



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 10**

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WATER  
DIVISION

July 3, 2023

Mr. Randy Bates  
Director  
Division of Water  
Alaska Department of Environmental Conservation  
P.O. Box 111800  
Juneau, Alaska 99811

Re: EPA Response to Alaska's Human Health Criteria Development Letter

Dear Mr. Bates:

Thank you for your letter, dated May 19, 2023, providing the U.S. Environmental Protection Agency (EPA) with an update on the Alaska Department of Environmental Conservation's (DEC) progress on its commitment to update the state's human health criteria (HHC) by the end of calendar year 2024. We continue to support DEC's efforts to develop new and revised HHC and are committed to engaging with DEC throughout its rulemaking process.

Your letter requested EPA's technical assistance and collaboration on a list of questions related to HHC development and implementation. EPA's responses to your questions are summarized in the enclosure to this letter, but several of the topics raised in the letter are complex issues that could benefit from follow up discussions. Therefore, we would like to offer an in-person working session with DEC staff at your office location this fall as the state continues to work towards developing new and revised HHC.

EPA looks forward to ongoing collaboration and coordination with DEC on this and other water quality standards priorities. Please do not hesitate to contact me at (206) 553-0279 or your staff may contact Rachael Renkens, Alaska Water Quality Standards Coordinator, at [Renkens.Rachael@epa.gov](mailto:Renkens.Rachael@epa.gov) or (206) 553-1580, with questions.

Sincerely,

*/s/ 07-03-2023*

Michael Szerlog  
Acting Director

Enclosure

**Enclosure to EPA’s response to the Alaska Department of Environmental Conservation’s (DEC) May 19, 2023 letter requesting information to inform the development of new and revised human health criteria (HHC)**

1. Many of the bioaccumulation/bioconcentration factors published by EPA as part of the national 2015 HHC update are built on the Great Lakes food web model. The user reference guide indicates the model is not recommended for use in modeling arctic conditions such as those in large portions of Alaska. Are there Alaska-specific or more relevant datasets that can be used to refine Alaska’s bioaccumulation factor or bioconcentration factor on a statewide/regional/site-specific level?

EPA Response: EPA derived its 2015 national default recommended bioaccumulation factors (BAFs) following the Agency’s peer reviewed, publicly vetted guidance (2000 *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (“2000 HHC Methodology”) and 2003 *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors*). The 1993 Gobas model that your question refers to is a food-web model that predicts bioaccumulation based on a multitude of customizable environmental parameters, contaminant-specific physical characteristics, and known principals of food web interactions. A dataset from Lake Ontario was used to test the model. Since the initial publication of the Gobas model, many datasets from varied ecosystems have been used to test and validate the results of the model (e.g., see section 5.2.2 in EPA’s 2009 *Technical Support Document, Volume 3: Development of Site-Specific Bioaccumulation Factors*). Because field and laboratory data are preferred sources of bioaccumulation data, predicted food chain multipliers are only used for organic compounds when (1) field or laboratory-based bioaccumulation data do not exist, (2) the  $K_{ow}^1$  of the compound is high (meaning that the compound is soluble in fat), *and* (3) the metabolic pathways for the compound are thought to be low or are unknown. The modeled food chain multipliers are only used for inorganic compounds, when (1) field or laboratory-based bioaccumulation data do not exist, *and* (2) there are known biomagnification effects in the food chain. For this reason, only 33 of the 94 chemicals included in EPA’s 2015 HHC update<sup>2</sup> incorporate a BAF based on a model-derived food chain multiplier factor.

Although EPA uses these default BAFs to calculate national Clean Water Act (CWA) section 304(a) recommended HHC, EPA’s 2000 HHC Methodology notes a preference for the use of local data to calculate HHC (e.g., waterbody-specific bioaccumulation rates) over national default values, where data are sufficient to do so, to better represent local conditions.<sup>3</sup> EPA is not aware of any state-specific bioaccumulation rate data available for the state of Alaska. In the absence of local data, it is appropriate to rely on the national default BAFs. Since receiving your letter, EPA Region 10 reviewed literature on temperature and climate sensitive parameters that were identified in the 2000 HHC Methodology as influencing bioaccumulation rates and did not find indications that the Gobas model is inappropriate for Alaska. EPA will share the references it found with DEC staff via email.

2. Can EPA provide any additional information, define any exposure differences, or identify any benefit or risk to including anadromous fish and/or marine mammals in the relative source contribution (RSC) rather than accounting for them via the fish consumption rate (FCR)? Has EPA’s guidance for balancing

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<sup>1</sup>  $K_{ow}$  is the Octanol-Water Partition Coefficient

<sup>2</sup> <https://www.epa.gov/wqc/human-health-water-quality-criteria-and-methods-toxics#2015>

<sup>3</sup> EPA’s 2000 HHC Methodology, pp. 2-2, 2-10.

the RSC when including marine species in the FCR been updated, revised, or otherwise informed based on recent science since the rule for Restoring Protective Human Health Criteria in Washington, November 2022 was released?

EPA Response: EPA has not issued any guidance since 2013 on adjusting the relative source contribution (RSC) input when species other than freshwater and estuarine fish and shellfish are included in the fish consumption rate (FCR).<sup>4</sup> EPA has not previously included species like marine mammals in the FCR when calculating national CWA section 304(a) recommended HHC because these species are not commonly consumed by the U.S. general population. However, EPA’s guidance provides that states and authorized tribes may account for the consumption of other organisms (e.g., marine and anadromous species) in the FCR to protect the population of concern.<sup>5</sup> Including marine and anadromous fish in the FCR may be particularly appropriate if it is clearly documented that a large proportion of fish consumption for the population to be protected consists of marine and anadromous fish, such as is the case for Alaska.<sup>6</sup> Exposure may be refined by adjusting the RSC input, however, the RSC only applies for non-carcinogens. As such, the incorporation of marine and anadromous species in the FCR where data exists helps ensure that the resulting HHC for both non-carcinogens and carcinogens are protective of a population that regularly consumes marine and anadromous species, in addition to freshwater and estuarine fish and shellfish.

3. The application of “regional criteria” rather than statewide criteria of HHC has been raised by different stakeholders.
  - a. On August 21, 2015, EPA commented on Idaho’s Department of Environmental Quality, Preliminary Draft Negotiated Rule disfavoring the use of regional criteria on the basis that residents should be able to “consume from local waters the amount of fish they would normally consume from all inland and near shore waters.” This indicates that HHC criteria should be developed without regard to geographical location.
  - b. In November 2022, EPA announced a proposal to Protect Tribal Reserve Rights (TRR) in Water Quality Standards. This proposal, along with the April 2023 Proposed Rule to promulgate federal baseline water quality standards (Baseline WQS) for waters on Indian Reservations, could effectively create regional HHC criteria in states.
  - c. These different actions by EPA conflict with each other. Please explain EPA’s view of the utility of developing statewide vs. regional criteria.

EPA Response: States must adopt criteria that are sufficient to protect the existing and designated uses of their waters.<sup>7</sup> EPA’s 2000 HHC Methodology recommends that priority be given to identifying and adequately protecting the most highly exposed population. Thus, if it is determined that a highly exposed population is at greater risk and would not be adequately protected by criteria based on the general population, EPA recommends that more stringent criteria are adopted using alternative exposure assumptions.<sup>8</sup>

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<sup>4</sup> EPA’s 2000 HHC Methodology, 4-25; *see also* EPA 2013, Human Health Ambient Water Quality Criteria and Fish Consumption Rates: Frequently Asked Questions, Q6. <https://www.epa.gov/sites/default/files/2015-12/documents/hh-fish-consumption-faqs.pdf>.

<sup>5</sup> *Id.*

<sup>6</sup> The Mountain-Whisper-Light Statistics (Mar. 20, 2019). Alaska Statewide and Regional Estimates of Consumption Rates in Rural Communities for Salmon, Halibut, Herring, Non-Marine fish, and Marine Invertebrates.

<sup>7</sup> 40 CFR 131.11.

<sup>8</sup> EPA’s 2000 HHC Methodology, p. 2-2

EPA recognizes that exposure and fish consumption patterns can vary substantially, and that highly exposed populations may be widely distributed geographically throughout a given state/area. In most cases, a statewide rate is a more practical approach than applying different sets of criteria to different regions in the state. With a set of statewide criteria, consumers would be provided the same level of protection, risks, and exposures, regardless of where in the state fish/shellfish are being acquired. Statewide criteria may also be appropriate in states where tribes hold reserved rights to fish for subsistence in many waters across the state (e.g., Washington). However, states may choose to adopt site-specific or regional criteria for certain waters, such as where there is a smaller/discrete set of waters where subsistence is being practiced (e.g., Maine), where it can show that doing so is consistent with applicable laws.

Regarding your reference to the Tribal Baseline WQS rule proposal, EPA would like to emphasize that the concept of having tribal WQS within Indian reservation and trust land waters is no different than when tribes apply for “treatment in a similar manner as a state” (TAS) and develop their own WQS. The baseline WQS would apply to waters within formal and informal reservations (lands held entirely in trust for a federally recognized tribe) that do not currently have WQS in effect under the CWA. These are waters where EPA is currently the primary CWA implementing authority. Therefore, the baseline WQS proposal should not be interpreted as EPA advocating for states to adopt region-specific criteria.

In Alaska, available state-specific community harvest and fish consumption data demonstrate a range of consumption patterns throughout the state and indicate that subsistence/sustenance fish consumption is widely practiced in rural areas.<sup>9</sup> As such, adopting statewide HHC that are protective of subsistence fishing would be a reasonable approach. This question was explored as Issue #7 in DEC’s *Human Health Criteria Technical Workgroup Report* (2018). The Workgroup concluded that the development of criteria based on a conservative statewide FCR was more appropriate for DEC’s regulatory purposes saying, “Establishment of a FCR that is protective of rural populations is anticipated to be protective of sub-populations within urban areas that may be high consumers.”<sup>10</sup> If DEC’s thoughts regarding statewide vs. regional criteria have shifted, EPA is available to engage in further discussion with DEC on this topic.

4. Please provide data relevant to appropriate averaging periods for determining lifetime exposure, including for sensitive populations, when generating waterbody assessments.

EPA Response: The duration component for HHC is “long-term” for the purposes of assessing the attainment of HHC in waterbodies.<sup>11</sup> The approach that states use to evaluate HHC in generating waterbody assessments can be found in states’ assessment methodologies. Assessment methodologies document the process by which a state evaluates monitoring results and information against WQS to determine water quality status. A clear methodology ensures that attainment/impairment determinations are transparent and reproducible. In general, states assess HHC by evaluating long-term aggregate data over time (e.g., annual averages, arithmetic means of three or more years of data, etc.) This general

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<sup>9</sup> The Mountain-Whisper-Light Statistics (Mar. 20, 2019). Alaska Statewide and Regional Estimates of Consumption Rates in Rural Communities for Salmon, Halibut, Herring, Non-Marine fish, and Marine Invertebrates.

<sup>10</sup> ADEC. (2018). *Evaluation of Key Elements and Options for Development of Human Health Criteria. Technical Workgroup Report*. November 13, 2018. FINAL DRAFT. Prepared by Alaska Department of Environmental Conservation, Division of Water., p. 33

<sup>11</sup> 65 FR 66443

practice is consistent with the approach outlined by DEC in the *Alaska Consolidated Assessment and Listing Methodology* (2021):<sup>12</sup>

For the human health and drinking water uses, the arithmetic mean of the most recent three years duration value may not exceed the magnitude of the pollutant criterion.<sup>16</sup>

<sup>16</sup> DEC will apply the arithmetic mean of the most recent three years of data unless a skewed dataset exists and application of a geometric mean is more appropriate for assessment purposes per EPA 2002 CALM

DEC's current approach for assessing the state's HHC is consistent with EPA's guidance and recommendations. However, if DEC is interested in evaluating the approaches that other states use for assessing their HHC, EPA suggests that DEC review other states' HHC implementation plans and consult their assessment methodologies. Below is a list of selected state assessment methodologies that may be of interest to DEC when reviewing other approaches for assessing data and information pertaining to HHC.

- *Methodology for Oregon's 2022 Water Quality Report and List of Water Quality Limited Waters* (2002)<sup>13</sup>
- *Water Quality Program Policy 1-11: Washington's Water Quality Assessment Listing Methodology to Meet Clean Water Act Requirements* (2023)<sup>14</sup>
- *Wisconsin's Consolidated Assessment and Listing Methodology (WISCALM)* (2023)<sup>15</sup>
- *Water Quality and Pollution Control in Michigan 2022 – Sections 303(d), 305(b), and 314 Integrated Report* (2022)<sup>16</sup>
- *Guidance Manual for Assessing the Quality of Minnesota Surface Waters for Determination of Impairment: 305(b) Report and 303(d) List* (2022)<sup>17</sup>

If upon review of other states' assessment methodologies DEC has follow-up questions or would like additional information, EPA would be happy to facilitate further conversations with state assessment contacts.

5. Of particular interest are the strategies for implementing HHC based on fish tissue concentrations. DEC has reviewed implementation documentation from Oregon and Idaho pertaining to methylmercury and notes that both states reference use of "narrative effluent limits." In both cases, the state is requiring use of pollutant/mercury minimization plans in lieu of new numeric criteria. DEC has also seen this approach used in Ohio, Michigan, and Wisconsin.

DEC recognizes that such an approach was referenced in the EPA 2010 Methylmercury guidelines but is curious if such an approach could be more broadly considered. In other words, is the use of pollutant minimization plans an acceptable alternative for addressing other

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<sup>12</sup> <https://dec.alaska.gov/water/water-quality/integrated-report>

<sup>13</sup> <https://www.oregon.gov/deq/wq/Documents/IR22AssessMethod.pdf>

<sup>14</sup> <https://apps.ecology.wa.gov/publications/documents/1810035.pdf>

<sup>15</sup> <https://dnr.wisconsin.gov/topic/SurfaceWater/WisCALM.html>

<sup>16</sup> <https://www.michigan.gov/egle/-/media/Project/Websites/egle/Documents/Programs/WRD/SWAS/2022-Integrated-Report.pdf?rev=0a6b006c0cc44bcd936c75d5608659ed&hash=03A5B2B0F3379B07D369F289BA32C483>

<sup>17</sup> <https://www.pca.state.mn.us/sites/default/files/wq-iw1-041.pdf>

challenging pollutants? In what cases would a state be restricted from using narrative effluent limits?

EPA Response: The National Pollutant Discharge Elimination System (NPDES) program implements water quality criteria through water quality-based effluent limits (WQBELs). When it is determined that a discharge has a reasonable potential to cause or contribute to an excursion above the criteria for a pollutant, the permit must contain WQBELs for the discharge of the pollutant.<sup>18</sup>

Your question mentions narrative effluent limits to address the fish-tissue based methylmercury HHC. Since the methylmercury criterion is a tissue-based value, without a nationally recommended or state specific BAF, it is sometimes considered infeasible to calculate an enforceable water-column value from the tissue-based criterion in permits. To implement the fish-tissue based criterion, a narrative approach can be employed, such as a mercury minimization plan. In this way, methylmercury is unique from the rest of the suite of HHC.

In certain situations, when the EPA-approved method analytical detection level for a pollutant exceeds the criterion for that pollutant, the analytical detection level (or quantitation limit) is considered sufficiently sensitive to represent the minimum enforceable level of the pollutant (referred to as the “compliance evaluation level”).<sup>19</sup> The *Technical Support Document for Water Quality-based Toxics Control* includes the following language related to permit conditions for parameters where the WQBELs are below the detection level achieved using approved EPA methods.<sup>20</sup>

Where water quality-based limits below analytical detection levels are placed in permits, EPA recommends that special conditions also be included in the permit to help ensure that the limits are being met and that excursions above water quality standards are not occurring. Examples of such special conditions include fish tissue collection and analyses, limits and/or monitoring requirements on internal waste streams,<sup>21</sup> and limits and/or monitoring for surrogate parameters. This information can be used to help support reopening the permit to establish more stringent effluent limits if necessary.

In such situations, a best management practice (BMP) based approach may be appropriate. BMPs can be used to ensure meaningful source control is incorporated into permits for parameters of concern. For example, EPA has previously shared with DEC permits in Washington with polychlorinated biphenyl (PCB) limits that have WQBELs that are under the detection limit for the chemicals. These permits include BMPs to reduce PCBs (e.g., monitoring requirements, phosphorus filtration year-round, etc.). However, the permits still include a WQBEL calculated from the applicable criterion (not “narrative effluent limits” alone). If the limit is below the level that can be detected, the enforceable limit would be the analytical detection level.

For the HHC parameters with sufficiently sensitive, approved methods and quantifiable limits, “narrative effluent limits” are not appropriate; however, the permits could still incorporate source control techniques in addition to enforceable WQBELs.

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<sup>18</sup> 40 CFR 122.44(d)(1).

<sup>19</sup> 40 CFR 122.44(i).

<sup>20</sup> EPA. 1991. Technical Support Document For Water Quality-based Toxics Control. EPA-505-2-90-001. <https://www3.epa.gov/npdes/pubs/owm0264.pdf>

<sup>21</sup> 40 CFR 122.45(h)

EPA welcomes future discussions on this topic with DEC. In those discussions, EPA would like to hear which pollutants DEC is anticipating to be especially challenging. Has DEC identified these pollutants based on an evaluation of current point sources?

6. A particular issue in Alaska is potential conflicts with fish consumption advisories, especially in areas with high subsistence use. DEC finds a general misunderstanding in the public of the relationship between HHC, fish consumption advisories, and subsistence fishing permits. DEC would appreciate assistance in crafting public messaging regarding these concepts.

EPA Response: EPA recognizes that the difference between a fish consumption rate used for the purposes of developing HHC and fish consumption advisories can be difficult to explain. However, based on the presentations provided by DEC staff regarding HHC and fish consumption advisories, it appears that the distinction is well understood.

One approach for distinguishing between the two is to focus on the purpose of HHC versus fish consumption advisories. HHC are used to implement CWA regulatory programs and represent specific levels of chemicals or conditions in a waterbody that are not expected to cause adverse effects to human health. The FCR used to develop HHC indicates the amount of fish and shellfish consumed by a person each day and is generally based on a percentile of FCRs from the population of interest (e.g., the 90<sup>th</sup> percentile). In contrast, the Fish Advisory program is non-regulatory and provides recommendations to state, territorial, and tribal programs on developing consumption advice to limit exposure from contaminants in fish caught in local waters. Fish consumption advisories recommend the number of fish servings per week that could be eaten by individuals based on chemical levels in fish.

It is EPA's understanding that the subsistence and personal use fisheries program is a state-specific program that is administered by the Alaska Department of Fish and Game (ADF&G), except for subsistence halibut fisheries which are managed by NOAA Fisheries.<sup>22</sup> As such, DEC, in coordination with ADF&G, would be better positioned to explain how subsistence fishing permits may relate to the state's HHC and fish advisory program.

7. EPA has previously identified the following as currently authorized tools for facilitating new HHC:
  - a. Compliance Schedules
  - b. Water Quality Standards Variances (Individual/Multi-discharger/Watershed)
  - c. Reclassification of Waters

Besides DEC's previous inquiry regarding the application of "narrative criteria" in a permitting context, are there any additional tools or approaches DEC should be actively considering?

EPA Response: As described in EPA's letter to DEC dated November 1, 2022, states may employ certain implementation approaches or policies that generally affect how their WQS are applied or implemented.<sup>23</sup> Your letter lists the main WQS implementation approaches that are available.

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<sup>22</sup> <https://www.adfg.alaska.gov/index.cfm?adfg=residentfishing.main>;  
<https://www.adfg.alaska.gov/index.cfm?adfg=residentfishing.matrix>

<sup>23</sup> 40 CFR 131.13-15.

A mixing zone provision is another approach that DEC could employ in permits to facilitate the implementation of HHC. A mixing zone is a limited area or volume of water where initial dilution of a discharge takes place and where certain numeric water quality criteria may be exceeded. Alaska's WQS includes a mixing zone policy at 18 AAC 70.240. Since EPA took action on revisions to Alaska's mixing zone policy in 2019, and DEC subsequently removed the portions of the policy that were disapproved by EPA, the full policy is currently in effect for CWA purposes. DEC could utilize this policy in the implementation of HHC in permits, where applicable.

8. Alaska has a complex legal tribal landscape. The Draft TRR and Baseline WQS's applicability in Alaska is not clear to us, which complicates the timeline for this rulemaking. Please articulate the applicability of these draft rules in the State of Alaska.

EPA Response: As an initial matter, states have the primary responsibility under the CWA for reviewing, establishing, and revising WQS applicable to their waters.<sup>24</sup> The CWA also requires that states hold a public hearing to review applicable WQS at least once every three years and, if appropriate, revise or adopt new standards.<sup>25</sup> This includes adopting criteria for priority toxic pollutants pursuant to CWA section 303(c)(2)(B) and revising existing priority toxic pollutant criteria as appropriate based on new information.<sup>26</sup> DEC has not updated the state's HHC for priority toxic pollutants in over 30 years, despite the availability of national and local fish consumption data indicating that revisions are needed to protect Alaska's residents. In light of this, EPA strongly supports DEC moving expeditiously to update the state's HHC to ensure that, consistent with the CWA, Alaska's HHC are protective of human health.

Your question refers to two federal rules that EPA recently proposed (the December 5, 2022, *Water Quality Standards Regulatory Revisions to Protect Tribal Reserved Rights*<sup>27</sup> and the May 5, 2023, *Federal Baseline Water Quality Standards for Indian Reservations*<sup>28</sup>). As you know, the public comment period on the first rule closed on March 6, 2023, and EPA is in the process of reviewing and evaluating the comments received. The public comment period for the second rule is open until August 3, 2023. With respect to the second rule, as proposed, the baseline WQS would generally apply to waters within formal and informal Indian reservations (lands held entirely in trust for a federally recognized tribe) that do not currently have WQS in effect under the CWA. While EPA appreciates Alaska's desire for certainty, it is not clear to EPA how a rule to establish WQS for Indian reservation waters, where EPA is the primary CWA implementing authority, may impact the timeline or substantive direction of Alaska's HHC rulemaking. Therefore, EPA is focusing the remainder of its answer on the first rule.

EPA's proposed *Water Quality Standards Regulatory Revisions to Protect Tribal Reserved Rights* rule is a national rule intended to create a regulatory framework that can be applied to the specific circumstances in each state with waters where reserved rights to aquatic and/or aquatic-dependent resources apply. A primary consideration that EPA identified in the proposed rule as a reason to treat tribal members exercising reserved rights as the target population for purposes of deriving HHC is that

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<sup>24</sup> 40 CFR 131.4.

<sup>25</sup> 40 CFR 131.20(a).

<sup>26</sup> U.S. EPA. (Dec. 22, 1992). *Establishment of Numeric Criteria for Priority Toxic Pollutants*, 57 FR 60848, 60873 (Explaining that "EPA expects to request States to continue to focus on adopting criteria for additional toxic pollutants and revising existing criteria in future triennial reviews which new information indicates is appropriate.").

<sup>27</sup> 87 FR 74361.

<sup>28</sup> 88 FR 29496.



they “are a distinct, identifiable class of individuals holding legal rights to resources, whose reserved rights are unique to them and have a defined geographic scope.”<sup>29</sup> EPA’s understanding, based on an evaluation of Alaska-specific community harvest and consumption data that EPA funded and developed in partnership with DEC,<sup>30</sup> is that subsistence consumption is a widespread existing practice across the state and is not limited to tribal consumers. Therefore, even if any EPA final rule to protect tribal reserved rights were to apply in Alaska, it would not change the fact that the current FCR (i.e., 6.5 grams/day) does not accurately reflect subsistence consumption, tribal or otherwise. EPA recommends that DEC select the inputs to derive revised HHC for Alaska, particularly the FCR and cancer risk level inputs, with protection of subsistence consumers as the focus. More specifically, this would mean selecting an FCR that represents a value at the high end (e.g., 90<sup>th</sup> percentile) of the state’s subsistence population, rather than a mean or median, paired with a cancer risk level of  $10^{-5}$  or  $10^{-6}$ . Other states with widespread subsistence fishing practices among their residents (e.g., Oregon and Washington) have taken a similar approach to developing HHC that protect all populations that fish for subsistence, including tribes with reserved rights.

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<sup>29</sup> 87 FR 74361, 74370.

<sup>30</sup> The Mountain-Whisper-Light Statistics (Mar. 20, 2019). Alaska Statewide and Regional Estimates of Consumption Rates in Rural Communities for Salmon, Halibut, Herring, Non-Marine fish, and Marine Invertebrates.