE OF HAWAII DEPARTMENT OF HEALTH
ENVIRONMENTAL HEALTH ADMINISTRATION
HONOLULU, HAWAII

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Part I. Executive Summary

This document explains two proposed revisions to subsection 11-54-4(b)(3) of the State Water Quality Standards. The proposed revisions to numeric standards for chlordane and dieldrin (applicable to all waters, for fish consumption) respond to a Petition for Rule Amendment submitted to the Department of Health (DOH) by the City and County of Honolulu Department of Environmental Services (Takemura, 2008). The current standards (Department of Health, 2004), promulgated in 1990, are based on 1986 U.S. Environmental Protection Agency (EPA) recommendations (Office of Water Regulations and Standards, 1986). We propose replacing the current standards with the latest EPA National Recommended Water Quality Criteria (Office of Science and Technology, 2002 & 2006.), which incorporate over 20 years of new, nationwide scientific research, particularly concerning the carcinogenicity of toxic pollutants.

Both the existing and proposed standards are derived on the basis of a lifetime excess cancer risk level of 10^{-6} , which EPA policy states reflects an appropriate risk for the general population (Office of Science and Technology, 2000). This risk level implies one additional cancer per one million people, assuming they all consume fish and shellfish from State waters at the same rate over an entire lifetime. The consumption rates used to calculate the existing and proposed standards are similar (within 12 to 14% of each other). Therefore, most of the difference between the numerical value of the existing and proposed standards is attributable to scientifically documented and nationally- accepted reductions in the estimated carcinogenicity of chlordane (78% reduction in potency factor) and dieldrin (47% reduction in potency factor).

DOH believes that the proposed standards protect the health of Hawaii consumers. EPA policy states that both 10^{-6} and 10^{-5} cancer risk levels are acceptable for the general population and that highly exposed populations should not exceed a 10^{-4} risk level (Office of Science and Technology, 2000a). This provides for a 100-fold safety factor in standards, like ours, that are based on a 10^{-6} risk level, since individuals consuming fish and shellfish at up to 10 times the average rate would not exceed a 10^{-5} risk level, and those consuming fish and shellfish at 100 times the average rate (almost 4 pounds per day) would still not exceed a 10^{-4} risk level. In addition, many other conservative assumptions were used in the development of the other factors used to derive the criteria. Thus the proposed, federally-recommended chlordane and dieldrin criteria provide substantial and sufficient public health protection for fish consumption, and are developed with nationwide resources and expertise that cannot be matched at the state level.

Part II. Existing and Proposed Chlordane and Dieldrin Criteria

Table 1 (below) compares the proposed chlordane and dieldrin criteria, as recommended by EPA (Office of Science and Technology, 2006), with the existing chlordane and dieldrin criteria in Hawaii Administrative Rules Title 11, Chapter 54 (HAR §11-54, effective October 02, 2004) and the EPA recommendations upon which they are based (Office of Water Regulations and Standards, 1986). The proposed chlordane criterion is greater than both the 1986 EPA recommendation and the existing State criterion, whereas the proposed dieldrin criterion is lower than the 1986 EPA recommendation but greater than the existing State criterion. However, taking into account the typographical error in the existing State chlordane criterion, note that for each pollutant, both of the EPA criteria (1986 and 2006) and the existing State criteria are all within the same order of magnitude. The rationale presented below (Part III) discusses the additional scientific evidence supporting the adoption of the proposed criteria.

Table 1. Existing and proposed toxic pollutant criteria for chlordane and dieldrin

Line in EPA 2006 table	Pollutant	CAS ¹ number	Fish Consumption in micrograms per liter			FR ² Cite/Source
			EPA 1986	EPA 2006	HAR §11-54-4(b)(3)	
107	Chlordane	57749	0.00048	0.00081	0.000016 ³	65FR66443
111	Dieldrin	60571	0.000076	0.000054	0.000025	65FR66443

¹CAS = Chemical Abstract Services (www.cas.org)

²FR = Federal Register (www.gpoaccess.gov/fr)

³Typographical error in rule. The correct value of 0.00016 is currently being adopted through a separate rulemaking process.

Part III. Rationale for Proposed Revisions to Chlordane and Dieldrin Criteria

A. Chemical Background and Purpose of Standards

Chlordane was first produced in 1947 and was used as a broad-spectrum insecticide for agricultural crops, livestock, and lawns and gardens, and also for underground treatment around the foundation of homes. EPA cancelled aboveground uses in 1978 because of concern about cancer risks, evidence of human exposure, and danger to wildlife, and cancelled all uses after 1988. Thus it is now a legacy pollutant with few, if any new sources adding to the existing contaminant pool. Chlordane is insoluble in water, but residues still exist in soils and bed sediments, and chlordane bioaccumulates in the fatty tissue of fish and humans. Chlordane has also been detected at various concentrations in ambient water, finished drinking water, rainwater, plankton, earthworms, birds, bird eggs, and several mammals (Criteria and Standards Division, 1980b).

From the 1950s until 1970, aldrin (which quickly transforms into dieldrin in the environment) and dieldrin were two of the most widely used pesticides in the U.S., particularly for control of corn, cotton, and citrus pests. The U.S. Department of Agriculture cancelled all uses of aldrin and dieldrin in 1970. Although EPA restricted uses after 1974, these compounds, particularly aldrin, continued to be used locally for ground termite treatment and non-food seed and plant dipping until 1987, when the manufacturer voluntarily canceled the registration. Dieldrin is

quite persistent in the environment, and like chlordane remains as a legacy pollutant with few, if any new sources adding to the existing contaminant pool (Criteria and Standards Division, 1980a).

The known presence and accumulation of toxic pollutants, including chlordane and dieldrin, in bed sediments and fish tissue from Hawaii waters was part of the rationale for initially establishing numeric state standards for these pollutants in 1990. More recent surveys and observations confirm their continuing presence (Brasher & Anthony, 2000), including occasional detection in ambient surface water. The numeric standards for chlordane and dieldrin applicable to all waters, for fish consumption, are calculated to prevent public health impacts from the long-term consumption of contaminated aquatic organisms. These human health criteria, in conjunction with the acute and chronic aquatic life criteria, are also intended to (1) prevent pollutant concentrations in commercially or recreationally important aquatic species from exceeding applicable U.S Food and Drug Administration action levels, thus avoiding negative effects on marketability, and (2) protect wildlife, including fishes and birds that consume aquatic organisms, from adverse effects. The standards provide a mechanism for limiting sources of toxic pollutants in waste discharges, and for determining if a waterbody receives excessive pollutant loading (Environmental Planning Office, 1989).

B. Methodology for Criteria Development

EPA calculates human health criteria (numeric standards for fish consumption) using data from three fields of scientific research – human toxicology, aquatic organism bioaccumulation, and human consumption of fish and shellfish – in the context of public health policy decisions about acceptable risk. The existing chlordane and dieldrin criteria are based on EPA’s 1980 methodology for the development of water quality criteria to protect human health (Federal Register Vol. 45, No. 231); EPA’s 1986 recommend criteria (Office of Water Regulations and Standards, 1986), based on earlier criteria documents (Criteria and Standards Division, 1980a and 1980b); and DOH’s adoption of the 1986 EPA recommendations (Environmental Planning Office, 1989). The proposed revisions to these criteria are based on EPA revisions to the 1980 methodology (Federal Register Vol. 65, No. 214; Office of Science and Technology, 2000a & 2000b); significant scientific advances in cancer risk assessments and exposure assessments (U.S. Environmental Protection Agency, 1997; National Center for Environmental Assessment, 1998 & 1991; Science Applications International Corporation, 2002); and resulting EPA recommendations and actions (Office of Science and Technology, 2002 & 2006; Federal Register Vol. 65, No. 97). The following discussion draws directly and heavily from EPA documentation and synthesis of these methodological revisions, scientific advances, and new recommendations.

Human Toxicology - If human or animal studies on a contaminant indicated that it induced a statistically significant carcinogenic response, the 1980 Ambient Water Quality Criteria (AWQC) National Guidelines treated the contaminant as a carcinogen and derived a low-dose cancer potency factor from available animal data using the linearized multistage model (LMS). The LMS, which uses a linear, nonthreshold assumption for low-dose risk, was used by EPA as a science policy choice in protecting public health, and represented a plausible upper limit for low-dose risk. The cancer potency factor (also known as slope factor) is used in risk assessment to estimate a lifetime probability of an individual developing cancer as a result of exposure to a

particular level of a potential carcinogen. It quantitatively expresses the relationship between dose and response in terms of the estimated upper-bound incremental lifetime risk per mg/kg average daily dose. In other words, it is the cancer risk (proportion affected) per unit of dose, expressed in milligrams of substance per kilogram of body weight per day. National policy and prevailing opinion in the expert community establish that the human health criteria for carcinogens should be derived assuming lifetime exposure of a 70 kg adult male over a 70-year time period.

Since 1980, EPA risk assessment practices have evolved significantly in all of the major areas for AWQC development: that is, cancer and noncancer risk assessments, exposure assessments, and bioaccumulation. When the 1980 AWQC National Guidelines were developed, EPA had not yet developed formal cancer or noncancer risk assessment guidelines. Since then, EPA has published several cancer risk assessment guidelines (most recently in Risk Assessment Forum, 2005; see Background at <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=116283>). In 1986, EPA made available to the public the Integrated Risk Information System (IRIS). IRIS is a database that contains risk information on the cancer and noncancer effects of chemicals. The IRIS assessments are peer reviewed and represent EPA consensus positions across the Agency's program and regional offices. In particular, there have been advances in the use of mode of action (MOA) information to support both the identification of potential human carcinogens and the selection of procedures to characterize risk at low, environmentally relevant exposure levels. For example, the Proposed Guidelines for Carcinogen Risk Assessment (Office of Research and Development, 1996) presented revised procedures to quantify cancer risk at low doses, replacing the default use of the LMS model. Thus, given new cancer potency information from IRIS, different cancer potency factors were used to calculate the existing and proposed chlordane and dieldrin criteria, as shown in Table 2 (below).

Aquatic Organism Bioaccumulation - Given long-term exposure, the concentration of a pollutant accumulated in an organism may be orders of magnitude higher than the ambient water column concentration. To calculate human health criteria, scientists determine the bioconcentration factor of a toxic pollutant – the concentration rate to which a pollutant will accumulate in aquatic organisms, relative to the concentration of the pollutant in water. The bioconcentration factors used to calculate the existing and proposed chlordane and dieldrin criteria, shown below in Table 2, have not changed since 1980.

Human consumption of fish and shellfish - Once both the cancer potency factor and bioconcentration factor are known for a pollutant, a water column concentration can be calculated which will ensure that the pollutant cannot bioaccumulate in aquatic organisms to a level that will cause a selected lifetime cancer risk level to be exceeded (**see Equation for Deriving Human Health Criteria Based on Carcinogenic Effects** below). This calculation is based upon the average amount of fish and shellfish a person is likely to consume. The daily consumption figures used to calculate the existing and proposed chlordane and dieldrin criteria are shown below in Table 2.

Due to the lack of adequate current fish consumption data for Hawaii, we use the updated national default fish consumption rate (used to calculate the 2002 and 2006 EPA National Recommended Criteria) to calculate the proposed State criteria. This rate (17.5 grams/person/day) approximates the 90th percentile of freshwater/estuarine finfish and shellfish

consumption estimates obtained for adult humans by the national survey (Office of Science and Technology, 2002; Science Applications International Corporation, 2002), and therefore represents the estimated average amount consumed by all but 10% of the population. A summary of these national survey results for finfish and shellfish from various habitats is shown below in Table 3. Note that selecting results for fish species from different habitats, and for consumption estimates from different statistical distributions (Statistic), would drive the calculated water quality criteria lower for higher fish consumption, and higher for lower fish consumption (see **Equation for Deriving Human Health Criteria Based on Carcinogenic Effects** below).

Acceptable Risk – EPA policy states that both 10^{-6} and 10^{-5} risk levels are acceptable for the general population and that highly exposed populations should not exceed a 10^{-4} risk level (Office of Science and Technology, 2000a). The existing and proposed State of Hawaii criteria are set at the one in one million lifetime excess cancer risk level (10^{-6}). Human health criteria for carcinogens are based on chosen risk levels that inherently reflect, in part, the exposure parameters used to derive those values. Therefore, changing the exposure parameters also changes the risk. Specifically, the incremental cancer risk levels are relative, meaning that any given criterion associated with a particular cancer risk level is also associated with specific exposure parameter assumptions (e.g., intake rates, body weights). When these exposure parameter values change, so does the relative risk.

For example, for criteria derived on the basis of a cancer risk level of 10^{-6} , individuals consuming up to 10 times the assumed rate would not exceed a 10^{-5} risk level. Similarly, individuals consuming up to 100 times the assumed rate would not exceed a 10^{-4} risk level. Thus, for criteria (like our proposed criteria) based on EPA’s default fish intake rate (17.5 grams/person/day) and a risk level of 10^{-6} , individuals consuming fish and shellfish at up to 10 times the average rate would not exceed a 10^{-5} risk level. Those consuming a pound of fish and shellfish per day (454 grams/person/day) would potentially experience between a 10^{-5} and a 10^{-4} risk level (closer to a 10^{-5} risk level), and those consuming fish and shellfish at 100 times the average rate (almost 4 pounds per day) would still not exceed a 10^{-4} risk level. This provides for a 100-fold safety factor in the proposed standards. In other words, we have an adequate margin of safety in using the Federal numbers even for subsistence eaters because of the stringent cancer risk level.

Equation for Deriving Human Health Criteria Based on Carcinogenic Effects
(adapted from Federal Register Vol. 45, No. 231 & Office of Water, 1994).

$$C = \frac{(WT \times P)}{q_1^*(DFC \times BCF)}$$

where:

- C = water quality criteria (mg/l)
- WT = weight of an average human adult (70 kg)
- P = lifetime risk level (10^{-6})
- q_1^* = cancer potency factor (mg/kg/day)⁻¹
- DFC = daily fish consumption (kg fish/day)
- BCF = bioconcentration factor (mg toxicant/kg fish divided by mg toxicant/l water)

Table 2. Cancer Potency Factor (q_1^*), Bioconcentration Factor (BCF), and Daily Fish Consumption (DFC) used to calculate existing and proposed toxic pollutant criteria (fish consumption) for chlordane and dieldrin

Criterion	q_1^* (oral slope factor) (mg/kg/day) ⁻¹	BCF ¹	DFC ² kg/day
Existing Chlordane Criterion	1.6075 ³	14,100	.0199
Proposed Chlordane Criterion	0.35 ⁴	14,100	.0175
Existing Dieldrin Criterion	30.37 ⁵	4,670	.0199
Proposed Dieldrin Criterion	16 ⁴	4,670	.0175

¹Based on the mean of two steady-state BCF values, normalized to 1% lipids, and adjusted to 3% lipids (the weighted average lipids % for consumed fish and shellfish), yielding the weighted average bioconcentration factor for the pollutant and the edible portion of all freshwater and estuarine aquatic organisms (Criteria and Standards Division, 1980a & 1980b).

²Existing criteria are based on an assumption that the Hawaii general population consumes 19.9 grams fish/day, which is 3.1 times the 1986 national freshwater/estuarine DFC of 6.5 grams fish/day (Environmental Planning Office, 1989; Office of Water Regulations and Standards, 1986, based on Stanford Research Institute International, 1980). Proposed criteria are based on the updated national default freshwater/estuarine DFC of 17.5 grams fish/day (Office of Science and Technology, 2002, based on Science Applications International Corporation, 2002). Note that this value is within 12 to 14% of the Hawaii DFC used to calculate the existing criteria, and that this Hawaii DFC is the same as the 2002 national mean DFC for fish species from all habitats (see Table 3 below).

³Criteria and Standards Division, 1980b.

⁴National Center for Environmental Assessment, 1991 (Chlordane) & 1998 (Dieldrin). Values in EPA Integrated Risk Information System (IRIS) confirmed by EPA Toxicologist William A. Frez, Ph.D. on March 05, 2009 via IRIS hotline at (202) 566-1676 and reply e-mail.

⁵Criteria and Standards Division, 1980a.

Table 3. Summary of Uncooked Daily Fish Consumption (DFC) Estimates, U.S. Population – Finfish and Shellfish, Individuals of Age 18 or Older (adapted from Office of Science and Technology, 2002)

Statistic	Estimated DFC (grams/person/day) for fish species from different habitats		
	Freshwater/Estuarine	Marine	All
Mean	7.50	12.41	19.91 ²
90 th %	17.37 ¹	48.92	74.79
99 th %	143.35	150.77	215.70

¹Approximates 17.5 grams/person/day national default rate

²Equivalent to the DFC used to develop existing State criteria

C. Conclusion

A preliminary survey of 26 other U.S. coastal water jurisdictions indicates that approximately 9 of these other jurisdictions have chlordane criteria that are more conservative than the national recommendation (but within the same order of magnitude), and only 2 have dieldrin criteria that are similarly more conservative. In the case of chlordane, at least 3 of these more conservative criteria appear to be a vestige of earlier federal regulation that has not yet been updated by states to incorporate the newer national recommendations.

DOH believes that the proposed standards are inherently and sufficiently conservative for several reasons, beginning with the selected one in a million lifetime risk level (10^{-6}), which is equal to

or more conservative than those routinely used in other DOH human health risk assessments. For example, target excess cancer risks used to develop the soil and groundwater Environmental Action Levels (EALs) range from 10^{-6} to 10^{-4} , depending on the contaminant and taking into considerations such factors as naturally occurring levels, dietary exposure, and uncertainty in toxicity factors (Hazard Evaluation and Emergency Response Office, 2008). The State of Hawaii drinking water Maximum Contaminant Level (MCL) for chlordane of 0.002 mg/l (Department of Health, 2005) equates to a selected cancer risk of 10^{-5} , and State fish consumption advisories are issued on the basis of 10^{-5} risk levels suggested by EPA guidance (Office of Science and Technology, 2000c).

The standards are also conservative because of the assumptions used in estimating the fish consumption factor. These estimates assume that all fish and shellfish consumed are from national/State waters, thus avoiding consideration of the potentially high levels of toxic pollutants in the locally consumed global supply. For example, the research used to establish the fish consumption factor used in the existing Hawaii standards (Hudgins, 1980) estimated that over an eight-year period (from 1970 to 1977), local commercial landings accounted for just 32% of the total Hawaii supply of commercial fish and shellfish (ranging annually from 21% to 46%). Also, of this locally caught seafood, it is likely that much of it is landed in waters that are relatively unaffected by sources of chlordane and dieldrin pollution.

Of the three other factors used to derive a fish consumption standard – cancer potency factor, bioconcentration factor, and consumption rate – the consumption rate is by far the most accurate, even if it is an average value. Bioconcentration factors have wide inter- and intraspecies variability. To account for these and other areas of uncertainty, numerous order-of-magnitude safety factors are used in deriving the final values. Adjustments to the fish consumption factor - even the three-fold increase in the old national figure used in the existing State standards, and the single order-of-magnitude variation in estimated nationwide fish consumption - are minor in comparison (Department of Health, 1989). Also, although cancer risk generally increases as fish consumption increases, there are potentially counterbalancing health benefits to eating more fish (as opposed to other items in the global food supply, which may also have higher levels of toxic pollutants).

The need to establish toxic pollutant criteria for the State of California was an impetus for much of the scientific work that generated the 2002 and 2006 National Recommended Water Quality Criteria, many of which were eventually promulgated by federal regulation as the criteria for the inland surface waters, enclosed bays and estuaries of that state (Federal Register Vol. 65, No. 97). The nationwide resources and expertise for this effort cannot be matched at the state level. Given California's large fisheries, large fish-eating populations, large scientific community, and more heavily polluted waters, we assume that the National Recommended Water Quality Criteria are equally suitable for Hawaii, and they will provide substantial and sufficient public health protection for fish consumption.

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