Amendments to the Water Quality Control Plan for Enclosed Bays and Estuaries of California:

Sediment Quality Provisions

Responses to Peer Review Comments

Peer Review Letter No.	Peer Reviewer	Conclusions Addressed[1]
1	Gary A. Buchanan, Ph.D.	Conclusions A5, A6, A7 and B1
2	Valery E. Forbes, Ph.D.	Conclusions A6 and A7
3	Robert J. Letcher	Conclusions A-3, A-4, A-5, A-6, A-7, B-1 and C
4	Elaine M. Faustman	Conclusions A1 and A2

Peer Review Request Package and responses are posted at https://www.waterboards.ca.gov/water_issues/programs/peer_review/date.shtml

[1] Conclusions addressed are described in Attachment 1 at the end of this document. Peer Reviewers were asked to address specific conclusions based on the reviewer's education and experience.

No.	Comment	Response	Revision[2]
1.1	In general, the primary documents were well-written, science based, supported by local, regional or state data, as well as substantiated by the supporting documents and appropriate peer-reviewed literature. Overall, the scientific portion of the proposed rule is based upon sound scientific knowledge, methods and practices. The only concern is with small sample size for Tier 1 evaluations as detailed in the specific comments.	Support for the overall scientific portion of the proposed Provisions is acknowledged. Comments related to sample size are addressed in responses to peer review comments 1.3, 1.7 and 1.9.	No.
1.2	Conclusion A5 – Site-specific and species-specific data are required to assess sediment linkage. This conclusion is fully supported by the science as detailed in the documents reviewed. Site specific and species-specific data are critical in the assessment of sediment linkage. Appendix 4, Sensitivity Analysis for Indirect Effects Assessment (Bay et al., 2017) provides evidence of the importance of obtaining site-specific data for sediment contaminant concentration and sediment total organic carbon. Having species-specific data are important to confirm that appropriate species are selected for the assessment and that they are based on a sediment related diet and appropriate home range. There is a sound scientific basis as detailed in Bay et al. (2017), e.g., Appendix 2 and 3.	Support for the site-specific and species-specific data to assess site linkage is acknowledged.	No
1.3	Conclusion A6 – The approach, methods and assumptions set forth in the optional Tier 1. Screening Evaluation are appropriate for screening low-risk sites or waterbodies. The Tier 1 approach, methods and assumptions are appropriate as a screening step in distinguishing low-risk sites. The conservative assumptions are generally appropriate for this initial assessment that would typically use available and potentially limited data. The use of C_{Tis95} data from the site to compare to the OEHHA ATL3 range maximum tissue threshold concentrations is appropriate and conservative. The sediment screening ~~threshold that is based o~~n the tissue screening threshold and BSAF for a change of sediment TOC is also appropriate.	This comment is more comprehensively addressed in peer review comment 1.7. Support for the proposed approach methods and assumptions that support Tier 1 is acknowledged.	No

[2] Revision pertains to a change made to the Proposed Appl Staff Report and/or the Proposed Final Sediment Quality Provisions. A revision will be marked "Yes" only in the first instance the revision is described in the responses to comments.

	and conservative. However, please see comment below for page 82 of the Draft Staff Report concerning the use of 'maximum concentration'. The use of less than 3 samples may not be appropriate or conservative depending on the size of the site, type of sample (composite or individual) and number of species tested. Clarification is recommended.		
1.4	Conclusion A7 – The approach, methods and assumptions set forth in Tiers 2 and 3 are appropriate for designating sites as either impacted or unimpacted. The more robust Tiers 2 and 3 are appropriate for designating sites as either impacted or unimpacted. The State of California has conducted significant research and a large volume of supporting information and data. The approach, methods and assumptions are clearly explained in the primary and supporting documents. I would consider this approach as setting a more concise, contemporary and scientifically supported benchmark for the assessment of sediments contaminated with organochlorine pesticides and PCBs.	Support for the proposed approaches, methods and assumptions that support Tiers 2 and 3 for organochlorine pesticides and PCBs. is acknowledged.	No
1.5	Conclusion B1 – The proposed approach to designate impaired sediment quality in relation to the SQO protecting benthic communities from direct exposure to contaminants in sediment is appropriate and scientifically sound. Use of severity of effects and spatial extent is appropriate when evaluating whether sediment dependent beneficial uses are supported in waterbodies. The existing use of multiple lines of evidence (MLOE) is appropriate and scientifically sound. This is further supported by the already developed indices for the benthic community, i.e., Benthic Response Index, Index of Biotic Integrity, Relative Benthic Index and River Invertebrate Prediction and Classification System. The use of the severity of effects, i.e., clearly impacted, to demonstrate exceedance of a receiving water limit at any station within a site is appropriate, as this reflects the highest severity of impacts based on the scientifically sound assessment approach. The use of 'possible impacted' and/or 'likely impacted' for total percent area greater than 15 percent for exceedance determinations is appropriate. While the chosen specific percent value for area is a policy decision, this level would generally be	Support for the proposed approach to incorporate spatial extent and magnitude for use in assessing impairments and in the implementation of receiving water limitations is acknowledged.	No

	protective. The requirement that the "calculation of percent area shall be based on data from spatially representative samples selected using a randomized study design or equivalent spatial analysis" provides a scientifically sound basis for this approach.		
1.6	Draft Staff Report Including Draft Substitute Environmental Documentation Amendments to the Water Quality Control Plan for Enclosed Bays and Estuaries – Part 1 Sediment Quality (Sediment Quality Provisions) Page 15, next to last sentence: Suggest removing the reference to methyl mercury, since it is distributed throughout the body and is not lipophilic. Page 74, 6.2.4, Alternative 3: Staff recommendation is alternative 3 and references Appendix A, C-6 (mislabeled (?) and assumed to be Draft Amendments Appendix A-6). However Alternative 3 recommends skin-on fillets, and Appendix A-6 lists skin-off fillets, which appears to support Alternative 4. This needs to be corrected and consistent in both primary review documents. Page 80: Reference to Fig 5.1 is a map and does not match the text description. Typo? Page 80 and 82, Tiered Assessment Framework: Page 80 states that "Tier 1 consists of a preliminary evaluation of either tissue data or sediment data…". Page 82 (6.4) states "or" and "or both" for Tier 1. Suggest making the sentences consistent or explaining the rationale more clearly.	These errors have been corrected in the Draft Staff Report.	Yes
1.7	Draft Staff Report Page 82, 6.4.1, use of maximum concentration: Less than three individual samples is not appropriate for a screening evaluation. One or two samples, even if using the maximum concentration, are not representative of conditions at a site and is not scientifically supported. This may be appropriate if the one or two samples were composites, i.e., multiple sites/fish combined in one sample and only for relatively small sites. If only one or two individual samples are available, recommend requiring a Tier 2 assessment. The other alternative is to allow this assessment with minimum data only if the data indicates	Draft Staff Report, Section 6.4.1 now identifies Alternative 2 as the preferred alternative. Accordingly, the use of a sample size of less than 3 and the related requirement to use the maximum concentration for sample sizes less than three has been removed from Chapter IV.A.2.c of the proposed provisions. These provisions now clarify that the minimum number of samples for either tissue or sediment is 3. Tier 1 does not require composite samples. A goal of Tier 1 is to support the use of readily available data in those waterbodies were the data has been collected.	Yes

	that a Tier 2 assessment is required, i.e., data that indicates no impact is not sufficient to characterize the site as unimpacted. While use of composite samples is mentioned elsewhere, it is not clear if that is the intent in this section of the document. In the Bay et al. (2017) supporting document (p. 44) state that OEHHA recommendations for screening surveys should be followed "…a minimum of three composite samples should be collected and analyzed for each target species…". Additional explanation/clarification should be added to both primary review documents.		
1.8	Draft Staff Report Page 83, 6.4.3: • References for BSAF are not listed on the References page or listed incorrectly in the text – Bay and Greenfield, 2015 and Greenfield et al, 2015. • The description of BSAF is adequate for the layman, but it does not follow the scientific definition for organic chemicals. BSAF is the ratio of the chemical concentration in the organism (normalized to the lipid fraction) to the chemical concentration in the sediment (normalized to the sediment organic carbon content) (Burkhard, 2009). It appears that the lipid and organic carbon content are accounted for in the Decision Support Tool and/or the bioaccumulation model in the calculation of the BSAF. If accurate, this should be noted in the document (e.g., footnote).	The references identified have been corrected and Greenfield et. al. 2015 has been added to the list of references. How the BSAF can be expressed and how it is expressed in the Draft Staff Report is now described in Section 6.4.3. The Gobas model (embedded in the Decision Support Tool) does take into account lipid and organic carbon.	Yes
1.9	Draft Staff Report Page 85, 6.4.4: Alternative 2 may not be adequately conservative in some instances, i.e., when tissue data shows no impact, but sediment sample size is small. See comment for section 6.4.1.	See response to peer review comment 1.7. Sample sizes less than 3 are no longer allowed in the Tier 1 assessment.	No
1.10	Draft Staff Report Page 91, Table 6.4: No footnote for "m" for lipid row. Does this indicate "modeled"?	"m' indicates measured value, and a footnote to explain this has been added to the table.	Yes
1.11	Draft Staff Report Page 133, last paragraph: The first two sentences are repeated in the next two sentences.	Repeated text referenced was deleted	Yes
1.12	Draft Staff Report Page 137, Mitigation: The fifth bullet in repeated further down on this page.	Repeated text referenced was deleted	Yes
1.13	Proposed Amendments Table of Contents: Appendix A-1 is not listed. Table 17 is listed twice.	These two errors were corrected in the Proposed Provisions Table of Contents	Yes
1.14	Page 4, III.A.1.d. Applicable Sediments: This states that	The intertidal zone limitation was necessary for the 2008 provisions	No

	the Sediment Quality Provisions apply to subtidal surficial sediments…seaward of the intertidal zone. Is the intertidal zone covered under another control plan? The sediments in intertidal zones can be a source of contamination to benthos and fish, e.g., during foraging at high tide.	because the benthic community metrics were derived from data sets that encompassed only subtidal communities. In order to maintain consistency and for simplicity of implementation, that limitation was retained for the human health SQO. If, however intertidal sediments represent a significant contaminant source into the waterbody and is entering the food web, it is unlikely that the adjacent subtidal sediments will be unaffected.	
1.15	Page 18, IV.A.2.b. In the last sentence under Tier 3, Chapter IV.A.2.b.7 is referenced. This section was not found in the document.	This error was identified in public comment letters and was corrected.	No
1.16	Page 20, IV.A.2.c.3. and Page 21, IV.A.2.c.4: same comment as Page 82, 6.4.1, use of maximum concentration, for the Draft Staff Report (see above).	See response to peer review comment 1.7 and the associated changes described.	No
1.17	Page 23, Table 17: It appears that the contaminant names in the second row on the table have shifted since “Chlor” is repeated twice under Benthic with piscivory, i.e., names are incorrect for that portion of the table.	The errors in Table 17 were identified in public comment letters and were corrected.	No
1.18	Page 54, Appendix A-5, consumption rates: Recommend that when identifying available information on local consumption rates that the effect of any fish consumption advisories in effect for the site on the consumption rate be considered. Fish advisories can reduce the consumption rate for some anglers, i.e., as compared to their consumption rate if there were no fish advisories for that waterbody, thus artificially reducing consumption rates for the assessment.	The text has been amended to include consideration for the influence of existing advisories on the consumption rate of those affected.	Yes
2.1	Comments on Conclusion A6: The approach, methods and assumptions set forth in the optional Tier 1 Screening Evaluation are appropriate for screening low risk sites or waterbodies. Overall, the approach, methods and assumptions proposed for Tier 1 seem appropriate in being standardized, require minimal data, are simple to apply, and are based on accepted human health thresholds for contaminant consumption.	Support for the approach, method and assumptions associated with Tier 1 is acknowledged.	No
2.2	It has been proposed that the 95th upper confidence limit of the mean sediment contaminant concentration be used when there are three or more sediment samples, and the maximum sediment concentration when there are fewer	The use of fewer than 3 samples in the Tier 1 assessment has been removed. See response to peer review comment 1.7 and associated changes.	No

	than three samples. To potentially base a Tier 1 assessment on only one or two sediment samples seems inadequate, particularly if the samples are below threshold, meaning that no further assessment would be required and potentially no further monitoring would be done for 5 years. If a Tier 1 assessment based on 1-2 sediment samples exceeds threshold and triggers a Tier 2 assessment, this is less problematic (though could still potentially result in a less efficient use of resources than a Tier 1 assessment based on a larger sample size). In my view there should be some minimum amount of information required at Tier 1 in order for a "no further assessment needed" decision to be made. For example, it should not be possible to conclude that a site is not degraded based on a Tier 1 assessment of one or two sediment samples alone (i.e., without corresponding fish tissue samples). If there are fish samples as well, and these support the conclusion based on the one or two sediment samples, this is probably sufficiently conservative for a Tier 1 assessment. Since a study design and workplan, based on a Conceptual Site Model (CSM), must be developed before sampling commences, the minimum number and spatial distribution of sediment samples would presumably be defined in this step. It would seem unlikely that a reasonable CSM would result in a study design that included only one or two sediment samples, so possibly this concern is unwarranted.		
2.3	However, whereas Tier 2 requires a minimum of 5 sediment samples per site in addition to a minimum of 3 tissue samples from at least two sportfish species, it would seem reasonable to set some minimum number of samples for Tier 1 as well. Potentially sites that are known to be unimpacted on the basis of previous monitoring studies and/or are located far from sources of contamination would warrant less sampling than other sites. The addition of guidance to this effect could potentially increase the efficiency of Tier 1 assessments further.	The use of fewer than 3 samples in the Tier 1 assessment has been removed. See response to peer review comment 1.7 and associated changes.	No
2.4	For fish tissue, the mean of the 95% upper confidence limit of the mean tissue concentration for each species is used.	See responses to peer review comments 2.3 and 1.7.	No

	If there are fewer than three samples for a given species the maximum concentration for that species should be used. Whether this is sufficiently protective will depend on whether/how many fish species are used in the Tier 1 assessment. This is not entirely clear from the document.		
2.5	The Tier 1 screening thresholds are based on Office of Environmental Health Hazard Assessment Advisory Tissue Levels based on three or five (for subsistence fishers) servings of 3 fish per week. The 95% UCL of the mean tissue concentration for sportfish is compared to the screening thresholds directly. For sediments, the 95% UCL of the mean site sediment concentration is compared to a sediment threshold calculated as the tissue threshold divided by the highest biota-sediment accumulation factor (BSAF) for the dietary guilds identified in the Conceptual Site Model. This seems a reasonable and conservative approach.	Support for the Tier 1 screening thresholds and the use of the 95% UCL of the mean is acknowledged.	No
2.6	The Tier 1 data requirements state that sediment and tissue data shall be no more than 6 years old at the time of the assessment and collected within site boundaries. This seems an arbitrary age that is given without any justification or reference to the published literature as far as I could tell. Also, this requirement says nothing about how the sediment or tissue samples should be stored prior to analysis although the document is rather explicit as to other aspects of sediment sampling such as method of collection, depth of sampling, etc.	The basis for the six years was a desire to accommodate data collected from regional monitoring programs, which vary in frequency. The largest effort, the Southern California Bight Regional Monitoring survey which encompasses the bays and estuaries as well as coastal waters from Point Conception to the Mexico Border, is conducted every five years. This requirement assumes that the data are available, and that the samples were collected and analyzed previously within conventional holding time limits (e.g., 6 months to 1 year).	No
2.7	Comments on Conclusion A7: The approach, methods and assumptions set forth in Tiers 2 and 3 are appropriate for designating sites as either impacted or unimpacted. The required Tier 2 site-specific information, including the minimum number and type of sediment and fish tissue samples, is clearly spelled out in Table 18 of the amendment. Assuming that there are multiple sediment samples taken at each site (as indicated in Table 18; a minimum of 5), it is not clear how these data enter into the subsequent calculations to estimate ΣC_{sed}, BSAF, and the sediment linkage factor. It sounds as if the first two might be based on a single estimate of sediment concentration, whereas the latter attempts to incorporate the variability in	Chapters IV.A.2.d.4) and 6) of the proposed Provisions have been amended to clarify calculations of ΣC_{sed} ,the BSAF, as well as the site linkage distribution.	Yes

	sediment concentration measurements at a site. This needs further clarification.		
2.8	Interpretation of Table 21 is somewhat difficult to follow, and an example in the text would help to add clarity. For example (and assuming I understand this correctly), if the estimated fish tissue concentration is less than half of the observed fish tissue concentration (i.e., linkage threshold < 0.5) for 75% or more of the samples, then the site sediment linkage (outcome in Table 21) is categorized as "very low". Possibly, addition of Figure 7 from Greenfield et al. (2015) would add clarity. A combination of the chemical exposure evaluation (Table 20) and the site sediment linkage evaluation (Table 21) is used to determine the overall site assessment over a range from "unimpacted" to "clearly impacted" (Table 22). Use of these multiple categories is much better than a simple binary impacted vs. unimpacted categorization.	Table 21 was modified in response to public comments and now presents ranges corresponding to each category. See table and figure provided in response to public comment 11.23.	No
2.9	A Tier 3 assessment may be triggered when there are unique conditions associated with a site, to incorporate spatiotemporal factors into the assessment, to test Tier 2 assumptions, or to increase the accuracy or precision of a Tier 2 assessment. The intent is to allow for greater flexibility by allowing some of the parameters held constant at Tier 2 to be modified while keeping the overall decision framework indicators and decision criteria the same (important for ensuring consistency and transparency). Approval from the Regional Board is required in order for a Tier 3 assessment to be conducted and any changes in parameters compared to Tier 2 must also be approved. The strategy to only require added Tier 3 refinements when the specific site situation requires them, and that any such refinements need prior approval, is clearly in line with goals 3, 4, and 5 above.	Support for the proposed approach is acknowledged. Note that collecting data necessary to complete Tier 3 no longer requires prior approval by the applicable Regional Water Board.	No
2.10	General Comments on Proposed Amendments. The proposed amendments associated with the SQO for human health are based on well-developed and published methods and employ a tiered approach. The models and methods have been thoroughly evaluated in the peer-reviewed literature and demonstrated to be scientifically sound. The tiered approach is cost effective and designed	Support for the proposed approaches is acknowledged.	No

	to minimize unnecessary testing, monitoring, and assessment. Likewise, the weight of evidence approach to determine impacts on benthic communities that combines toxicity, benthic community condition, and sediment chemistry is a reasonable and pragmatic approach that has a long history of use. Thus, the proposed amendments fulfill the five goals outlined above.		
2.11	In general, the proposed amendments do an excellent job of minimizing reliance on best professional judgement compared to current practice (Attachment 6 – Draft Staff Report). This is an important improvement that will enhance consistency and transparency of the assessment process.	Support for the proposed approach in comparison to the existing approach is acknowledged.	No
2.12	The most important limitation of the approach is that it is restricted to a few legacy chemicals, and other groups of chemicals will continue to be assessed using current methods. As the revised approach begins to be implemented, it could be worthwhile to estimate the actual benefits (time, effort, money saved) of the revised approach as well as any improvements to beneficial uses of California's enclosed bays and estuaries compared to historical practices.	On the recommendation of the Scientific Steering Committee (Section 2.8 of the Draft Staff Report) the assessment framework was limited to legacy organochlorine compounds because the fate, transport, and trophic transfer were better understood for this group of contaminants than other contaminants that bioaccumulate into tissue. In addition, PCBs and DDTs are frequent causes of sediment and tissue related impairments within bays and estuaries throughout the state. Further, these contaminants are routinely measured in fish tissue and sediment in regional monitoring programs and permits such that significant data is available for those intending to apply the framework. The overall framework and indicators used is believed to be transferable to additional contaminants (including contaminants of emerging concern) that bioaccumulate from sediment into tissue in the future, provided required chemical exposure thresholds and model parameters are available.	No.
2.13	Clearly the Conceptual Site Model development (Appendix A-5) is a key part of the overall process. Based on the description, it would seem that this could possibly be the most time consuming step in a site assessment. Presumably, the largest effort would be required the first time that a site was being considered for assessment, and future assessments would only require minor revisions to existing CSMs. Since my understanding is that a goal of the amendments is to promote the efficient use of resources, it might be worth adding some text to this effect	In response to public comments, the CSM requirements have been simplified for Tier 1 (Appendix A-5). An appendix specific to CSM development for aquatic life SQO assessment was not included because such assessments are already widely conducted and the study design considerations are familiar to many permittees through existing permit requirements and through participation in ongoing regional monitoring programs.	No

	to Appendix A-5. Why is there no corresponding Appendix to address the aquatic life SQO? Overall, the proposed amendments document (Attachment 6) is rather difficult to follow with multiple cross-listings to various appendices. This is not facilitated by the rather complicated structure of the document, e.g., Chap IV.A.4.d.5. A more logical and hierarchical structure could be: Chap 1; section 1.1; subsection 1.1.1, etc.		
2.14	Additional Specific Comments: The proposed amendment document contains a mix of Roman and Arabic numerals to describe the Tiers (e.g., 2 or II). This should be cleaned up for consistency.	Format of numerals has been standardized for consistency. Replaced Roman with Arabic numerals in the proposed Provisions as well as the Draft Staff Report.	Yes
2.15	It is unclear how the weighting factors were derived for the CSI in Table 6. This should be explained.	Development of the CSI is described in the record for the 2008 proceedings. For description of how the CSI was developed see the 2008 SCCWRP Annual Report available here: http://ftp.sccwrp.org/pub/download/DOCUMENTS/AnnualReports/2008AnnualReport/AR08_091_105.pdf	No
2.16	For ease of reference, a table should be provided with the OEHHA Advisory Tissue Levels based on 5 day consumption rates for subsistence fishers along with Table 16.	Because the applicable Regional Water Board must first designate such beneficial uses, the table may not be applicable across all enclosed bays and estuaries and, to avoid confusion, is not included.	No
3.1	A-3. The relative influence of site sediment contamination on fish contamination is an appropriate indicator of the contribution of site sediment contamination. In order to address the second question, the assessment framework requires an evaluation of site linkage; the proportion of measured tissue contaminant concentration estimated to result from site sediment contamination, calculated as a ratio of the estimated tissue concentration and the measured tissue concentration. R. Letcher review: The assessment framework for this SQO relies on the chemical exposure indicator for measures of sport fish contamination from the site and in comparison to consumption advisory thresholds. The SQO also relies on the site linkage indicator, which compares sport fish contamination measurements to estimated sport fish	Support for the chemical exposure and site linkage indicators is acknowledged.	No

	concentrations that would result from site exposure. The relative influence of site sediment contamination on fish contamination is an appropriate indicator of the contribution of site sediment contamination. The site linkage is sound based on the proportion of measured tissue contaminant concentration as a good estimate from site sediment contamination, which is calculated as a ratio of the estimated tissue concentration and the measured tissue concentration. The reasons for this agreement by the reviewer are described, and in the context of the tiered assessment framework in the subsequent conclusions. However, some additional factors to consider and recommendations are also detailed.		
3.2	With respect to the chemical exposure indicators, and in the context of the actual chemical contaminants to which the assessment framework applies, the target chemicals represent but of fraction of the known and unknown substances (Appendix A-7). Since the framework is specific to non-polar (or more lipophilic) chlorinated hydrocarbons (e.g. DDTs, PCBs, chlordanes and Dieldrin), these chemicals do not necessarily reflect the complexity of sediment contamination, which may be contributing to the contaminant burden in exposed fish. Numerous emerging and new chemicals have been reported in marine and freshwater sediment and in biota (including fish) in respective sites and ecosystems. Many of these new contaminants are more polar in nature and in many cases are short abiotic and biotic half-lives due to their instability to e.g. photolytic, microbial and metabolic degradation processes. Furthermore, many new chemicals are less lipophilic and thus bioaccumulation factors from sediment will be much lower than e.g. PCBs and also are likely to be cleared and depurated more rapidly. Such new chemical contaminants include emerging flame retardants (Chen et al. 2015), and pharmaceutical and personal care products (PPCPs). PPCPs currently number in the thousands of different compounds (e.g., antibiotics, blood lipid regulators, analgesics/anti-inflammatory agents, antidepressants, antiepiletics, and antineoplastics), and they comprise a wide range of different chemical	Comment acknowledged. See response to peer review comment 2.12.	No

	structures (Hua et al. 2006). PPCPs are viewed as emerging or newly established environmental contaminants and have experienced decades of unrestricted discharge to the environment. Point sources, such as wastewater and sewage treatment plants as well as surface runoff, are the main sources of PPCPs to the aquatic environment have been reported in WSTP effluent, surface waters and groundwaters. Organophosphate esters (OPEs) are current-use and high production volume chemicals, and are a good example of contaminants that have been shown recently to be unstable in aquatic media (e.g. Su et al. 2016) and via rapid metabolism in wildlife and fish (Greaves and Letcher 2017; Greaves et al. 2016a, 2016b).		
3.3	It is true that organisms can be exposed to and affected by sediment contaminants by multiple pathways that are both direct and indirect. Contamination in organisms can occur via direct contact with the sediment and sediment ingestion. Organisms living in the sediment are also exposed through the uptake of contaminants from pore water and via ingestion of sediments and subsequent accumulation by desorption during digestive processes in the gut, and via the consumption of contaminated prey. It is correct that the direct affect of the benthic community present at a site may be altered by a variety of environmental factors in addition to adverse effects from contaminants. Therefore, it is necessary to understand how these environmental factors affect benthic communities before the effects of contaminants can be discerned. The tools used to determine benthic community condition (benthic indices) should be calibrated to specific habitat types in order to provide an accurate assessment of biological condition of a site-specific community.	Comment acknowledged.	No
3.4	Described in the Draft Amendments Section, Chapter IV (A. 2. b3) are the field procedures for the assessment framework for the SQO components of chemical exposure indicators and site linkage indicators. The field procedures for sediment and fish collections are comprehensive and well designed. Grab sampling of surface sediment from the upper 5 cm for chemistry analyses is logical as the upper	Support for the field and sampling procedures is acknowledged.	No

	5-10 cm best reflects the benthic community exposure and the real-time variations in the sediment contamination as this top layer is subject to continuous changes to the physical and ecological aspects and the aquatic system and site. Such surface sediment sampling is routine for ongoing contaminant monitoring in Great Lakes jurisdictions by e.g. the US EPA and Environment and Climate Change Canada. A good example of Canada-U.S. cooperation in this regard is the study of flame retardant and other chemicals in sediment from several important sites in the Great Lakes (Letcher et al. 2015; Lu et al. 2015; Trouborst et al. 2015).		
3.5	The eight dietary guilds and the nine primary guild fish species identified in Appendix A-6 for sampling, is a comprehensive design to provide a good coverage of the sport fish species and the dietary exposure pathways from sediment, which are inherent to the bays and estuaries of California. It is also wise to have an alternate list of relevant and harvestable secondary species in the event that a primary species cannot be collected from the given site. Unless there are compelling reasons to do so, such alternate species inclusions should be keep to a minimum so that there is maximum similarities on the suite of species tested for optimal comparisons between affected sites.	Support for the dietary guilds, primary and secondary (alternative) species is acknowledged.	No
3.6	As for the sediment and tissue chemical analysis to be included as per Appendix A-7, see this reviewer`s earlier concern regarding the breadth of chemicals of aquatic concern, which should include priority substances that are not necessarily nonpolar and lipophilic with respect to bioaccumulation. The attention to sampling design details is supported by this reviewer. That is, before commencing with sample collection, a study design and work plan must be developed and approved by the Regional Board, but with a conceptual site model serving as the basis for the study design, define the site boundaries, guide selection of sport fish species to evaluate, and identify appropriate sediment contamination data.	Support for the need to develop a study design and work plan is acknowledged. Concerns regarding other pollutants is addressed in response to peer review comment 3.2	No
3.7	Finally, it is stated that all (fish and sediment) samples are tested in accordance with USEPA or American Society for	As stated in response to peer review comment 2.12, this framework was intentionally limited to organochlorine pesticides	No

	Testing and Materials (ASTM) methodologies where such methods exist. As listed in Table 15 in the Draft Amendments Section, Chapter IV (A. 2. b4), such testing is specific only for selected organochlorine pesticides (DDTs, chlordanes and Dieldrin) and a suite of PCB congeners (Appendix A-7). As mentioned previously, there are no details for the testing inclusion for newer and current-use chemicals (e.g. flame retardants and PPCPs) that are produced in high volume and found to be globally ubiquitous in aquatic environments, and particularly ones that receive heavy inputs from densely populated centers such as for bays and estuaries of California. It appears that some allowance for other priority contaminants is insinuated in the statement that where no EPA or ASTM methods exist, the Water Boards shall approve the use of other methods. It is strongly encouraged by this reviewer that this statement be expanded to include details that allow for the sediment and fish testing of newer chemicals that have been established as (aquatic) environmental pollutants. Further, to indicate some testing flexibility in this regard where new contaminant issues specific to certain bays and estuaries of California are warranted and represent a proven or potential exposure issue for benthic sediment communities and the primary and secondary gild fish species that exist in these affected sites. For sediment exposed aquatic organisms, the approach is sound that laboratory toxicity tests be used to assess the direct effects of, as well as the bioavailability of, sediment contaminants are based on lethal or sublethal responses of test species exposed to the sediment under controlled conditions.	and PCBs for the reasons described in that response. The overall framework that integrates chemical exposure with site linkage could be applied to any pollutant that bioaccumulates from sediment into tissue. The site linkage calculation would need to account for each contaminant's fate and transport, bioavailability and other characteristics. If resources are made available, such studies necessary to expand the list of contaminants can be initiated. The SQO framework is not intended as an early warning system for CECs in tissue. Existing regional monitoring programs as well as individual permittees evaluate a variety of tissue types for CECs in coordination with the Water Board's Surface Water Ambient Monitoring Program Bioaccumulation Oversight Group and also through supplemental environmental projects.	
3.8	A-4. Bioaccumulation modeling is an appropriate method to evaluate site sediment linkage. Estimated tissue concentrations are obtained using the steady state Gobas Food Web Model, calibrated for eight different feeding guilds. These feeding guilds encompass a variety of fish and their associated dietary preferences within California enclosed bays and estuaries. R. Letcher review:	Comment acknowledged. The proposed provisions utilize site sediment chemistry to assess only the contribution from the site and not the contribution from offsite sources.	No

	The eight dietary or feeding guilds and the nine primary guild fish species are identified in Appendix A-6. There is also an alternate list of relevant and harvestable secondary species in the event that a primary species cannot be collected from the given site. The assessment framework estimates fish tissue concentrations of the prioritized contaminants (Appendix A-7) using the steady state Gobas Food Web Model. It is true that chemical indicator-site linkage is typically evaluated by calculation of an empirical biota-sediment accumulation factor (BSAF; Gobas and Arnot 2010), using available field data as well as calculation methods. Although useful for risk assessment screening and planning purposes, BSAFs are indeed influenced by factors not directly related to sediment contamination at the site of interest, such as atmospheric inputs, currents, watershed runoff, and fish migration from other sites. The influence of various unknown site-specific and biological factors can be substantial. As a consequence it is true that BSAFs have been shown to vary by an order of magnitude or more between sites for similar chemicals and species. It is agreed that the determination of site linkage for the purposes of SQO assessment represents a special situation that may not be effectively represented by the BSAF. Since the SQO is intended to protect sediment quality at the site, it is important to distinguish the influence of site sediment contamination on the seafood from that due to other sources (e.g., off site contamination).		
3.9	As described in the Draft Amendments Section, Chapter IV (A. 2. d4) for determination of the site linkage, using an alternate approach rather than using BSAF values alone (Gobas and Arnot, 2010), is sound as it considers the possible influence of various unknown site-specific and biological factors for a given contaminant. That is, comparing tissue concentrations estimated from site sediments to the observed sport fish tissue contaminant concentration for a given fish species used in the chemical exposure evaluation. The use of the Monte Carlo simulation is appropriate and sound to generate a cumulative distribution of the site linkage factor. This	Support for the site linkage factor and how that relationship is established is acknowledged.	No

	reviewer is in agreement with seafood bioaccumulation from site sediment contamination should be model-based and relative to bioaccumulation derived from all field data sources that are available and applicable.		
3.10	As for quantification of site-related accumulation of contaminants, it is true that the food web bioaccumulation model for PCBs (or Gobas food web model) has been validated for several fish species relevant to assessing human health impacts (Gobas and Arnot 2010). Furthermore, this model has been shown to be effective in estimating PCB bioaccumulation from sediment in fish and wildlife. While it is true that the structure of this model is adaptable for other fish species, this reviewer notes a few caveats that should be considered in this assumption that the model can be applied to other chemical contaminants. This model is proven for contaminants such as PCBs that are among the more recalcitrant and bioaccumulative environmental contaminants in biota including in fish. However, for many emerging chemicals of concern there remains a dearth of available information on physico-chemical properties, environmental persistence, bioaccumulation, fate and other behaviors, as well as compound-specific information on uptake, deposition and depuration processes in exposed biota and including for fish. Many of these `new` contaminants are biotically and abiotically unstable including enzyme-mediated metabolism and other species-specific depuration pathway in exposed organisms. A prime example are organophosphate ester (OPE) flame retardants and plasticizers, which have been shown to be rapidly metabolized in a limited number of studies that are field and lab (in vivo and in vitro) based for exposed mammal, bird and fish species from both marine and freshwater aquatic environments (Fernie et al. 2015; Greaves et al. 2016a, 2016b; Greaves and Letcher, 2017). This is also true of many of the new flame retardant chemicals that have been mostly regulated (e.g. polybrominated diphenyl ethers and exabromocyclododecane) but more so for the (brominated) chemicals that are replacement and in current-use and	See response to peer review comment 3.7. Caution employing the Gobas food web model for less recalcitrant compounds in potential future application is acknowledged.	No

	that have been identified as contaminants in aquatic environments and ecosystems (e.g, Chen et al. 2015; Giraudo et al. 2017; Su et al.2017). An important point to mention is that if food web bioaccumulation models that do not adequately account for (e.g. fish) metabolism for a given chemical contaminant, than the (Gobas) food web model may be underestimating the sediment-based exposure and accumulation in fish, and thus an accurate categorization of the chemical exposure-site linkage.		
3.11	A-5. Site specific and species-specific data are required to assess sediment linkage. Measured site sediment concentrations, dissolved water concentrations, sediment total organic carbon, fish forage area, and site area represent key bioaccumulation model inputs. R. Letcher review: I fully concur that measured site sediment concentrations, dissolved water concentrations, sediment total organic carbon, fish forage area, and site area represent key bioaccumulation model inputs. Exposure of fish to sediment contamination within the assessment site has a major influence on the strength of the linkage between site sediment contamination and bioaccumulation. Other important factors are home range (in conjunction with the size of the area selected for assessment), and fish movements, foraging area and habitat quality. Also, variability in sediment chemical concentration is influenced by heterogeneity, gradients, hotspots and the physio-chemical properties of the contaminant in question such as the variability of bioaccumulation factors for nonpolar organics in aquatic organisms. It is good practice that using an expansion of the site area of the assessment provides greater confidence that the home range of a given fish species is included to reduce the sensitivity of the assessment to detect a significant site linkage.	Support for the site-specific and species-specific measurements proposed, and minimum site area is acknowledged.	No
3.12	As described in the Draft Amendments Section, Appendix A and Chapter IV (A. 2. d4) for site specific and species-specific data to assess sediment linkage, the recommendation of using alternate 2 is an appropriate choice. That is, adjust the site linkage calculation for offsite	Support for the site-specific and species-specific data to assess site linkage is acknowledged.	No

	foraging through use of a site use factor and consider fish movement and sediment contamination heterogeneity in selection of site boundaries (as per Table 6.5).		
3.13	A-6. The approach, methods and assumptions set forth in the optional Tier 1 Screening Evaluation are appropriate for screening low risk sites or waterbodies. The assessment framework consists of three tiers to address varying site conditions and situations from the simple (Tier 1) to complex (Tier 3). The optional Tier 1 is a conservative screening evaluation intended to distinguish low risk sites that clearly meet the SQO from those sites that require the full analysis of Tier 2 to make a confident assessment. Tier 1 uses either sediment or tissue data to directly compare tissue concentrations to OEHHA tissue thresholds. A table of model generated biota-sediment accumulation factors is used to convert sediment concentrations to expected tissue concentrations for comparison with tissue thresholds. The two possible outcomes from Tier 1 are Pass (sediment is unimpacted and meets the SQO) or conduct Tier 2 assessment. R. Letcher review: As described in the Draft Amendments Section, Chapter IV (A. 2. b and c), Tier I screening assessment allows for the rapid site assessment and uses conservative assumptions with low data requirements for assessments of low risk sites and waterbodies. The Tier 1 Screening Evaluation uses standardized conservative methods to evaluate the potential chemical exposure to human consumers of sport fish. The purpose of this tier is to determine whether site sediments pose a sufficient risk to warrant a complete (i.e., Tier 2) site assessment.	Comment acknowledged.	No
3.14	An upper confidence limit (UCL) of 95% of the arithmetic mean is generally used as a conservative assumption in risk assessment. It was initially suggested that for a Tier 1 assessment that the 95% URL be used for contaminant concentrations from sediment or tissue data. A drawback is that such an assessment uses available data and for cases where a small sample size is used to calculate the contaminant concentration. As recommended in the Staff	The use of the maximum concentration has been removed. See response to peer review comments 1.7, 2.3, and 2.4.	No

	Draft Report (pg. 83), the alternative 3 approach is recommended where the 95% UCL of the mean is used to estimate a contaminant concentration, but in cases where the sample size is less than three use the maximum concentration. This reviewer agrees that because of the increasing uncertainty associated with smaller sample sizes, it would be more logical to use the more conservative maximum concentration in place of the 95% UCL for a given chemical. However, this reviewer recommends caution in the use of maximum concentration for assessment at the Tier 1 level for data from very small sample sizes. For sample sized below 10, it becomes increasingly likely that a maximum concentration for a given sample may not be representative of the sample set and could possibly be an outlier. There would be greater confidence in the maximum concentration approach is for e.g. 3 samples there was a clear consensus in the values where perhaps a 20% variation exists among the three measurements.		
3.15	Tier 1 sediment evaluation is based on chemical exposure and is performed by comparing the measured contaminant concentration in sediment to the sediment thresholds (listed in Table 16 of the Draft Amendments Section, Chapter IV). The sediment threshold is calculated by dividing the tissue threshold by the BSAF. In general, this reviewer agrees the recommendation of alternate 2 (Draft Staff Report, pg. 83) to calculate standardized Tier 1 BSAF results for each contaminant in each dietary guild, at incremental organic carbon intervals to be used in determining sediment thresholds. It was previously commented in conclusion A-4 that it is true that the structure of the Gobas food web model is based on PCBs and may be adaptable for multiple fish species and to DDTs and chlordanes. A note that the sediment contaminant complexity goes well beyond PCB a few legacy pesticides (Appendix A-7). There are many new and emerging aquatic contaminants and ones of priority to a given site should (eventually) be considered. For a given emerging contaminant, caution and the testing and further validation of the Gobas food web model is recommended,	See response to peer review comments 3.7 and 3.10. The use of the Gobas food web model is limited to those compounds for which it has been validated and there is currently no effort underway to expand the use of the model to other contaminants.	No

	and the model is not likely to be well suited for chemicals of concern that are more polar, lipophilic and environmentally unstable.		
3.16	Any Tier 1 interpretation in considering fish tissue or sediment concentrations in samples are made relative to threshold levels (Draft Amendments, Table 16). As per Table 6.2 (pg. 84) in the Draft Staff Report, for all eight sediment and tissue evaluation scenarios it is only when above scenario six (sediment impacted, tissue potentially impacted) that Outcome Approaches 1 and 2 differ. This reviewer agrees with alternative 2 for scenario seven (sediment potentially impacted, tissue not impacted) that an assessment should not advance to Tier 2. This makes sense because the contaminant exposure from the sediment may exceed the threshold but the concentration in the fish tissue is not high enough to warrant Tier 2 concern. This may be due to some pathway specific inefficiency in the uptake of the contaminant in the fish, or possibly a relatively efficient rate of clearance results in lower tissue concentrations in the fish.	Support for the interpretation of Tier 1 results is acknowledged.	No
3.17	A-7. The approach, methods and assumptions set forth in Tiers 2 and 3 are appropriate for designating sites as either impacted or unimpacted. Tiers 2 and 3 require analysis of both sediment and tissue chemistry data to assess whether site sediments meet or exceed the narrative objective; these tiers differ in the level of standardization and incorporation of site-specific parameters or conditions. A logic matrix is used for Tiers 2 and 3 in order to integrate the outcomes of the two indicators into site categories of Unimpacted, Likely Unimpacted, Possibly Impacted, Likely Impacted and Clearly Impacted. Sediments designated as Unimpacted and Likely Unimpacted meet the SQO, while sediment categorized Possibly Impacted, Likely Impacted and Clearly Impacted do not meet the SQO. R. Letcher review: As described in the Draft Amendments Section, Chapter IV (A. 2. d and e), Tier 2 screening assessment is the main approach proposed for evaluating sediment quality in	Support is acknowledged for using the proportion of seafood bioaccumulation determined from modeled site sediment contamination relative to field-measured bioaccumulation derived from all sources.	No

	relation to the human health narrative SQO. Tier 2 consists of an evaluation of both tissue data and sediment data to determine potential hazard to human health, using available site-specific information. For SQO assessment, a method is needed to determine the relative influence of site sediment contamination on tissue burden, in comparison to other sources not associated with the site. Bioaccumulation models can theoretically be used to estimate the relative influence of site vs. offsite exposure sources on tissue burden (e.g., by comparing estimated tissue concentrations for each type of source), but modelling of offsite sources can be very complex and the needed data are rarely available. As noted in the Draft Staff Report, this reviewer agrees with alternative 4 where the proportion of seafood bioaccumulation determined from site sediment contamination (model-based) is relative to bioaccumulation derived from all filed data sources.		
3.18	The Tier 2 evaluation utilizes a combination of site specific variables presented in Table 18 (Draft Amendments Report) and fixed model input parameters. In addition to tissue and sediment contaminant concentrations, the Tier 2 evaluation depends on four other variable plus three optional variables, which define the specific site. Tissue samples are from the nine primary fish species for each dietary guild shall (Appendix A-6), which are California halibut, Spotted sand bass, White catfish, Queenfish, White croaker, Shiner perch, Common carp, Topsmelt and Striped mullet. The fish tissue threshold concentrations in Table 19 are the basis of the Chemical Exposure Evaluation, and based on human consumption serving of one, two and three 8-ounce servings over the course of a week. Tissue categories and outcomes are presented in Table 20. Tier 2 also employs the Gobas food web model to calculate the BSAF for each of the fish guild species. These approaches and methods are reasonable and sound but as previously mentioned, the Gobas food web model as applied to PCBs does not account for metabolic processes and assumes that PCBs in the model are driven by uptake only. This means that there is some limitations	See response to peer review comment 3.10.	

	to the BSAF for PCBs as well as for DDTs, chlordanes and Dieldrin, and some BSAF over-estimation is possible. Also, many of `new` contaminants are biotically and abiotically unstable including enzyme-mediated metabolism and other species-specific depuration pathway in exposed organisms.		
3.19	A Monte Carlo simulation is conducted using many random subsamples of the contaminant concentration and BSAF distributions on a log normal basis. Since there are various unknown site-specific and biological factors for a given contaminant, the use of the Monte Carlo simulation is appropriate and sound to calculated cumulative distribution of the site linkage factor. This reviewer is in agreement with seafood bioaccumulation from site sediment contamination should be model-based and relative to bioaccumulation derived from all field data sources that are available and applicable. The sediment linkage thresholds (Table 19) for PCBs, Dieldrin and chlordanes is used to determine the site linkage category (Table 21 in the Draft Amendments Report). The overall site assessment category is determined using the decision matrix presented in Table 22 (or Table 6.7 in the Draft Staff Report). As noted in the Draft Staff Report, this reviewer agrees with alternative 3 where a logic matrix is used to provide a standardized interpretation of each indicator combination relating to multiple categories of impact.	Support for the use of Monte Carlo simulation, the bioaccumulation model to evaluate linkage as well as the use corresponding logic matrix to standardize interpretation is acknowledged.	No
3.20	Tier 3 assessment is intended to provide flexibility in the assessment approach to address special circumstances or complex situations where the standardized Tier 2 assessment is not able to provide an accurate result. As a Tier 3 assessment uses nonstandard methods for determining chemical exposure and/or site linkage, such an assessment may require substantially more time and cost to implement. Also, the results may not be comparable with assessments based on the Tier 2 approach, resulting in difficulty in comparing conditions among sites and prioritizing the need for management actions. This reviewer agrees with the stated criteria to proceed	Support for the intent and basis for conducting Tier 3 and criteria is acknowledged.	No

	with Tier 3 assessment (pg. 30, Draft Amendments Report) where a site must meet one of several conditions that are based on the variation in factors or processes are present that affect contaminant bioaccumulation from sediment, and resulting in a difference in Sediment Linkage category. An important factor is when there are differences in physiological processes affecting bioaccumulation model performance, such as growth rate or assimilation efficiency. Another important factor is when the measured sediment concentrations are not representative of actual fish forage area due to spatial or temporal variations in sediment contaminant distribution, fate, or transport.		
3.21	B-1. Use of severity of effects and spatial extent is appropriate when evaluating whether sediment dependent beneficial uses are supported in waterbodies. The State Water Board is proposing a new approach that considers severity (any station classified as clearly impacted) and percent area of impact (stations classified as likely or possibly impacted, not to exceed 15 percent). The State Water Board currently relies on a frequency of exceedance approach based on the binomial statistic that was originally intended for water column applications. R. Letcher review: The implementation of the SQOs is to be conducted in accordance with several provisions. Each addresses a different receptor and/or exposure pathway, and sediments that meet one objective may not meet the other objective. It is logical that compliance with aquatic life objective is determined based on the individual assessment of two or more stations within a site. It also makes sense that compliance with the sport fish objective is based on an overall assessment of a site that encompasses multiple sediment and tissue samples from the site. Therefore, assessment of sediment quality relative to each objective may require a unique study design	Support for unique approach based on receptor and exposure pathway is acknowledged. Each objective requires a unique study design and assessment as described in the proposed and existing provisions included in Chapter IV.	No
3.22	Detailed on pages 32 and 33 of the Draft Amendment Report are the exceedances of a receiving water limit to	Support for the use of spatially representative samples and randomized design is acknowledged.	No

	protect aquatic life. The total percent area categorized as Possibly Impacted and/or Likely Impacted equals or exceeds 15 percent of the site area over the duration of a permit cycle. It is reasonable that the calculation of percent area be based on data from spatially representative samples selected using a randomized study design or equivalent spatial analysis.		
3.23	As detailed in the Draft Staff Report on pages 104-106, the existing approach adopted to apply the SQO protecting benthic communities from pollutants in sediment relies on the binomial statistic to assess whether sediment quality is impaired and whether an exceedance of the receiving water limit has occurred. It is agreed that there is one important difference between the two applications. That is, implementation of the receiving water limitation requires that the degradation must be linked with the discharge. It is agreed that in a case where two stations are categorized as Possibly, Likely or Clearly Impacted within a single waterbody or segment that has two to twenty-four sediment quality stations monitored, a listing would be required. This reviewer agrees that for delisting a waterbody or segment, the minimum number stations required is twenty-eight stations with a maximum of two stations categorized as Possibly, Likely or Clearly Impacted. As recommended in the Staff Draft Report (pg. 106), this reviewer agrees with the alternative 2 approach recommendation to develop an approach based on size of area impacted and severity of impact.	Support for the use of area and severity of impact as a replacement for the frequency based approach is acknowledged.	No
3.24	C. Additional Issues related to the big picture Questions: 1) In reading the Draft Staff Report and proposed rule, are there any additional scientific findings, assumptions, or conclusions that are part of the scientific basis of the proposed rule not described above? R. Letcher response: In the context of the SQOs, and as detailed earlier, sediment and fish associated contaminants are complex and not simply restricted to lipophilic and nonpolar compounds such as PCBs, chlordanes, DDTs and Dieldrin. These all constitute historical or legacy	If resources are made available, the assessment framework could be expanded to address other contaminants. See response to peer review comment 2.12	No

	contaminants, and do not reflect the complexity of pollutants in aquatic environment where there are many emerging contaminants and where many are currently is use. Many of these new chemicals are less lipophilic and although could accumulated in fish, metabolic and other depuration processes can result in more rapid clearance and different toxicities due to such degradation products. New chemical contaminants include emerging flame retardants, and PPCPs. PPCPs currently number in the thousands of different compounds (e.g., antibiotics, blood lipid regulators, analgesics/anti-inflammatory agents, antidepressants, antiepiletics, and antineoplastics), and they comprise a wide range of different chemical structures (Hua et al. 2006). Another important classes of aquatic contaminants from WSTP discharges and run-off are antimicrobials such as triclosan (Hua et a. 2005). PPCPs are viewed as emerging or newly established environmental contaminants and have experienced decades of unrestricted discharge to the environment. Point sources, such as wastewater and sewage treatment plants as well as surface runoff, are the main sources of PPCPs to the aquatic environment have been reported in WSTP effluent, surface waters and groundwaters. Therefore, the scientific basis of the proposed rule in the present proposed amendments to the SQOs should not assume that this rather small suite of contaminants (OCBs, chlordanes, DDTs and Dieldrin) is entirely reflective of accumulated burden of contaminants in biota and fish from the bays and estuaries of California, and what constitutes contaminant exposure to the people that consume these sport fish.		
3.25	2) Taken as a whole, is the scientific portion of the proposed rule based upon sound scientific knowledge, methods, and practices? R. Letcher response: On the whole, this reviewer agrees that the scientific portion of the proposed rule is based upon sound scientific knowledge, methods, and practices. The approaches, methods and assumptions that form the basis of the Tier 1,	Support for the scientific portions of the proposed rule is acknowledged.	No

	2 and 3 assessments of sediment and fish tissue contaminant concentrations and biota-sediment bioaccumulation and the resulting evaluation outcomes are well designed. This include a comprehensive array of scientifically proven justifications to meet the SQOs for designating and categorizing assessed sites as Unimpacted, Likely Unimpacted, Possibly Impacted, Likely Impacted and Clearly Impacted.		
4.1	Reviewer Responses: The documents given to the reviewer provided excellent, detailed but very clear justification for assumptions made, equations proposed and tiered approaches for assessment that are both scientifically justifiable, human health protective but also cognizant of need for prioritization in a cost and labor efficient manner. The assessment framework presented and the alternatives chosen in all cases provide an improved approach to evaluate whether contaminants in resident fish tissue pose an unacceptable health risk to humans who eat sport fish. This reviewer agreed with almost all of the alternatives chosen and these provided guideline users a better, more site specific set of options to evaluate California contaminated enclosed bays and Estuaries. Examples were given that supported the translation of these guidelines. When this reviewer has some issues that needed clarification, the issues are detailed below.	Comment acknowledged. See responses to peer review comments 4.3 through 4.23 below.	No
4.2	One set of questions that this reviewer had was addressed for several of the initial key assumptions. These questions should be clarified in the document to ensure that all users are aware of potential challenges to the assumptions made. In no cases are these requested clarifications "show-stoppers" but rather require some responses to ensure all initial assumptions are put into the site specific context, the focus of the written amendments.	Comment acknowledged. See responses to peer review comments 4.3 through 4.23 below.	No
4.3	For example, this reviewer read with great interest Section 3.2 that establishes the Receptors and Exposure Pathways and Direct Effects to Benthic Communities and Indirect Effects on the Human Consumers of Fish. In general, this section established the rationale for site directed considerations. These are important and this	See response to peer review comment 1.18.	No

	reviewer does not dispute these approaches. Where this reviewer requests some additional acknowledgement is when these site based assessment fail. For example, fishing rates in areas where there are already restricting fish consumption advisories cannot reflect true fish consumption as this has already been suppressed by the advisory and pollution in place. Thus the use of the site specific consumption values is very limited and would bias towards not cleaning up a site when it is needed.		
4.4	Another example that needs to be clarified for the site specific basis of the sediment standards is the lack of discussion on tribal "usual and accustomed uses" of these sites. In section 4.1.4 on Native American Consultation there is a discussion of outreach to Tribal governments for their input in this document. However, I did not see any discussion of legally mandated access. A brief review of the Tribal governance literature for the Pacific Coast would suggest that such considerations should be addressed and discussed within the initial context for these revised amendments. There is a literature that suggests that if sediment assessments and clean-up efforts are not sufficient to ensure "usual and accustom use of sites" then this would be considered as an "environmental taking "as the fish would be contaminated and not of use. In addition, the emphasis on sport fish is rather irrelevant for these tribal assessments as again the literature suggests a much broader portfolio of fish consumption and use. Regardless, these considerations need to be discussed and stated upfront as the assumptions for use that need to be considered.	The proposed Provisions attempt to establish a uniform assessment framework that can be applied across all enclosed bays and estuaries of California. Where tribal related beneficial uses have been adopted by a regional water board, the proposed provisions provide exposure thresholds for higher consumption rates (e.g. Chapter IV.A.2.c.3.). Where additional site-specific factors require consideration, the proposed provisions include Tier 3, which is only limited by how the indicators are assessed. The potential site or waterbody specific data considered (including consumer information) are not restricted in Tier 3, so the assessment could be adapted to the factors or concerns that justify the Tier 3 assessment. In regard to cleanup, when a regional water board initiates cleanup actions, the regional water board must consider many factors including fishers, consumers, associated consumption rates, tissue types consumed, preparation methods as wells as sensitivity of consumer groups in consultation with toxicologist in the Office of Environmental Health Hazard Assessment. To provide a detailed analysis, summary and guidance for all factors to consider during the planning of cleanup actions would significantly expand the scope of these proposed Provisions.	No
4.5	By using site specific "use" data the assumption is made that this is a relatively "stable" condition. Although some limitations are discussed, (For example, section 6.5.4 addresses both lack of knowledge and variability in fish movement) this reviewer would suggest adding several additional statements.	See responses to peer review comments 4.6 and 4.7.	No
4.6	In this era of anticipated climate changes, it would also be good to state that site specific changes would be anticipated to change as well. In the document climate changes could be considered as part of needs assessment	Appendix A-5 of the proposed Provisions has been amended to describe the need to periodically refine the conceptual site model in order to address biological factors that could be altered due to climate change.	Yes

	for remediation actions. Again the report could make a statement on the time context for considering the "site specific" conditions.		
4.7	Other considerations for fish consumption should be the types of fish that subsistence fisherpersons consume. Again these can be quite different than sport fish lists and can be more determined on cultural differences, availability of fish and ease of catching fish. Some individuals desire to optimize their omega 3 fatty acid intake and although there was some discussion of these factors in the document, minimal information was presented on how such information would be integrated or affect site prioritization.	See response to peer review comment 4.4. The proposed Provisions are written to address all bays and estuaries using a framework that is consistent with the methodology employed by OEHHA to develop tissue advisories. The proposed Provisions cannot describe all possible scenarios or iterations that could be employed or addressed by the Tier 3 assessment.	No
4.8	In Section 3.2 there is a good background to the concepts regarding habitats and life histories of resident fish as well as anadromous fish and the approaches proposed in the document are sophisticated and accurate for how to address these differences in relationship to quantitation of contaminant loading. Other factors that could be mentioned include hatchery raised fish. Are these present in these waters covered by this document? If so some recognition regarding changes and shifts in husbandry should be mentioned. Changes in these practices can shift the loyalty of the fish to specific regions and can increase fishes return and time spent in local sites and thus increase their load of local contaminants. This should at least be mentioned and would support many of the revisions to accept site by site considerations.	Hatchery raised fish are generally freshwater (trout) or anadromous (salmon and steelhead) and are not considered in this framework as they are transient, with limited exposure to contaminants in bay sediment in comparison to resident fish. White seabass is raised in some enclosed bays but it also spends the majority of time upon release foraging in ocean waters.	No
4.9	Section 4.2.4 discusses regional monitoring and assessment programs. This section is very impressive and the importance of these programs in providing site specific information is great. It would be good to see a set of summary tables that summarize in tabular form the information on dates each program has been in place, frequency of sampling, what is sampled and results and availability to public. For example, monitoring data presented in Appendix 6 of Attachment 7 "Development of Sediment Quality Assessment Framework for Human Health Effects" presents some of this data. Please provide	Due to the size and complexity of the regional monitoring and assessment programs, this section was only intended to identify these efforts. Each of these programs includes some common elements. However, the details change from event to event based on the issues and concerns identified during each monitoring cycle. Where data and program information are available online, links to specific programs were added to the Section 4.2.4 of the Draft Staff Report.	Yes

	a link and possibly add to this information details about sampling frequency and timing.		
4.10	Section 4.2.4 also provides some specific highlighted examples from the monitoring program. For example, the Central Coast Long-term Environmental Assessment Network (CCLEAN) discussion describes sea otter issues and impacts. It is surprising given this example and the other numerous published reports on sea otters, that these species are not identified in Figure 3.3 as they are resident vertebrates with high local food consumption fish consumption (primary diet is macro invertebrates and epidentic fish and shellfish) and they have been noted as being affected by pollutants including PCBs in the relevant areas of this report. (See comments below about ecological impacts for Goals 3 and 4)	The focus of the proposed Provisions is on human consumers of sportfish and the food web diagram was not intended to represent all potential receptors. While there are some aspects that also address the aquatic life SQO there is no effort at this time to amend the existing provisions that address contaminant impacts to fish and wildlife. Protection of resident fish and wildlife were the focus of the 2011 amendments. See https://www.waterboards.ca.gov/water_issues/programs/bptcp/docs/sediment/012811staff_rpt.pdf.	No
4.11	Appendix 2 of the "Development of Sediment Quality Assessment Framework for Human Health Effects" presents the Dietary guild and Target Species Development. This was a very informative section and presented rationale for target species considered in the sediment assessments.	Comment acknowledged.	No
4.12	Equations presented in Section 4.2.4 for both Carcinogens and Non-carcinogens are accurate and scientifically defensible.	Comment acknowledged.	No
4.13	Reviewer responses: This reviewer had some conceptual questions on this statement. The report provides an excellent strategy to address the fundamental question of "Are sediment-associated contaminants at the site or area of interest contributing to the contaminate burden in fish tissue?" A detailed and scientifically justifiable set of approaches is presented. However this reviewer also read as two of the goals of these amendments was to (Goal 3) "Provide regulators, stakeholders and interested parties with transparent and scientifically sound process to better assess the effects caused by pollutants in sediments within California's enclosed bays and estuaries and (Goal 4) Provide regulators, stakeholders and interested parties with an effective process that will promote the protection of sediment quality as well as management of sediments that do not meet the SQOs." To meet these goals, the	See response to peer review comment 4.10.	No

	assessment and proposed amendments should expand and consider impacts on other consumers than humans of organisms associated with contaminated sediments. Please see my example of sea otters as one excellent example where it is unclear that protecting just human health will achieve the same protections for these sea mammals (vertebrate resident consumers) as called for in Goals 3 and 4. In the state of Wa for example water quality standards are driven by pesticide levels and toxicity for salmon not for toxicity in human eating salmon. Please expand or highlight the sections that meet these goals. Just evaluating the most frequently consumed sport fish species for humans will not ensure that these two goals are met. Note also that in the case of sea otters they are endangered species in California regions (See Table 7.8).		
4.14	Section 6 of the report addresses point my point alternatives and presents the recommended alternatives for the revisions. This reviewer felt that the alternative identified were rationale and agreed with choice of all except for a few discussion points listed below.	Comment acknowledged.	No
4.15	For section 6.2.2 on fish species used in evaluation of chemical exposure this reviewer had several questions. Please see my note above about expanding beyond "sport fish".	See response to peer review comment 4.7.	No
4.16	For section 6.2.3 on species to be monitored and assessed please see my comments above regarding suppression of fish consumed by current fish advisories thus for this change I would suggest broadening the input to choose fish species beyond just site specific info. Use of different dietary guilds is good.	See response to peer review comment 1.18. In the development of the conceptual site model, it would be helpful for the end user to consider these factors where fish advisories are in place. However, the list of species for Tier 1 and Tier 2 assessment is unchanged.	No
4.17	For section 6.2.4 on tissue types to be used, several factors need to be considered. First there are cultural difference in how the fish is consumed. For example, many south east Asian communities leave the head on the fish. Note that other consumers of the local fish (i.e. non-human consumers) do not know that they are supposed to remove the internal organs before consuming so to address goals 3 and 4 and not just human associated impact from sediment contamination these whole fish estimates should be retained.	There are many different ways to prepare fish. However, a goal of Tier 2 is to provide a consistent framework that utilizes data that is comparable from different sites. As a result, the tissue preparation methods specified for Tier 2 assessment represent common approaches that are also employed in monitoring programs. If the objective is to evaluate the site in relation to unique preparation methods a Tier 3 analysis is necessary.	No

4.18	For section 6.2.7 on application of OEHHA Tissue Advisories and Goals and Section 6.2.8, I would concur with the choice of Alternative 3 for 6.2.7 however the fish consumption values used in setting the OEHHA guidelines need to updated to reflect more reasonable estimates of fish consumption. Only the three 8 oz. consumption levels approach levels that both WA and Oregon will use. Note that using site specific consumption rates for previously contaminated sites represent repressed levels. Also need to consider both Tribal as well as subsistence fisher people. Hence I would support alternative 2 for section 6.2.8 Is this where some considerations of health benefits of fish should be considered? How? I think more clarity is needed in these two sections.	The one through three meals per week consumption rate encompasses the general range of sportfish consumers in California bays and estuaries. See appendix G Final Staff Report: Part 2 of the Water Quality Control Plan for Inland Surface Waters, Enclosed Bays, and Estuaries of California – Tribal and Subsistence Fishing Beneficial Uses and Mercury Provisions (https://www.waterboards.ca.gov/water_issues/programs/mercury/docs/hg_SR_final.pdf) The Draft Staff Report erroneously identified Alternative 3. The correct alternative is Alternative 2. This change was made to the Draft Staff Report.	Yes
4.19	For section 6.2 Tiered Decision Frameworks—I am supportive of these prioritization schema except for the assumptions and alternative chosen in 6.4.2 where I would support alternative 2 and not 3 as proposed for the reasons listed above. For Section 6.4.4 evaluation of impact, this reviewer would have preferred to see more information in this document about acceptable sampling plans to consider the site has been sufficiently evaluated for site specific information to be included in the assessments. This reviewer supports the use of tissue level contaminate values to drive the decision for action when there are differences between tissue levels and site contamination.	Alternative 3 does support higher consumption rates as recommended by the reviewer in the previous comment. The minimum monitoring requirements have been amended to require an increased sample size to better reflect site conditions. The purpose of the CSM is to guide the design of the monitoring and assessment to ensure that the assessment is representative of the site. As stated previously, there are far too many unique factors to list all issues that could be considered in designing and developing a work plan for an individual site. See Appendix 5 of the proposed Provisions on CSM and study design.	No
4.20	For section 6.5.3 on food web variation I am supportive of the third alternative however this guidance of using “multiple” bioaccumulation models maybe too unrestricted. Perhaps some specific model use could be included as a part of this assessment.	Section 6.5.3 of the Draft Staff Report has been clarified to state that the Tier 2 model type is restricted to a single modeling approach that is parameterized specific to the primary species food web and foraging range that it is applied to.	Yes
4.21	For section 6.5.8 on protective condition, I was supportive of alternative 2 as I have had experience with the risk matrix approach and have found the 3 options as better able to clarify differences in scenarios and level of protection. Please note however I was surprised to see in the matrix only one cell with “possibly impacted” as it appears to be a lopsided example.	The category Possibly Impacted is relatively rare occurrence based on the technical team’s application of the framework in several waterbodies. Where it does occur, the category reflects high exposure and low site linkage that results in substantial uncertainty regarding whether it meets the definition of the protective condition. This designation of Possibly Impacted is also consistent with the use of this category adopted for the aquatic life SQO in 2008.	No

4.22	For section 6.6.1 this reviewer would suggest a recommendation to use Value of Information approaches to estimate the overall value in missing or confounded site information. Sensitivity analysis could identify key drivers in these comparisons and further support the tiered approaches.	Value of Information approaches may be considered by the end user to make a decision on whether or not Tier 3 should be performed. However, the identification of tools used to inform the decision are outside the scope of these proposed amendment and should be left to the end user to determine what analyses or tools should be conducted to determine if Tier 3 assessment should be proposed.	No
4.23	In summary, the overall document is exceptionally well done, clear, comprehensive and scientifically robust. Please feel free to use my suggestions to slightly adjust the alternative and discussion. Please see also my suggestion on expanding the context for assessment in order to address both the goals and the two questions posed to the reviewers.	Comment acknowledged, see responses to peer review comments 4.1 through 4.22.	

Attachment 1
Description of Scientific Conclusions to be Addressed by Peer Reviewers

The State mandate for external scientific peer review (Health and Safety Code Section 57004) states that the reviewer's responsibility is to determine whether the scientific portion of the proposed rule is based upon sound scientific knowledge, methods and practices. We request that you make this determination for each of the following issues that constitute the scientific basis of the proposed regulatory action. An explanatory statement is provided for each issue to focus the review.

A. The proposed assessment framework to assess sediment quality in relation to narrative sediment quality objective (SQO) protecting human consumers from contaminants that bioaccumulate from sediment into fish tissue is appropriate and based on a sound approach and developed using sound scientific information and methods. The specific scientific findings, assumptions and conclusions to be evaluated for their basis in sound scientific knowledge, methods and practices are detailed below

This narrative SQO states: Pollutants shall not be present in sediments at levels that will bioaccumulate in aquatic life to levels that are harmful to human health in bays and estuaries of California. Since adopted by the State in 2008, this SQO has been assessed and evaluated on a case-by-case basis, with little guidance other than a requirement to be based upon a human health risk assessment. Since 2009, the State Water Board's technical team has been developing an assessment framework based on a conceptual approach that addresses two fundamental questions:

- Do contaminants in resident fish tissue pose an unacceptable health risk to humans consuming those fish?
- Are sediment-associated contaminants at the site or area of interest contributing to the contaminant burden in fish tissue?

1. **Evaluation of health risk to humans is based on comparison to tissue contamination thresholds established by the State of California to protect consumers of local fish.** In order to address the first question, the assessment framework requires a comparison of average fish tissue contaminant concentrations to contamination goals and advisory tissue levels used to develop fish tissue consumption advisories for California sportfish derived by the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA). **Suggested Expertise:** Public Health Toxicologist and Environmental Chemist. **Suggested References:** Draft Amendments Tables 16 and 20, Draft Staff Report (Sections 3.2, 4.2.4 and 6.2), OEHHA's Development of Fish Contaminant Goals and Advisory Tissue Levels for Common Contaminants in California Sport Fish, and Bay et al, 2017, Development of Sediment Quality Assessment Framework for Human Health Effects (Section 2.1 thru 2.4)

2. **Health risk evaluation is based solely on fish likely to live within the site of interest and be consumed by the local population.** To ensure the tissue data fulfill the requirements of the assessment framework, only those bay and estuarine fish species that exhibit some level of site fidelity, consume benthic macrofauna as part of their diet and are commonly consumed by humans are considered in this framework.

Suggested Expertise: Public Health Toxicologist and Fish Ecologist. **Suggested References:** Draft Amendments Section IV. A.2.b, Appendix A-5 and A-6, Draft Staff Report (Sections 3.2, 4.2.4 and 6.2) and Bay et al, 2017, Development of Sediment Quality Assessment Framework for Human Health Effects (Section 2.1 thru 2.6, 6.1, Appendix 2 and 3)

3. **The relative influence of site sediment contamination on fish contamination is an appropriate indicator of the contribution of site sediment contamination.** In order to address the second question, the assessment framework requires an evaluation of site linkage; the proportion of measured tissue contaminant concentration estimated to result from site sediment contamination, calculated as a ratio of the estimated tissue concentration and the measured tissue concentration. **Suggested Expertise:** Bioaccumulation Modeler, Environmental Chemist. **Suggested References:** Draft Amendments Section IV. A.2.d.1), 2), 4), 5), 6), 7), Tables 18 and 21, Appendix A-5, A-6, A-7 and A-8, Draft Staff Report (Sections 3.2, 6.5.1 thru 6.5.5) and Bay et al, 2017, Development of Sediment Quality Assessment Framework for Human Health Effects (Section 2.1 thru 2.6, 4.2, 6.2, 6.3, 6.4 and Appendix 1) Gobas, Frank and Jon A. Arnot, 2010, Food Web Bioaccumulation Model for Polychlorinated Biphenyls in San Francisco Bay, California, USA. Environmental Toxicology and Chemistry, Vol. 29, No. 6, pp. 1385–1395, 2010

4. **Bioaccumulation modeling is an appropriate method to evaluate site sediment linkage**. Estimated tissue concentrations are obtained using the steady state Gobas Food Web Model, calibrated for eight different feeding guilds. These feeding guilds encompass a variety of fish and their associated dietary preferences within California enclosed bays and estuaries. **Suggested Expertise:** Bioaccumulation Modeler, Fish Ecologist. **Suggested References:** Draft Amendments Section IV. A.2.d.1), 2), 4), 5), 6), 7), Tables 18 and 21, Appendix A-5, A-6, A-7 and A-8, Draft Staff Report (Sections 3.2, 6.5.1 thru 6.5.5) and Bay et al, 2017, Development of Sediment Quality Assessment Framework for Human Health Effects (Section 2.1 thru 2.6, 4.2, 6.2, 6.3, 6.4 and Appendix 1), Gobas, Frank and Jon A. Arnot, 2010, Food Web Bioaccumulation Model for Polychlorinated Biphenyls in San Francisco Bay, California, USA. Environmental Toxicology and Chemistry, Vol. 29, No. 6, pp. 1385–1395, 2010

5. **Site specific and species-specific data are required to assess sediment linkage.** Measured site sediment concentrations, dissolved water concentrations, sediment total organic carbon, fish forage area, and site area represent key bioaccumulation model inputs. **Suggested Expertise:** Bioaccumulation Modeler, Environmental Chemist. **Suggested References:** Draft Amendments Section IV. A.2.d.2) Table 18, Appendix A-5, A-8, Draft Staff Report (Section 6.5.1 thru 6.5.5) and Bay et al, 2017, Development of Sediment Quality Assessment Framework for Human Health Effects (Sections 4.2, 4.3, 4.4 and 4.5, Appendix 1), Ben K Greenfield, Aroon R Melwani, and Steven M Bay (2015), A Tiered Assessment Framework to Evaluate Human Health Risk of Contaminated Sediment, Integrated Environmental Assessment and Management.

6. **The approach, methods and assumptions set forth in the optional Tier 1 Screening Evaluation are appropriate for screening low risk sites or waterbodies.** The assessment framework consists of three tiers to address varying site conditions and situations from the simple (Tier 1) to complex (Tier 3). The optional Tier 1 is a conservative screening evaluation intended to distinguish low risk sites that clearly meet the SQO from those sites that require the full analysis of Tier 2 to make a confident

assessment. Tier 1 uses either sediment or tissue data to directly compare tissue concentrations to OEHHA tissue thresholds. A table of model generated biota-sediment accumulation factors is used to convert sediment concentrations to expected tissue concentrations for comparison with tissue thresholds. The two possible outcomes from Tier 1 are Pass (sediment is unimpacted and meets the SQO) or conduct Tier 2 assessment. **Suggested Expertise:** Environmental Risk Assessor, Public Health Toxicologist, and Bioaccumulation Modeler. **Suggested References:** Draft Amendments Section IV. A.2.b, c, e, f, Draft Staff Report (Section 6.3, 6.4, 6.5, 6.6) and Bay et al, 2017, Development of Sediment Quality Assessment Framework for Human Health Effects (Sections 2, 3, 4, 5), Ben K Greenfield, Aroon R Melwani, and Steven M Bay (2015), A Tiered Assessment Framework to Evaluate Human Health Risk of Contaminated Sediment, Integrated Environmental Assessment and Management.

7. **The approach, methods and assumptions set forth in Tiers 2 and 3 are appropriate for designating sites as either impacted or unimpacted.** Tiers 2 and 3 require analysis of both sediment and tissue chemistry data to assess whether site sediments meet or exceed the narrative objective; these tiers differ in the level of standardization and incorporation of site-specific parameters or conditions. A logic matrix is used for Tiers 2 and 3 in order to integrate the outcomes of the two indicators into site categories of Unimpacted, Likely Unimpacted, Possibly Impacted, Likely Impacted and Clearly Impacted. Sediments designated as Unimpacted and Likely Unimpacted meet the SQO, while sediment categorized Possibly Impacted, Likely Impacted and Clearly Impacted do not meet the SQO. **Suggested Expertise:** Environmental Risk Assessor, Public Health Toxicologist. **Suggested References:** Draft Amendments Section IV. A.2.d, e, Draft Staff Report (Section 6.5, 6.6) and Bay et al, 20107, Development of Sediment Quality Assessment Framework for Human Health Effects (Sections 4, 5), Ben K Greenfield, Aroon R Melwani, and Steven M Bay (2015), A Tiered Assessment Framework to Evaluate Human Health Risk of Contaminated Sediment, Integrated Environmental Assessment and Management.

B. The proposed approach to designate impaired sediment quality in relation to the SQO protecting benthic communities from direct exposure to contaminants in sediment is appropriate and scientifically sound.

This narrative SQO states: Pollutants in sediments shall not be present in quantities that, alone or in combination, are toxic to benthic communities in bays and estuaries of California. This narrative is assessed by evaluating sediment toxicity, sediment chemistry and biological condition at each station and integrating the responses into station categories consisting of; Unimpacted, Likely Unimpacted, Possibly Impacted, Likely Impacted and Clearly Impacted.

1. **Use of severity of effects and spatial extent is appropriate when evaluating whether sediment dependent beneficial uses are supported in waterbodies.** The State Water Board is proposing a new approach that considers severity (any station classified as clearly impacted) and percent area of impact (stations classified as likely or possibly impacted, not to exceed 15 percent). The State Water Board currently relies on a frequency of exceedance approach based on the binomial statistic that was originally intended for water column applications. **Suggested Expertise:** Environmental Risk Assessor, Environmental Chemist. **Suggested References:** Draft Amendments Section IV. A.4. c. 2) and e.1), Draft Staff Report (Section 6.7.1).

C. Additional Issues related to the big picture

Reviewers are not limited to addressing only the specific conclusions presented above, and are asked to contemplate the following questions:

1. In reading the Draft Staff Report and proposed rule, are there any additional scientific findings, assumptions, or conclusions that are part of the scientific basis of the proposed rule not described above?
2. Taken as a whole, is the scientific portion of the proposed rule based upon sound scientific knowledge, methods, and practices?

Reviewers should also note that some proposed actions may rely significantly on professional judgment where available scientific data are not as extensive as desired to support the statute requirement. In these situations, the proposed course of action is favored over no action. The preceding guidance will ensure that reviewers have an opportunity to comment on all aspects of the scientific basis of the proposed rule.

At the same time, reviewers should recognize that the State Water Board has a legal obligation to consider and respond to all feedback on the scientific portions of the proposed rule. Because of this obligation, reviewers are encouraged to focus feedback on scientific conclusions that are relevant to the central regulatory elements being proposed.