Dear Colleague:

The following are EPA’s recommendations on the use of fish and shellfish consumption advisories and certain shellfish growing area classifications in determining attainment of water quality standards and listing impaired waterbodies under section 303(d) of the Clean Water Act (CWA). EPA is issuing this guidance to promote consistency in the use of fish and shellfish tissue data by States, Territories, authorized Tribes, and EPA Regional Offices in such decision making. This guidance does not impose any legally binding requirements, and may not apply to a particular situation based on the circumstances. EPA may also change this guidance in the future.

EPA generally believes that fish and shellfish consumption advisories and certain shellfish growing area classifications based on waterbody specific information demonstrate impairment of CWA section 101(a) “fishable” uses. This applies to fish and shellfish consumption advisories and certain shellfish area classifications for all pollutants that constitute potential risks to human health, regardless of the source of the pollutant.

Background

Section 101(a)(2) of the CWA establishes as a national goal “water quality which provides for the protection and propagation of fish, shellfish, and wildlife, and recreation in and on the water, wherever attainable.” These are commonly referred to as the “fishable/swimmable” goals of the Act. Section 303(c)(2)(A) requires water quality standards to protect the public health and welfare, enhance the quality of water, and serve the purposes of the Act. Water quality standards include the designated use or uses to be made of the water, criteria necessary to protect those uses, and an antidegradation policy. EPA’s water quality standards regulations interpret and implement these provisions by: (1) requiring water quality standards that, at a minimum, provide for fishable/swimmable uses unless those uses have been shown to be unattainable; and (2) requiring adoption of water quality criteria that protect the designated uses. Such criteria must be based on sound scientific rationale, must contain sufficient parameters to protect the designated use, and may be expressed in either narrative or numeric form. Narrative criteria are descriptions of the conditions necessary for a waterbody to attain its designated use, while numeric criteria are values expressed as levels, concentrations, toxicity units or other numbers deemed necessary to protect designated uses.
EPA interprets “fishable” uses under section 101(a) of the CWA to include, at a minimum, designated uses providing for the protection of aquatic communities and human health related to consumption of fish and shellfish. In other words, EPA views “fishable” to mean that not only can fish and shellfish thrive in a waterbody, but when caught, can also be safely eaten by humans. This interpretation also satisfies the section 303(c)(2)(A) requirement that water quality standards protect public health. Including human consumption of fish and shellfish in the definition of section 101(a) “fishable” uses is not new. For example, in the National Toxics Rule, all waters designated for even minimal aquatic life protection (and therefore a potential fish and shellfish consumption exposure route) are protected for human health (see 57 FR 60859, December 22, 1992).

Under section 303(d)(1), States, Territories, and authorized Tribes must identify waterbodies that are not attaining applicable water quality standards, and prioritize such waterbodies for TMDL establishment. For purposes of determining whether a waterbody is impaired and should be included on section 303(d) lists, States, Territories, and authorized Tribes are required to consider all existing and readily available data and information (see 40 CFR 130.7). This should include physical, chemical and biological data, including data on pathogens (such as bacteria and phytotoxins) as well as fish and shellfish tissue concentration data, where such data are existing and readily available. States, Territories, and authorized Tribes collect several types of monitoring data to help determine if waterbodies are attaining or maintaining applicable water quality standards. If a State, Territory, or authorized Tribe does not consider particular existing and readily available data and information in deciding which waterbodies are impaired and must be placed on the section 303(d) list, they must provide an explanation to EPA of why they did not use such data and information.

Discussion

It has been suggested that consumption advisories for contaminated fish and shellfish tissue and shellfish growing area classifications should not be used in determining attainment of water quality standards because (1) a scientifically defensible method for determining the attainment of standards already exists through numeric ambient water quality criteria, and (2) the CWA does not explicitly direct the use of fish and shellfish consumption advisories or shellfish growing area classifications in determining attainment of water quality standards.

While numeric human health criteria for ambient water column concentrations of pollutants are a basis for determining impairment, the attainment of such criteria does not always mean that designated uses are being protected. Waterbody-specific factors sometimes cause pollutants, including pathogens, to accumulate in fish and shellfish tissue at higher levels than predicted by the methodology used to derive the numeric human health criteria. Examples of such factors include water temperature, nutrient levels, food web structure, the concentration of dissolved organic carbon in the ambient water, and accumulations in the sediment. Hence, a waterbody can be meeting numeric ambient water quality criteria, but not attaining the designated uses because fish or shellfish tissue concentrations exceed levels that are protective of human health. In instances where tissue concentrations indicate an impairment of the designated use, even though
ambient water column concentrations of pollutants do not indicate an exceedance, EPA recommends States, Territories, and authorized Tribes translate the applicable narrative criteria on a site-specific basis or adopt site specific numeric criteria to account for higher than expected exposures from contaminated fish or shellfish tissue and protect designated uses.

Certain shellfish growing area classifications should be used as part of determinations of attainment of water quality standards and listing of impaired waterbodies. Shellfish growing area classifications are developed by the National Shellfish Sanitation Program (NSSP) using water column and tissue data (where available), and information from sanitary surveys of the contributing watershed, to protect public health. The States review these NSSP classifications every three years. There are certain NSSP classifications that are not appropriate to consider, and certain data and information that should not be considered independently of the classification (unless the data and information were not used in the development or review of the classification). These instances are: “Prohibited” classifications set as a precautionary measure due to the proximity of wastewater treatment discharges, or absence of a required sanitary survey; shellfish tissue pathogen data (which can fluctuate based on short-term conditions not representative of general water quality); or short-term actions to place growing areas in the closed status.

When deciding whether to identify a water as impaired, States, Territories, and authorized Tribes need to determine whether there are impairments of designated uses and narrative criteria, as well as the numeric criteria. Although the CWA does not explicitly direct the use of fish and shellfish consumption advisories or NSSP classifications to determine attainment of water quality standards, States, Territories, and authorized Tribes are required to consider all existing and readily available data and information to identify impaired waterbodies on their section 303(d) lists. For purposes of determining whether a waterbody is impaired and should be included on a section 303(d) list, EPA considers a fish or shellfish consumption advisory, a NSSP classification, and the supporting data, to be existing and readily available data and information that demonstrates non-attainment of a section 101(a) “fishable” use when:

1. the advisory is based on fish and shellfish tissue data,
2. a lower than “Approved” NSSP classification is based on water column and shellfish tissue data (and this is not a precautionary “Prohibited” classification or the state water quality standard does not identify lower than “Approved” as attainment of the standard)
3. the data are collected from the specific waterbody in question and
4. the risk assessment parameters (e.g., toxicity, risk level, exposure duration and consumption rate) of the advisory or classification are cumulatively equal to or less protective than those in the State, Territory, or authorized Tribal water quality standards.

This applies to all pollutants that constitute potential risks to human health, regardless of the source of the pollutant. (See attached flow charts 1 and 2.)
However, for fish/shellfish advisories for “dioxin and dioxin-like compounds”¹, due to unique risk characterization issues, listing decisions should be made on a case-by-case basis. EPA is currently evaluating the role of fish advisories as part of its overall strategy to reduce human exposure to dioxin and dioxin-like compounds. EPA will be developing additional guidance specific to dioxin and dioxin-like compounds in the near future. In the meantime, EPA Regional offices should work closely with EPA’s Office of Water when providing guidance to States, Territories, and authorized Tribes on issuing fish/shellfish advisories for, or listing waters for 303(d) purposes for dioxin and dioxin-like compounds.

EPA acknowledges that in some cases, fish and shellfish consumption advisories may not demonstrate that a section 101(a) “fishable” use is not being attained in an individual waterbody. For example, a State may have issued a statewide or regional warning regarding fish tissue contaminated with a bioaccumulative pollutant, based on data from a subset of waterbodies. A State may use a higher fish consumption value in determining the need for an advisory compared to the value used in establishing water quality criteria for the protection of human health. As noted above, a State may also classify shellfish growing areas “Prohibited” as a precautionary measure due to the proximity of wastewater treatment discharges or where a required sanitary survey has not been conducted. In such instances, or where waterbodies have a fish or shellfish consumption advisory, they need not be listed as impaired under section 303(d) unless there are waterbody-specific data (and the data were not considered during the development or review of a non-precautionary NSSP classification), showing non-attainment of section 101(a) uses.

Where States, Territories, or authorized Tribes do not include a waterbody on the section 303(d) list because the advisory or the NSSP classification may not demonstrate impairment, EPA recommends that the waterbody be listed as threatened under section 305(b). Examples of such situations include a statewide fish or shellfish consumption advisory, the use of risk parameters in a fish or shellfish consumption advisory program or the NSSP classification which are more protective than those used in the water quality standards, or where a shellfish growing area is classified as lower than Approved (and this is not a precautionary “Prohibited” classification or the state water quality standard does not identify lower than “Approved” as attainment of the standard).

Some fish and shellfish consumption advisories and NSSP classifications are based on Food and Drug Administration (FDA) action levels as opposed to EPA’s risk-based methodology for the protection of human health. FDA action levels are established to protect consumers of interstate shipped, commercially marketed fish and shellfish rather than fish and shellfish caught and consumed within the state. FDA action levels also include non-risk based factors (e.g., economic impacts) in their derivation, while water quality criteria must protect the designated uses without regard to economic impacts. EPA has therefore concluded that FDA action levels do not provide a greater level of protection for consumers of fish and shellfish caught and consumed within the state than do human health criteria.

¹Van den Berg, et. al. 1998. Toxic Equivalency Factors (TEFs) for PCBs, PCDDs, PCDFs for Humans
Because tissue contamination that triggers an advisory based on FDA action levels would also trigger an advisory based on human health criteria, EPA believes that a fish or shellfish consumption advisory based on FDA action levels also indicates section 101(a) “fishable” uses are not attained.

Conclusions

Under the CWA, States, Territories, and authorized Tribes are required to adopt water quality standards that protect public health. EPA considers fish and shellfish tissue pollutant concentrations a scientifically defensible basis for determining attainment of water quality standards. Therefore, fish and shellfish consumption advisories and NSSP classifications as described above should be used as a source of data and information for section 303(d) determinations.

EPA recommends that a State, Territory, or authorized Tribe include on its section 303(d) list, at a minimum, waters where a fish or shellfish consumption advisory or NSSP classification demonstrates non-attainment of water quality standards (i.e., the advisory or classification is based on tissue data, the data are from the specific waterbody in question, and the risk assessment parameters of the advisory or classification are cumulatively equal to or less protective than those in the water quality standards). When listing waters for 303(d) or 305(b), based on a fish advisory, common migratory waters of the monitored species should also be listed. In addition, EPA believes it is reasonable for a State, Territory, or authorized Tribe to include any other water having a fish or shellfish consumption advisory or NSSP lower-than-Approved (non-precautionary) classification as impaired on its section 303(d) list if the State, Territory, or authorized Tribe believes it is appropriate.

If you have any questions or concerns regarding this guidance, please contact either of us, or have your staff contact Elizabeth Southerland, Director, Standards and Applied Science Division, at 202-260-3966, or Elizabeth Fellows, Director, Assessment and Watershed Division, at 202-260-7082.

Sincerely,

Signed by Geoffrey H. Grubbs, October 24, 2000
Geoffrey H. Grubbs, Director
Office of Science and Technology

Signed by Robert H Wayland, October 20, 2000
Robert H. Wayland III, Director
Office of Wetlands, Oceans and Watersheds
Attachments
Making 303(d) & 305(b) Listing Decisions based on Fish/Shellfish Advisories
Chart 1 of 2

Q1: Is the advisory based on fish/shellfish tissue data?
   Yes
   No, e.g., the advisory is due to a natural or administrative closure

Q2: Was the tissue data collected from the waterbody in question?
   Yes
   No, e.g., the waterbody in question is part of a regional or statewide advisory

Q3: Is the advisory based on FDA action levels?
   Yes
   No

Q4: Are the risk assessment parameters (i.e., toxicity, risk level, exposure duration and consumption rate) of the fish advisory equal to or less protective than those specified in the state/tribal water quality standards?
   Yes, they are equal to or less protective
   No, they are more protective

List as impaired under 303(d) and 305(b). Advisory indicates water quality standards are exceeded for a pollutant for which a TMDL can be developed. Common migratory waters of the monitored species should also be listed.

List as threatened under 305(b). It is uncertain that the advisory indicates a water quality standards exceedance. Common migratory waters of the monitored species should also be listed.
Chart 2

Precautionary Classification* "Prohibited"?

Yes

NSSP

Advisory or Classification under NSSP?

Yes

Advisory

Follow Fish/Shellfish Advisory Chart (Chart 1)

No

Classification otherwise lower than "Approved"?

No

Not necessary to list under §303(d) or §305(b)

Yes

START HERE

Classification reflect attainment of WQS?

List as threatened under 305(b)

Are risk assessment parameters ≤ WQS?

List as impaired under 303(d) & 305(b)

Is the Classification based on FDA action levels?

Is waterbody specific tissue data available?

+ 1999 NSSP Model Ordinance Subsection IV 03 Growing Area Classification

Making §303(d) & §305(b) CWA Listing Decisions Based on National Shellfish Sanitation Program (NSSP) Growing Area Classifications