Procedures for Issuing Fish Consumption Advisories in the State of Colorado

Colorado Department of Public Health and the Environment Water Quality Control Division

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#### I - Purpose

The purpose of this document is to describe and standardize the process by which fish consumption advisories (FCAs) are developed and publicly disseminated in Colorado. This document identifies the roles and responsibilities of the state agencies involved in the process, and describes the steps involved in implementing this policy.

The deposition of contaminants such as heavy metals, pesticides and toxic organic compounds in aquatic ecosystems and the consequent accumulation in fish tissue is a concern for public and environmental health. Aquatic organisms can bioaccumulate some environmental contaminants up to 1,000,000 times the concentrations detected in the water column. This enables state agencies to detect levels of contamination in fish and shellfish that might be harmful to human consumers (U.S.EPA 2000).

The Colorado Department of Public Health and Environment (the Department) and other local, state and federal agencies conduct regular investigations on the concentration levels of certain contaminants in fish tissue in Colorado waterbodies. When concentration levels established for the protection of human health are exceeded, the Department issues FCAs.

It is important to note that there are several other entities in the state (i.e. counties, cities, the Department of Defense, the Department of Energy) that can also issue FCAs independently from the Department, using their own data, protocols and authorities. This document describes the mechanism to coordinate these actions with the efforts that occur at the state level.

The Department's policy is to set FCAs to protect public health and to address human health risk questions associated with consuming fish potentially contaminated with certain chemicals of concern. This policy does not address other related water quality programs such as the 303(d) listing process, the development of Total Maximum Daily Loads (TMDLs), clean-up and remediation procedures, sources controls, or potential paths of contamination.

### II - Background

Since the 1980's, the Department has been aware of the need to screen fish for the presence or absence of certain potential contaminants, especially mercury. Until recently, several studies were conducted in lakes, reservoirs and rivers throughout the state, mostly in areas known to be desirable fisheries. These studies were designed as screening surveys; this meant that only a few fish were collected and analyzed from each waterbody and no statistical inferences could be made from the results. The Department had a written interagency coordination procedure for evaluating the health risks associated with contaminants in fish and an *ad hoc* committee that oversaw the fish advisory program and processes. The *ad hoc* committee met whenever there was a need to review fish data and issue FCAs. The professional disciplines represented on that committee included: fisheries, toxicology/epidemiology, water pollution assessment/control and risk

Table 1							
List of active and inactive FCAs that have been issued in Colorado.							
Waterbody Name	Year of FCA	Contaminant	Fish Species	Advisory Codes			
	Issuance						
Lake Ladora*	1993	Mercury, Aldrin. Dieldrin, Chlordane	All fish	NKZ			
Lake Mary*	1993	Mercury, Aldrin. Dieldrin, Chlordane	All fish	NKZ			
Lower Derby Lake*	1993	Mercury, Aldrin. Dieldrin, Chlordane	All fish	NKZ			
McPhee Reservoir	1993	Mercury	Black Crappie	RGP,RSP			
			Kokanee Salmon	RGP,RSP			
			Largemouth Bass	RGP,NCSP			
			Rainbow Trout	RGP,RSP			
			Smallmouth Bass	RGP,RSP			
			Yellow Perch	RGP,RSP			
Narraguinnep Res.	1993	Mercury	Channel Catfish	RGP,RSP			
			Northern Pike	RGP,RSP,NCSP			
			Walleye	RGP,RSP,NCSP			
			Yellow Perch	RGP,RSP			
Navajo Reservoir	1993	Mercury	Channel Catfish	RGP,RSP			
			Northern Pike	RGP,RSP,NCSP			
			Smallmouth Bass	RGP,RSP			
Sanchez Reservoir	1994	Mercury	Brown Trout	RGP,NCSP			
			Common Carp	RGP,NCSP			
			Northern Pike	RGP,RSP,NCSP			
			Walleye	RGP,NCSP			
			Yellow Perch	RGP,RSP			
Sheldon Lake*	1993	Gasoline	All fish	NCGP			
Sweitzer Reservoir	1986	Selenium	All fish	NCGP			
Teller Reservoir	1994	Mercury	Bullhead	RGP,NCSP			
			Channel Catfish	RGP,NCSP			
			Crappie	RGP,NCSP			
			Largemouth Bass	NKZ			
			Northern Pike	NKZ			
Willow Springs Ponds	1997	Perchloroethylene	All fish	NCGP			
Advisory Codes: <b>RGP</b> = Restricted Consumption – General Population: advises the general population to restrict							

communication. Table 1 shows the FCAs advisories that have been issued in Colorado by the Department and other federal or local agencies.

- **RGP** = Restricted Consumption General Population: advises the general population to restrict the size of the organism and/or the frequency of meals consumed.
- **RSP** = Restricted Consumption Sub-Population(s): advises subpopulations potentially at greater risk, e.g., pregnant or nursing women and/or small children to restrict the size of the organism and/or frequency of meals consumed.
- **NCGP** = No Consumption General Population: advises against consumption by the general population.
- **NCSP** = No Consumption Sub-Population(s): advises against consumption potentially at greater risk, e.g., pregnant or nursing women and/or small children.
- **NKZ** = No Kill Zones: indicates that it is illegal to take, kill or process any fish from specified waters due to chemical contamination.
- \* = rescinded

Only recently, with the emergence of the Total Maximum Daily Loads (TMDL) program did the need to have a stronger, more formal FCA program become more pressing. In this document, the FCA process is formalized and described. There are now five components to the FCA process: 1) development of the sampling plan; 2) collection, analyses and management of data; 3) assessment of the human health risks, both carcinogenic and non-carcinogenic, and development of risk-based fish consumption limits; 4) development of risk management strategies; and 5) development of effective tools to communicate risk. Fish consumption advisories are issued for specific waterbodies where the risk of consuming contaminated fish has been determined by steps above. These steps are charted in Appendix A. It also identifies who is responsible for implementing each step, the issues and critical components associated with each step, and identifies the product that evolves from the accomplishment of each step.

#### **III - Development of the FCAs**

In order to describe the process, it is important to identify the roles and responsibilities of the parties involved. The development and implementation of the FCA program in the State of Colorado is accomplished with the efforts of the following entities:

<u>CDPHE Water Quality Control Division (Division)</u>: has statutory authority over matters affecting water quality, including assessment of water quality and implementation of water quality standards. The Division also participates in developing and disseminating fish consumption advisories due to its interest in measuring the quality of the waters of the state and ensuring the maintenance of the associated beneficial uses.

<u>CDNR Division of Wildlife</u>: has statutory authority over matters affecting fish and wildlife management, including sport fishing and other activities relating to the public's use of fishery resources.

<u>CDPHE Disease Control and Environmental Epidemiology Division (DCEED)</u>: has statutory authority to establish and operate programs which the department determines are important in promoting, protecting, and maintaining the public's health by preventing, delaying, or detecting the onset of environmental and chronic diseases.

The Division has participated in past dissemination of FCAs. For the purposes of this policy, the DCEED will conduct a health risk assessment and develop risk-based fish consumption limits by employing a tiered health risk assessment process as described below in Section 3.

<u>Technical Advisory Committee</u>: The agencies involved in the implementation of this policy mutually agree to establish and participate in the Technical Advisory Committee. The Committee will consist of two members from each participating agency, namely DCEED, Division and DOW. The main purpose of the committee is to make the risk management decision, based on data results and the DCEED recommendations, on the need to issue or rescind fish consumption advisories for the waterbodies of concern.

The following text describes each component of the FCA program in the State of Colorado in detail.

#### 1) Sampling Plan

Because the Department is responsible for issuing FCAs, it has identified the need to gather fish tissue data throughout the State. In order to address these data needs, the Division's Monitoring Unit designed the *Colorado Fish Tissue Study* (the QAPP, found in Appendix B), which aims to investigate potential chemical contaminants in fish found in lakes and reservoirs (and rivers), in a comprehensive and systematic manner across the state over a five year period.

The objectives of the study are to collect sufficient fish tissue samples to be able to identify sites where concentrations of chemical contaminants in fish exceed human health screening values. The Division followed the statistical sampling design, rationale, and calculations recommended in the USEPA (2000a) guidance for an optimal monitoring design. Optimal designs require prior information about population standard deviation and the actual difference between the mean contaminant concentrations and its associated screening value. For situations where this information is lacking, USEPA (2000a) Volume I provides guidance, in Table 6.1 and 6.2, for estimating sufficient sample size. The Division consulted these tables and selected the following specifications in its sampling design:

- A detectable difference of 50 percent between the site-specific mean contaminant concentrations and the screening value;
- A probability of detecting a true difference between the mean and the screening value of 70 to 80 percent (statistical power);
- A level of statistical significance of 0.05 (commonly used in biological sampling);
- The need to minimize the costs associated with analysis of the samples because of a fixed analytical budget;
- The need to protect waterbodies from intensive sampling pressures;
- The decision to assign a maximum estimated population standard deviation of 0.024 as the target for attaining the desired statistical power.

The resultant design is conservative in that it likely requires more samples to be collected than actually are required to achieve the desired statistical power. It calls for the collection of 120 fish per waterbody with 60 fish collected per species from two different species and 30 fish collected for each of 2 size classes within each species. The desired number of fish per composite is 6 and the number of replicate composite samples is 5. When it is not possible to collect this combination of fish per composite and the number of composite and the number of fish per composite standard error remains less than or equal to 0.024. For these situations, the new estimated standard error is calculated and supplied with the results. There are other circumstances when samples of a single fish specimen will be used; in those cases, Appendix C (USEPA 2000a) *Use of Individual Samples in Fish* 

*Contaminant Monitoring Programs* will be consulted. Unique circumstances will be carefully addressed by the Technical Advisory Committee.

In the Division's 5-year study plan, it will investigate approximately 150 lakes and reservoirs and several rivers. The following criteria were used to choose which waterbodies to investigate: 1) frequently fished sites where commonly consumed fish species may be contaminated and may pose a risk to human health; 2) whether there are historical data on fish contamination; 3) the need to update FCAs; 4) whether there are any on-going collaborative studies with other agencies. Although specific years to sample all these sites are identified in a 5-year table, there is flexibility to change the sampling events according to the CDOW's regular schedule of fish population surveys. The flexibility allows for efficient use of resources by the CDOW and the Monitoring Unit's staff. Waterbodies that have a FCA are re-sampled three to five years after a FCA is issued to re-evaluate the levels of contaminants in fish tissue in the waterbody and to ascertain the need to continue, update or rescind the FCA.

For further detail on field and laboratory procedures, and statistical design and analysis, consult the Quality Assurance Project Plan (QAPP) and associated Standard Operating Procedures for the Collection and Processing of Fish Tissue (SOPs), in Appendix B.

As captured in the chart entitled *Procedures to Implement the Colorado Fish Consumption Advisories Policy* (Appendix A), the successful completion of this step produces a **Sampling Plan**, which is used in the **Data Collection/Data Management** step, next in the process. Division staff develops, reviews and updates the sampling plan, with input from CDOW and any other interested parties. The sampling plan is evaluated yearly and adjusted to reflect any modification that becomes necessary for the implementation of the other components of the FCA process.

### 2) Data Collection/Data Management

Several agencies in the State of Colorado collect fish for tissue analysis, such as USEPA, U.S. Bureau of Reclamation, U.S. Fish and Wildlife Service, U.S. Geological Survey, CDOW, universities and other entities. Some of these data may be useful in indicating potential contamination of fish and the need for more studies. Also, there are some limited historical data that can be used to assess trends. Although the Division may use data from different sources to evaluate the need to issue fish consumption advisories, all new FCAs issued by the Department will be developed according to the procedures described in this document. There may be situations when another agency collects data; the technical advisory committee will carefully address each unique case and make a decision.

The Division works collaboratively with the CDOW in the collection of fish from the lakes, reservoirs and rivers. Every effort is made to coordinate fish collection with the CDOW's routine fish population surveys. When that is not possible, a targeted sampling effort is scheduled, also with the collaboration of CDOW; it is important to note that CDOW requires a permit to collect fish. Fish are collected by electrofishing or by using

gill-nets. Because the objective of the study is to protect for human health, the most commonly considered edible portion (skinless fillets) of the fish are extracted and kept frozen, although the Division might choose to use skin-on fillets, whole body or other types of edible portions.

The Division prepares the samples to be submitted to the laboratory and is the repository for all the fish tissue data (those generated from the Colorado Fish Tissue Study and those from other sources). The Division also conducts quality assurance verification steps to ascertain data quality and integrity.

Data collected in this study are stored in a Microsoft Access database, which is populated and maintained by the Division. The data are shared with all interested parties only after quality control checks have been performed. The Division also prepares reports summarizing the sampling efforts and data results. Reports are posted on the Department's website: http://www.cdphe.state.co.us/wq/monitoring/monitoring.html

After data results are verified by the Division and the determination has been made that the data set is of sufficient quality and integrity, the data set is reviewed by the project manager to ascertain whether chemical contaminant concentrations exceed the human health screening values. If they do, the technical advisory committee is convened to review the data and make a determination on the appropriate risk management actions for that waterbody. If they don't, data are kept on file, but no further action is warranted, unless there is a change in the circumstances surrounding that waterbody.

#### 3) Risk Assessment and Development of Risk-Based Fish Consumption Limits: Overview of the Process

### 3.1. Objective and Scope

The objective of the risk assessment process is to: 1) investigate the health risk of consuming the contaminated fish; and 2) develop risk-based fish consumption limits for each contaminant of concern, for the general population and for sub-populations that may be at a greater risk. The assessment process is conducted per contaminant of concern and per waterbody and considers the range of risk associated with the species and size for which data are available. For example, when investigations of mercury in fish specimens from a certain waterbody show mercury fish tissue concentrations of 0.2, 0.3 and 0.4 parts per million (ppm or mg/kg or  $\mu$ g/g) the risk assessment process will generate recommendations of meals sizes and frequencies relating to the consumption of fish that contain 0.2, 0.3 and 0.4 ppm of mercury in their tissue. Those recommendations are developed for the general population and for any sub-populations at a greater risk, such as pregnant or nursing women and/or small children. The risk assessments conducted by the DCEED may also evaluate sub-populations at a greater risk due to known differences in fish consumption patterns and habits. The recommendations generated by this step of the process are reviewed by the Technical Advisory Committee and form the basis for issuing a fish consumption advisory or for any other risk management actions.

#### 3.2. Tiered Risk Assessment Framework

Traditionally, EPA recommends a tiered framework for risk assessment. EPA's tiered health risk assessment approach is a process for a systematic progression from a relatively simple risk-based screening analysis to a more complex site-specific (or more realistic) health risk assessment. The tiered framework could include an initial screening analysis; a refined or simple site-specific risk assessment using EPA's default exposure assumptions; and a detailed site-specific risk assessment using actual site-specific data. The DCEED uses the following three tiers for the purposes of this policy:

- **Tier I:** is a screening-level risk-based analysis using two types of USEPA (2000a; Volume 1) recommended screening values (SVs). These screening values are defined by the EPA as concentrations of target analytes in fish or shellfish tissue that are of potential public health concern and that are used as threshold values against which levels of contamination in similar tissue collected from the ambient environment can be compared. Exceedance of these SVs should be taken as an indication that more intensive site-specific monitoring and/or evaluation of human health risk should be conducted (USEPA, 2000a)
  - Step 1 Based on screening values, using a default fish consumption rate of 17.5 g/day for general population, for target analytes provided in Table 5-3 of Volume 1 (USEPA, 2000a).
  - Step 2 Based on screening values for a subsistence fisher, using a default fish consumption rate of 142.4 g/day, provided in Table 5-4 (USEPA, 2000a). This step is conducted, on an as needed basis, in an effort to determine potential adverse effects for subsistence fisher and sensitive subpopulations. For example, methyl mercury screening value for subsistence fisher is 0.049 PPM (vs. 0.4 PPM for general population).
- **Tier II:** is a more intensive site-specific risk assessment step using EPA's default exposure assumptions and sensitive subpopulations such as women of childbearing age and young children.
- **Tier III:** is a more realistic site-specific risk assessment step, using actual site-specific data in terms of exposure assumptions and types of subpopulations.

# **3.3. Risk Assessment Method for Developing Risk-based Fish Consumption Limits**

EPA has recently issued detailed guidelines that focus primarily on risk assessment as it applies to fish advisories. DCEED follows the EPA guidelines to conduct Tier II and Tier III health risk assessments and to develop risk-based fish consumption advisories; these guidelines and are listed below along with other EPA guidelines for exposure assumptions pertaining to various types of subpopulations:

• US EPA, 2000a &b: Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories: Volume 1 and Volume 2

Other Sources:

- USEPA, 2002a: Estimated Per Capita Fish Consumption in the United States Based on Data Collected by the United states Department of Agriculture 1994-1996 Continuing Survey of Food Intake by Individuals. Office of Water.
- USEPA, 2002b: Child Exposure Factor Handbook.
- USEPA, 1997: Exposure Factor Handbook

DCEED bases the risk assessment process on USEPA risk assessment techniques for carcinogenic and non-carcinogenic effects, which in turn, follow the National Academy of Sciences (NAS). According to the NAS:

... risk assessment can be divided into four major steps: hazard identification, doseresponse assessment, exposure assessment, and risk characterization. (NAS, 1983)

**3.3.1 Hazard identification** entails data collection and analyses relevant to human health evaluation in order to determine site-specific chemicals of potential concern. For example, the collection of site-specific fish tissue data discussed in Section 2 of these procedures is a part of the hazard identification step. The hazard identification step for chemically contaminated fish has been refined by USEPA through careful review of biological and toxicological characteristics of contaminants, and by clearly characterizing the 25 target analytes addressed in Volume 1 of USEPA (2000a).

**3.3.2 Toxicity (Dose-response) assessment** evaluates the dose-response relation for the potential chemicals of concern by considering: (a) the type of adverse health effects associated with chemicals of potential concern; and (b) the relationship between magnitude of exposure and adverse effects. To evaluate dose-response relationship, the existing information on human epidemiological and animal toxicity studies is reviewed by focusing on the carcinogenic and noncarcinogenic (i.e., systemic) effects. This toxicity information is quantitatively evaluated to determine the relationship between the exposure dose and the incidence of adverse effects in the exposed population. This quantitative evaluation is used to derive toxicity reference values that can be used to estimate the incidence of adverse effects occurring in humans at different exposure levels. These toxicity reference values can be found in USEPA Integrated Risk Information System (IRIS). DCEED recommends using EPA's toxicity reference values for its assessment process in accordance with EPA's tiered approach for the selection of toxicity reference values (EPA, 2003), and the Department's toxicology policy (Colorado Department of Public Health and Environment, 2004).

**3.3.3 Exposure assessment** estimates the magnitude of actual and/or potential human exposures by taking into consideration the following components: a) the variance of contaminant concentration among different fish species; b) individual

exposure based on consumption rate (meal size), body weight and contaminant concentration; c) type of exposed population; and d) frequency and duration of exposures. In the exposure assessment, average (central tendency) and high-end (reasonable maximum) estimates may be developed for both current and future exposures.

**3.3.4 Risk characterization** combines outputs of the exposure assessment and toxicity assessment to characterize potential cancer and non-cancer risks, both as quantitative and qualitative statements. For this policy, risk characterization involves developing the risk-based fish consumption limits for general population and/or sensitive subpopulations. Risk assessment is not an exact science. Therefore, quantitative risk estimates can be integrated with qualitative and quantitative information regarding uncertainty and variability to characterize risk. The risk characterization step also serves as the bridge between risk assessment and risk management.

#### 4) Risk Management

The Department implements risk management activities based primarily on the risk evaluations and recommendations of DCEED, and secondarily, on nutritional aspects of fish consumption and local socio-economic conditions. As such, the goals of risk management activities when issuing fish consumption advisories are to minimize health risks associated with consuming contaminated fish and minimize the negative impacts of restricting fish consumption. This can be achieved by issuing advisories that contain specific language about fish species that are unsafe and those that are safe to eat, specific information on meal size restrictions and meal preparation, including information that addresses sub-populations at different levels of risk such as subsistence versus recreational anglers, local Native American tribes, young children, etc. The Department posts and CDOW maintains the advisory signs located at the properties under CDOW management; all other signs located at properties under other agencies' management are managed by the respective agency, such as U.S. Forest Service, Bureau of Land Management, cities and counties.

The data collected in the fish tissue study will be converted by the DCEED to recommended consumption rates, i.e., meal sizes and frequencies. The recommendations will be specific to fish species and size class. If a waterbody has one fish tissue sample exceedance of a certain action level for the contaminant of concern, the recommendation is that a fish consumption advisory be issued for that waterbody, for that contaminant. Action levels are defined as the concentrations of target contaminants in fish tissue that trigger the issuance of a fish consumption advisory by the Technical Advisory Committee. The Technical Advisory Committee meets to review the recommendations and make decisions whether issuing a fish consumption advisory is warranted, or whether additional sampling and analysis, and/or collection of other site-specific data is appropriate.

There are several options available for limiting consumption of contaminated fish, ranging from general advisories (require less resources but have less effectiveness) to site-specific advisories (resource-intensive efforts that can potentially be more effective).

The Department will also make every effort to conduct educational and outreach activities in the communities impacted by a local advisory.

#### 5) Risk Communication

The Department uses the following general guidelines when issuing FCAs: a general statement about the contaminants of concern; a brief discussion of the benefits of eating fish and the potential hazards associated with the contaminant of concern, and preparation and cooking advice. Advisories also include information on recommended meal sizes, frequency of meals per fish species, and specific consumption information for sub-populations at greater risk.

Every effort is made to address local needs, in terms of information dissemination – appropriate second languages, educational and outreach activities and materials. The Division will also work closely with local health departments and other entities.

**Agency Notification**. Division staff updates the USEPA National Fish Tissue Data Repository. The results of the contaminants analysis are also disseminated to the CDOW, and the U.S. Fish and Wildlife Service, the U.S. Geological Survey and any other interested party via annual reports. Currently, the data are stored in an Access database within the Monitoring Unit, but eventually they will be stored in STORET as well.

**Public Notification.** When a fish consumption advisory is issued in Colorado, the public may be notified through press releases and/or posted notifications at the effected waterbody. Every effort is made to hold a public meeting at the community potentially being impacted by the FCA, to present and explain the details about the FCA being issued.

The Department and the CDOW also work together to consider what fish consumption advisory information might be included in the CDOW's Fishing Regulations. The information is disseminated to the public when they purchase licenses or visit CDOW offices for information.

The Division has a Fish Consumption Advisory Hotline, where the public can also get information, request mailing pamphlets and access staff for questions. There is also FCA information on the Department's website. The Monitoring Unit staff maintains and updates the information.

Advisory Evaluation. Currently, there is no formal program for evaluating the effectiveness of fish consumption advisories in Colorado. EPA suggests the following measures to enhance program effectiveness: conduct fish consumption studies,

unsolicited telephone calls, focus group evaluation at beginning of new health advisory process, surveys by citizen groups, in-house assessment by staff issuing the advisory, public meetings, tear-out sheet return form from health advisory booklet or fishing regulations, on-site visits with anglers, follow-up questionnaires, or information collected during creel surveys.

#### **IV - Summary**

The Department has developed this process for implementing the fish consumption advisory policy to protect public health and to address human health risk questions associated with consuming fish potentially contaminated with certain chemicals of concern.

This document describes and standardizes the process by which fish consumption advisories are developed and publicly disseminated in Colorado. It also identifies the roles and responsibilities of the state agencies involved in the process, describes the steps involved in implementing this policy and the mechanism to coordinate these actions.

The Department implements the fish consumption advisory program in accordance with available resources. Some elements of the program that are currently being implemented are: fish tissue sampling, laboratory analysis, statistical analysis, risk assessments for mercury, data storing and reporting. There are some components of the program that still need to be implemented, such as 1) toxicological assessment of the data and recommendations of fish consumption levels for several other parameters; 2) assessment of patterns of fish consumption specific to Colorado sub-populations, and 3) the development of the information dissemination materials (signage, language, outreach and education activities and materials, etc.). As funding sources are identified and secured, the currently un-funded components of the program will be implemented.

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