UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION I
FIVE POST OFFICE SQUARE – SUITE 100
BOSTON, MASSACHUSETTS 02109-3912

November 6, 2019

Gerald D. Reid, Commissioner
Maine Department of Environmental Protection
17 State House Station
Augusta, ME 04333-0017

Re: Review and Approval of Maine's Sustenance Fishing Designated Use Subcategory and the Assignment of that Subcategory to the Waters Identified

Dear Commissioner Reid:

By letter dated August 12, 2019, the Maine Department of Environmental Protection (DEP) submitted to Region 1 of the U.S. Environmental Protection Agency ("Region" or "EPA") for review and approval or disapproval under section 303(c) of the CWA, several revisions to its water quality standards, set forth in legislation signed into law by Governor Janet T. Mills on June 21, 2019 (Public Law Ch. 463 - An Act to Protect Sustenance Fishing (H.P. 1262, L.D. 1775)).[1] The law became effective September 19, 2019. The Region has completed its review of the revisions to the WQS and the results of that review are described in the attachment.

The EPA's review of L.D. 1175 was limited to the provisions that are new or revised water quality standards, consistent with the authority provided in Section 303(c)(3) of the CWA. Pursuant to Section 303(c)(3) of the CWA and 40 C.F.R. Part 131, I hereby approve the following provisions, as more specifically described and for the reasons explained in the attachment:

- Sustenance Fishing Designated Use Subcategory (SFDU) set forth in 38 M.R.S.A. §466(10-A).

[1] In addition to Public Law 2019 Ch. 463, DEP submitted 1) a Certification by Assistant Attorney General Scott Boak that the designated use subcategory was duly adopted pursuant to state law, August 12, 2019; 2) Testimony of Commissioner Gerald D. Reid to the Legislature's Environment and Natural Resources Committee explaining the basis for the fish consumption rate and the waters to which it applies; 3) a marked-up version of P.L. 2019, Chapter 463 as enacted by the Maine Legislature; 4) L.D. 1775, Original text of the legislative document; 5) the Committee Amendment to L.D. 1775, Amendment with Summary; and 6) Public comments submitted at legislative hearing.

- Provisions related to the SFDU to establish human health criteria to protect the SFDU at 38 M.R.S.A. §466-A.
- Revisions to the methylmercury criterion at 38 M.R.S.A. §420(1-B)(A)(2).
- Identification of waters to which the SFDU subcategory applies at 38 M.R.S.A. §465-A(1) new paragraph D, 38 M.R.S.A. §467, 38 M.R.S.A. §468, and 38 M.R.S.A. §469.

The attachment also identifies those provisions in L.D. 1775 that EPA either is not yet acting on or does not consider to be a new or revised WQS subject to EPA's CWA section 303(c) review.

We look forward to continued cooperation with Maine in the development, review and approval of water quality standards pursuant to our responsibilities under the Clean Water Act. Please contact Ralph Abele (617-918-1629) if you have any questions.

Sincerely,

Ken Moraff, Director
Water Division

Attachment

cc: Don Witherall, MEDEP
Brian Kavanah, MEDEP
Jenn Brundage, EPA-HQ

The EPA's Approval of Maine's Sustenance Fishing Designated Use Subcategory Set Forth in 38 M.R.S.A. §466(10-A), and Related Provisions Set Forth in 38 M.R.S.A. §466-A and 38 M.R.S.A. §420(1-B)(A)(2), and Approval of the Assignment of that Subcategory to the Waters Identified in 38 M.R.S.A. §§465-A(1); 467(7), (13), and (15); 468(8); and 469(7).

A. Description of Maine's Legislation that Establishes a Sustenance Fishing Designated Use Subcategory

On August 12, 2019, the Maine Department of Environmental Protection (DEP) submitted to the EPA for review and approval or disapproval under section 303(c) of the CWA, several revisions to its water quality standards, set forth in legislation signed into law by Governor Janet T. Mills on June 21, 2019 (Public Law Ch. 463 - An Act to Protect Sustenance Fishing (H.P. 1262, L.D. 1775)).[1] This legislation: 1) establishes and defines a new sustenance fishing designated use (SFDU) as a subcategory of Maine's fishing designated use for certain specified water body segments within Maine's water classification program; 2) requires DEP to, no later than March 1, 2020, calculate and establish human health criteria (HHC) for the identified water body segments using a fish consumption rate (FCR) of 200 grams per day, and a cancer risk level (CRL) of one in 1,000,000 ($1x10^{-6}$) except for inorganic arsenic, which remains subject to a 1 in 10,000 ($1x10^{-4}$) CRL, and deems the HHC based on such factors to be protective of the SFDU; 3) establishes an ambient fish tissue-based criterion for methylmercury of 0.03 mg/kg (which is based on the 200 g/day FCR); and 4) identifies the waters to which the SFDU and associated HHC apply. The legislation also states that nothing in the bill applies to discharges of mercury, which are governed exclusively by 38 M.R.S.A. §§420(1-B) and 413(11).

B. The EPA's Approval and Rationale

The EPA approves, pursuant to section 303(c)(2) of the CWA and 40 C.F.R. Part 131, the following revisions of Maine's WQS for the reasons explained below.

1. Sustenance Fishing Designated Use Subcategory

Maine amended 38 M.R.S.A. §466 to add new subsection 10-A, which establishes and defines a "sustenance fishing designated use" as "a subcategory of the applicable fishing designated use that protects human consumption of fish for nutritional and cultural purposes and applies only to those water body segments that are identified in this article as subject to sustenance fishing designated use."

[1] In addition to Public Law 2019 Ch. 463, DEP submitted 1) a Certification by Assistant Attorney General Scott Boak that the designated use subcategory was duly adopted pursuant to state law; 2) Testimony of Commissioner Gerald D. Reid to the Legislature's Environment and Natural Resources Committee explaining the basis for the fish consumption rate and the waters to which it applies; 3) a marked-up version of P.L. 2019, Chapter 463 as enacted by the Maine Legislature; 4) L.D. 1775, Original text of the legislative document; 5) the Committee Amendment to L.D. 1775, Amendment with Summary; and 6) Public comments submitted at legislative hearing.

States have the discretion, under 40 C.F.R. §131.10(c), to adopt subcategories of a designated use and set appropriate criteria to reflect varying characteristics of waterbodies subject to the use. Maine has adopted the SFDU subcategory of its fishing use for waters "where there is or may be sustenance fishing or increased fish consumption by members of the Indian tribes in Maine or other Maine citizens."[2]

The EPA approves 38 M.R.S.A. § 466(10-A) as being consistent with Sections 101(a)(2) and 303(c)(2)(A) of the CWA and 40 C.F.R. §131.10(a) and (c). It is within Maine's discretion to adopt a subcategory of its fishing use to protect human health for waters where increased fish consumption is or may be occurring.

2. Requirements to Establish HHC to Protect the SFDU

Maine also adopted 38 M.R.S.A. §466-A, which includes provisions related to the SFDU defined in §466(10-A). Subsection 1 provides that DEP "shall establish water quality criteria for human health using a fish consumption rate of 200 grams per day and a cancer risk level of one in 1,000,000, except that the calculation for water quality criteria for inorganic arsenic is governed by section 420, subsection 2, paragraph J."[3] Subsection 2, in turn, deems the SFDU to be protected through the calculation and establishment of the HHC criteria per subsection 1.[4]

a. Fish Consumption Rate

To protect the SFDU, Maine's new law requires DEP to establish HHC that are based on a 200 g/day FCR. In explaining the basis of this 200 g/day FCR, DEP stated in testimony in support of the proposed legislation, that while HHC are typically based on a FCR that is actually occurring, "in the current context [that approach] did not make sense because Tribal members are not consuming the levels of fish that they would in the absence of concerns about the health effects of toxic contamination."[5] DEP therefore "decided that under these unique circumstances the fish consumption rate should be set as a matter of public policy, through the legislative process."[6] DEP chose the 200 g/day FCR to be used for the establishment of HHC that are deemed protective of the SFDU, after noting EPA's default subsistence-level FCR of 142 g/day set forth

[2] *See* L.D. 1775, original text of the legislative document, summary section, at page 9-129LR2522(01)-l, May 23, 2019, available at http://legislature maine.gov/legis/bills/bills_129th/billtexts/HP126201.asp

[3] Section 16 of P.L. 463 also directs DEP to adopt such HHC as routine technical rules, no later than March 1, 2020. The EPA does not consider the provisions related to the date and method of rulemaking to be new or revised WQS and therefore is taking no action to review and approve or disapprove them.

[4] Subsection 3 of 38 M.R.S.A. §466-A describes limitations on how the SFDU may be construed, so as to not create any other right or protection, or limit any existing right or protection, or affect the regulation of mercury in discharges. The EPA does not consider the provisions of subsection 3 to be new or revised WQS and therefore is taking no action to review and approve or disapprove them.

[5] Testimony of Gerald Reid, Commissioner, Maine Department of Environmental Protection (May 29, 2019) at page 3, available at http://legislature maine.gov/bills/getTestimonyDoc.asp?id=127872

[6] *Id.*

in EPA's 2000 Human Health Methodology,[7] and surveying other states' FCRs. DEP identified Oregon and Washington as the states having the highest FCR at 175 g/day. DEP recommended 200 g/day as "a conscious choice to establish in Maine the most protective fish consumption rate in the country for those select waters where we believe it is appropriate."[8] DEP also determined that "potential impacts to the regulated community" due to the adoption of the 200 g/day FCR for HHC applicable to the specified waters would be "minimal to non-existent."[9] EPA understands that the four federally recognized Tribes in Maine, who practice sustenance fishing and use the waters to which the SFDU applies, have expressed support for the 200 g/day FCR.[10]

In EPA's 2000 Human Health Methodology, EPA provides guidance to the states on the use of local and regional data to develop an appropriate fish consumption rate for the use in criteria derivation and encourages the states to use this data to determine the level of protection appropriate for state waters. In this case, Maine has chosen a conservative FCR well above EPA's national recommended FCR to protect sustenance/subsistence fishers and higher consuming Maine citizens. Although Maine's FCR is not based on local or regional data, the EPA approves §466-A, subsections 1 and 2, because Maine has made a reasonable risk- and resource-management decision, in the absence of more site-specific information, to protect the SFDU. Maine's decision to adopt an FCR well above the national default FCR of 142.4 g/day to protect subsistence fishing recommended in the 2000 Methodology is consistent with states' authority to choose an FCR that results in more stringent criteria.[11]

EPA concludes that 200 g/day is a reasonable estimate, based on available information, for Maine to use to protect a contemporary sustenance level of consumption. Although EPA previously relied on the Wabanaki Cultural Lifeways Exposure Scenario (the "Wabanaki Study" or "Study") as "the best currently available estimate for contemporary tribal sustenance level fish consumption for waters where the sustenance fishing designated use applies" 81 Fed. Reg. 92466, 92473 (Dec. 19, 2016), EPA now concludes upon further reflection that it was improper for it to rely on the Study as the best available information for evaluating the appropriate FCR. Furthermore, EPA believes that the State has the discretion not to use or rely on the Wabanaki Study when establishing HHC to protect its sustenance fishing use subcategory and EPA concludes that the State's decision not to use or rely on the Wabanaki Study is reasonable and appropriate. EPA supports the State's decision not to use or rely upon the Wabanaki Study.

EPA reaches its conclusion that the Study was not the best available information for deriving an FCR to address tribal sustenance fishing in Maine for several reasons. Notwithstanding EPA's

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[7] USEPA. 2000. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health. Page 1-13. U.S. Environmental Protection Agency, Office of Water, Washington, DC. EPA–822–B–00–004. http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf

[8] Testimony of Gerald Reid, at page 3.

[9] *Id.*

[10] *E.g.*, Testimony of Maulian Dana, Penobscot Nation Tribal Ambassador (May 29, 2019) (Stating an FCR of 200 g/day "would be a great improvement and a goal that would benefit tribal citizens and all Maine citizens").

[11] *See* 40 C.F.R. § 131.4(a) ("As recognized by section 510 of the Clean Water Act, States may develop water quality standards more stringent than required by [40 C.F.R. Part 131]."

previous conclusion that the Study includes "the best currently available estimate for contemporary tribal sustenance level fish consumption," 81 Fed. Reg. at 92473, the Study does not include any information or data on contemporary fish consumption among tribal populations in Maine. See Wabanaki Study at 15 ("[S]tatistical food consumption and time-activity survey data are not available for describing traditional cultural lifeways[.]"). Furthermore, the Study's scope spanned four centuries generally (but not entirely) in pre-industrial times, and the Study's estimation of sustenance fish consumption was based on a dietary "reconstruction" that used approximations of natural conditions from those time periods. Wabanaki Study at 8-9, 15. The Study did not differentiate between historical periods with specificity or attempt to present fish consumption information with the precision of statistically-derived calculations. Indeed, this lack of precision means that the Study does not lend itself for use establishing a historical FCR at a particular point in history. In light of these and other limitations in the Study, EPA now concludes that the Study does not provide an adequate basis from which to derive a contemporary or historical sustenance level of tribal fish consumption.

In addition, deriving a sustenance FCR from the Study required EPA to make a number of assumptions. Upon reconsideration, EPA's decision to draw an FCR of 286 g/day from the Study did not provide adequate support for some of these assumptions. For example, of the three "lifestyle models" analyzed in the Study, EPA selected the FCR from the model with the highest estimated "resident fish and other aquatic resources" FCR (the "inland non-anadromous" lifestyle). EPA supported this decision by pointing to its consistency "with the Penobscot Nation's approach to deriving a current, unsuppressed FCR to protect sustenance fishing." 81 Fed. Reg. at 23247. EPA now concludes that this decision lacked adequate record support. EPA also concluded that it was "reasonable to assume that the inland anadromous and coastal lifestyle tribes would have shifted a substantial percentage of the sustenance fishing diet from the formerly widely available but now less available anadromous species (such as salmon) or protected marine mammals to resident fish species . . . ." Id. EPA now concludes that it did not adequately substantiate its assumption that reduced availability of anadromous fish and marine fish and shellfish means that modern-day native populations would replace that portion of their historical diet with a greater percentage of freshwater fish than the historical amounts included in the Study, and EPA lacks the data needed to support this assumption. See Wabanaki Study 61-67.

For these reasons, EPA concludes it was reasonable and appropriate for Maine not to use or rely upon the conclusions of the Study or EPA's Study-derived FCR, as the Study is not fit for the purpose of determining an FCR for the purpose of calculating Clean Water Act human health criteria.

b. Cancer Risk Levels

As noted above, §466-A(1) requires DEP to calculate the HHC to protect the SFDU, using the same CRLs that DEP uses to calculate HHC to protect other waters not subject to the SFDU (i.e., 10^{-6}, except 10^{-4} for arsenic). The EPA's national 304(a) recommended HHC are typically based on the assumption that carcinogenicity is a "non-threshold phenomenon," which means that there are no "no-effect" levels, because even extremely small doses are assumed to cause a finite increase in the incidence of cancer. Therefore, the EPA calculates 304(a) HHC for carcinogenic effects as pollutant concentrations corresponding to lifetime increases in the risk of developing

cancer. The EPA calculates its national 304(a) recommended HHC values at a 10^{-6} (one in one million) cancer risk level and recommends states incorporate lifetime cancer risk levels of 10^{-6} or 10^{-5} (one in one hundred thousand) for the general population. Consistent with the 2000 Methodology, a 10^{-5} risk level can be appropriate to protect the general population, as long as the criteria ensure that highly exposed populations (e.g., sport fishers or subsistence fishers) do not exceed a 10^{-4} risk level. [12]

The EPA has previously approved Maine's requirement to use a 10^{-6} CRL for all carcinogens other than arsenic, for all waters in Maine. Similarly, the EPA now approves the 10^{-6} CRL in §466-A(1) to be used in calculating HHC for all carcinogens other than arsenic to protect the SFDU. This CRL is consistent with the range of CRLs that the EPA considers to be appropriate for the general population which the HHC are derived to protect and is the risk level that the EPA uses when publishing its CWA § 304(a) recommended criteria.

The EPA is deferring action on subsection 1's reference to the continued applicability of 38 M.R.S.A. §420(2)(J) to require use of a 10^{-4} CRL for arsenic until Maine submits new arsenic HHC established to protect the SFDU. At that time, the EPA will evaluate the adequacy of arsenic criteria based on the CRL in conjunction with all of the other inputs for the criteria (e.g., cancer slope factor, bioaccumulation factor).

3. Methylmercury Criterion

Maine amended 38 M.R.S.A. §420(1-B)(A)(2) to provide that the fish tissue residue criterion for methylmercury applicable to water body segments subject to the SFDU shall be "0.03 milligrams per kilogram in the edible portion of the fish." Maine derived this value by using the equation underlying the EPA's 2001 CWA section 304(a) national recommended methylmercury criterion and replacing the FCR with the same FCR of 200 g/day that applies to the other HHC to protect the SFDU.[13]

The EPA approves the revised methylmercury criterion based on the 200 g/day FCR because the criterion is based on sound science and will be protective of the SFDU EPA is approving as part of this action. This is consistent with the 40 C.F.R. § 131.11 requirement that criteria "must be based on sound scientific rationale and must contain sufficient parameters or constituents to protect the designated use."

4. Waters to Which the SFDU Subcategory Applies

Maine has amended its Standards of Classification of Lakes and Ponds (38 M.R.S.A. §465-A(1)) to include new paragraph D, which contains a list of lakes that are subject to the SFDU. Maine

[12] USEPA. 2000. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health. Pp 1-12 & 2-6. U.S. Environmental Protection Agency, Office of Water, Washington, DC. EPA–822–B–00–004. http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf

[13] USEPA, 2001. Water Quality Criterion for the Protection of Human Health: Methylmercury. U.S. Environmental Protection Agency, Office of Water, Washington, DC. EPA-823-R-01-001. https://www.epa.gov/wqc/human-health-criteria-methylmercury

also amended 38 M.R.S.A. §467, Classification of Major River Basins; 38 M.R.S.A. §468, Classification of Minor Drainages; and 38 M.R.S.A. §469, Classification of Estuarine and Marine Waters, to specifically identify the rivers, streams, and tidal waters (or segments thereof) that are subject the SFDU pursuant to §466-A. In conversations with Maine DEP, the Tribes "identified these waterbodies as having particular significance to their communities for the purpose of fishing."[14]

Maine's approach to identifying the waters to which the SFDU subcategory applies is different from the approach that the EPA used in 2015, and in the associated 2017 federal rulemaking, to protect sustenance fishing. The EPA did not name specific waters that were covered, but rather identified waters categorically – i.e., those associated with reservations and trust lands and where any Tribe has reserved fishing rights outside those lands. Maine, on the other hand, has identified specific water body segments where there is or may be sustenance fishing or increased fish consumption, based on information provided by the Tribes. Some of the waters are within tribal lands, and some are not. Maine's approach is reasonable, and it is within the State's discretion to choose to protect specific waters with a SFDU subcategory where sustenance fishing is or may be occurring rather than covering waters on a categorical basis as the EPA did.[15] Further, Maine's approach "does not preclude a future designation of other such waters through a similar legislative process or as otherwise provided by law."[16]

The EPA approves the identification of waters to which the SFDU subcategory applies as being reasonable and consistent with Sections 101(a)(2) and 303(c)(2)(A) of the Clean Water Act and 40 C.F.R. § 131.10(a).

[14] Testimony of Gerald Reid, at page 4.

[15] The EPA is currently in the process of reconsidering the approach it took in 2015, in conjunction with its reconsideration of its WQS decisions in 2015 that Maine challenged and that have been remanded to the Agency by the federal district court in Maine.

[16] Testimony of Gerald Reid, at page 3.