Proposal Reviews

#6: A survey of endocrine disrupting chemicals and occurrence of fish reproductive dysfunction in the CalFed solution area

Applied Marine Sciences, Inc.

Research and Restoration Technical Panel Review	
Bay Regional Review	
Delta Regional Review	
San Joaquin Regional Review	
Sacramento Regional Review	
External Scientific Review	#1 #2 #3
Environmental Compliance	
Budget	

Research and Restoration Technical Panel Review:

CALFED Bay-Delta 2002 ERP PSP
Research and Restoration Technical Panel Review Form

Proposal Number: 6

Applicant Organization: Applied Marine Sciences, Inc.

Proposal Title: A survey of endocrine disrupting chemicals and occurrence of fish reproductive dysfunction in the CalFed solution area

Review:

Please provide an overall evaluation summary rating:

Superior: outstanding in all respects;
Above Average: Quality proposal, medium or high regional value, and no significant administrative concerns;
Adequate: No serious deficiencies, no significant regional impediments, and no significant administrative concerns;
Not Recommended: Serious deficiencies, significant regional impediments or significant administrative concerns.

Overall Evaluation Summary Rating	**Provide a brief explanation of your summary rating**
-Superior	**While overall the proposed work is interesting and reasonably well supported by existing literature, some of the methods are sketchy at best, and the requested budget seems extraordinarily excessive. The proposal was too broad and unfocused. The proponents might wish to consider a more narrowly focused research proposal. While the proponents have excellent credentials, the overall proposal is lacking in several key areas as noted above and in the external reviews.**
-Above average	
-Adequate	
XNot recommended	

1. **Goals and Justification.** Does the proposal present a clear statement of goals, objectives and hypotheses? Does the proposal present a clear justification and conceptual model for the project?

   The goal of this project is to identify potential endocrine disruption problems and reproductive dysfunction in the CALFED region in order to determine if the recovery of resident fish populations could be limited by water quality. This is a timely and important project, because of the existence of a number of listed species in this area, and because of strong evidence for the presence of endocrine-disrupting compounds in these waters.

   Hypotheses are clearly stated and consistent with the goal, and this area of study is justified by existing knowledge.

2. **Likelihood of Success (Approach, Feasibility, Capabilities and Performance Measures).** Is the project likely to succeed based on the approach, feasibility and project team capabilities? Are

the proposed performance measures adequate for measuring the project's success?

The proposed approach is generally well-documented and technically feasible, and within the grasp of the authors. However, there are inconsistencies, omissions, and deficiencies in the project approach as it is described. Most notably, some obvious important biological endpoints were not considered (e.g. sexual differentiation), and the flow through exposures seemed poorly thought through.

3. **Outcomes and Products.** Will the project advance the state of scientific knowledge in general and/or make an important contribution to the state of knowledge of the Bay-Delta Watershed? For restoration proposals, is the project likely to contribute to ecosystem restoration or species recoveries in a significant way? Will the project produce products useful to decision-makers and scientists?

   The anticipated products from this project are journal articles and a final report. These could certainly be produced, and should contain useful information on concentrations of EDCs and their effects on some fish species in the CALFED region. It may be possible to identify areas where the presence of these substances in the aquatic environment could impede recovery of protected species. The authors also indicate that data will be available upon request for incorporation into regional database systems.

4. **Cost/Benefit Comments.** Is the budget reasonable and adequate for the work proposed?

   The budget is excessive, and this was noted by a number of reviewers.

5. **Regional Review.** How did the regional panel(s) rank the proposal (High, Medium, Low)? Did the regional panel(s) identify significant benefits (regional priorities, linkages with other activities, local involvement) or impediments (local constraints, conflicts with other activities, lack of local involvement) to this proposal? What were they?

   Generally ranked low to medium by regional panels.

6. **Administrative Review.** Were there significant concerns about the proposal with regard to the prior performance, environmental compliance and budget administrative reviews? What were they?

   Some minor administrative issues, including whether permitting had been adequately considered, and minor budgetting inconsistencies.

Miscellaneous comments:

Bay Regional Review:

Proposal Number: 6

Applicant Organization: Applied Marine Sciences, Inc.

Proposal Title: A survey of endocrine disrupting chemicals and occurrence of fish reproductive dysfunction in the CalFed solution area

Overall Ranking: **-**Low **X**Medium **-**High

Provide a brief summary explanation of the committee's ranking:

Research into this issue is important; however, it is unclear whether this is a significant enough problem in the Bay region to warrant a study of this magnitude. The panel recommends that after funding higher ranked proposals, Phase 1 of this proposal could be considered for funding provided sufficient funds.

1. Is the project feasible based on local constraints?

   XYes **-**No

   How?

   The first phase of the project appears very feasible, the literature review, analysis of existing chemical data and research into the development of fish exposure tests. However, even this aspect of the project has such a large geographic scope that it is our opinion that the proposal would have been more realistic if written for an area of smaller regional scope, i.e, San Francisco Bay, Delta or the major rivers. The data resources in many areas, particulary the Bay region are immense. It takes a significant effort to complete a literature and data gathering effort of this magnitude. The following phases depend on the results of Phase 1 and are therefore less secure in their feasibility.

   Also, some of the proposed research in later phases, especially if it addresses gathering at-risk species in the field, may require take permits and it is unclear if the authors already possess these permits.

2. Does the project pursue the restoration priorities applicable to the region as outlined in the PSP?

   XYes **-**No

   How?

   Somewhat important, but importance unclear. Little is known about the impacts of endocrine disrupting chemicals on fish and other organisms in the area, so some emphasis should be placed on this issue. However, it is unclear what the magnitude and scope of the problem is and how important it is to the restoration issues of fish species at large. A more targeted research plan in Phase II would get at this question.

Other possible linkages include BR-7: Improve scientific understanding of the linkages between populations of at-risk species and inflows, especially relative to regulatory measures like X2 . BR-8: Use monitoring, evaluations of existing monitoring data and new investigations to develop improved strategies for restoring Bay fish populations and at-risk species.

3. Is the project adequately linked with other restoration activities in the region, such as ongoing implementation projects and regional planning efforts?

   XYes **-**No

   How?

   In general this project has indirect connections to restoration programs; however, there is a significant possibility that direct connections can be made, once the literature and data collection phase is complete.

   Specifically, there is at least one other CALFED project underway on effects of contaminants on reproductive success (Pogonichthys macrolepidotus): A Biomarker Approach". P.I., Dr. Swee The a more lab based study. The proposal mentions possible coordination where appropriate.

4. Does the project adequately involve local people and institutions?

   XYes **-**No

   How?

   Local consultants are involved and there appears to be good coordination with local institutions.

Other Comments:

Phase 1 is important. This is an important topic, and the researchers are well qualified; however, the research proposal is so large in geographic scope that there is a risk that the project would be difficult to complete. Tackling a subset of this problem and focusing on specific area or type of EDC, would have presented a clearer proposal that could be more easily evaluated for its efficacy.

Delta Regional Review:

Proposal Number: 6

Proposal Title: A survey of endocrine disrupting chemicals and occurrence of fish reproductive dysfunction in the CalFed solution area

Overall Ranking: **-**Low **X**Medium **-**High

Provide a brief summary explanation of the committee's ranking:

Generally meets all four regional criteria for the Delta and focuses on a pertinent problem that is important to drinking water quality as well as threatened and endangered species.

1. Is the project feasible based on local constraints?

   XYes **-**No

   How?

   Phase I is largely a literature/data review of EDCs that occur in the CALFED area.

   Phase II calls for water and sediment samples to be collected "throughout the CALFED region at sites with known elevated EDCs and reference sites. To the extent possible we will take samples also in areas that co-occur with the expected presence of sensitive life stages of fish species of concern." Such sites should exist in the Delta.

   Phase III calls for lab experiments that may use threatened or endangered species; permits may be required. The universities apparently have appropriate lab facilities.

   Applicants will use results from earlier phases to support work in later phases.

2. Does the project pursue the restoration priorities applicable to the region as outlined in the PSP?

   XYes **-**No

   How?

   From the Restoration Priorities for the Delta and Eastside Tributaries Region:

   "6. Restore shallow water habitats in the Delta for the benefit of at-risk species while minimizing potential adverse effects of contaminants

   · Effects of contaminants. Studies should consider effects under the specific environmental conditions and exposures typical of the Delta, so as to prioritize effects on populations and restoration outcomes compared to other stressors (Strategic Goal 6, water and sediment quality)

   · Emerging chemicals: Pyrethroids. Baseline techniques for studying pyrethroids, and study pyrethroid occurrence, fate and toxic effects in eastside tributary floodplains, inundated Delta Islands, and tidal wetland ecosystems (Strategic Goal 6, water and sediment quality)."

And, from the Restoration Priorities for Multi-Region Bay-Delta Areas: "5. Ensure that restoration is not threatened by degraded environmental water quality

· Pesticides (including Organochlorine Pesticides): Pesticide residues from agricultural applications and residential use can enter watercourses and cause toxicity to resident organisms, including those upon which other organisms must depend for food. Stage 1 includes actions to reduce impacts of current-use pesticides (including diazinon and chlorpyrifos) through developments and implementation of Best Management Practices, for both urban and agricultural uses. Actions include studies on current and new-use (pyrethroids) pesticides and education and assistance in implementing control strategies for pesticide users. Studies that increase knowledge of occurrence, status, trends, and processes that determine exposure and effects of pesticides are critical to achieving the actions. Sources, effects and trends must be better understood to best implement such actions, or decide where actions are appropriate. Sediment control can reduce inputs and will also protect topsoil and prevent costly maintenance of drainage systems

· Pollutant effects. Insufficient study of pollutant effects exist anywhere in the watershed. The studies most needed are those that evaluate effects expected within the context of the contaminated environment. For example, work is needed to better understand what causes fish mortality in the Central Delta; or if ecosystem processes or populations of species of concern, in areas undergoing restoration, are affected by pollutants. The Science Conference Summary noted the need for understanding contaminant effects, in an ecological/hydrologic context, as a large gap in knowledge about threats to restoration. General implications of contaminants for food webs is a special need. Linkages between contaminant exposure and physiological processes, reproduction and biomarker (biochemical) responses are needed for all pollutants."

3. Is the project adequately linked with other restoration activities in the region, such as ongoing implementation projects and regional planning efforts?

   XYes **-**No

   How?

   The applicants indicate that field sample collection in Phase II will be coordinated as much as possible with "other on-going monitoring programs (SRWP, USGS, NAWQA, and RMP).

4. Does the project adequately involve local people and institutions?

   XYes **-**No

   How?

   The applicants are from UC-Davis, the University of Texas, SFEI, and Bay Area consulting firms. Results will be published in scientific journals and presented at scientific meetings. However, the regional panel felt that the project would be improved with more public involvement/outreach.

Other Comments:

N/A

San Joaquin Regional Review:

Proposal Number: 6

Applicant Organization: Applied Marine Sciences, Inc.

Proposal Title: A survey of endocrine disrupting chemicals and occurrence of fish reproductive dysfunction in the CalFed solution area

Overall Ranking: **X**Low **-**Medium **-**High

Provide a brief summary explanation of the committee's ranking:

The study is too wide-ranging and has too many components; it is not well focused. The lack of connection to local interests and no evidence of communication with other potentially complementary research efforts also contributed to the ranking.

1. Is the project feasible based on local constraints?

   -Yes **X**No

   How?

   The proposal states that little has been published, particularly locally, on this subject, yet the authors propose to base their study sites on information gleaned from a literature survey. It is questionable whether this methodology will yield a working sampling strategy in the time allotted.

2. Does the project pursue the restoration priorities applicable to the region as outlined in the PSP?

   XYes **-**No

   How?

   It proposes to address an identified multi-regional priority, identifying toxicity currently of unknown origin and also proposes to use a species of concern, the delta smelt, in its investigations.

3. Is the project adequately linked with other restoration activities in the region, such as ongoing implementation projects and regional planning efforts?

   -Yes **X**No

   How?

   The proposal states that the researchers will contact others working in this area and attempt to use archived samples from their collections, but no specific information is provided.

4. Does the project adequately involve local people and institutions?

   -Yes **X**No

   How?

   One of the investigators works for the Central Valley CRWQCB, but there is no mention of an integration with Regional Board work. No other local connection is evident.

Other Comments:

We recognize that the subject of the proposal is important and that the investigators have the expertise to do the work. We would encourage them to develop a more focused investigation.

Sacramento Regional Review:

Proposal Number: 6

Applicant Organization: Applied Marine Sciences, Inc.

Proposal Title: A survey of endocrine disrupting chemicals and occurrence of fish reproductive dysfunction in the CalFed solution area

Overall Ranking: **-**Low **X**Medium **-**High

Provide a brief summary explanation of the committee's ranking:

Seems unclear as to how much of a problem EDC's represent and the answers will probably be a long time in coming. Must decide if this is a worthwhile line of study to pursue. This proposal very similar to the UC Davis proposal (# 192) and the technical review committee should evaluate and compare these two proposals and determine which has more merit.

1. Is the project feasible based on local constraints?

   XYes **-**No

   How?

   This research project will use standard, accepted protocols.

2. Does the project pursue the restoration priorities applicable to the region as outlined in the PSP?

   XYes **-**No

   How?

   This project addresses the issue of assessing the magnitude and significance of EDC's in the Bay/Delta ecosystem (discussed in PSP Restoration Priority #7)

3. Is the project adequately linked with other restoration activities in the region, such as ongoing implementation projects and regional planning efforts?

   XYes **-**No

   How?

   Other than a general concern about EDCs, there are currently no specific planning or implementation efforts to link to.

4. Does the project adequately involve local people and institutions?

   -Yes **X**No

How?

This type of research effort does not require significant involvement of locals but there is need to coordinate with other stakeholder organizations such as Sacramento River Conservation Area Board and SRWP (i.e. Strategy to Address Unknown Sources of Toxicity).

Other Comments:

Seems unclear as to how much of a problem EDC's represent and the answers will probably be a long time in coming. Must decide if this is a worthwhile line of study to pursue. This proposal very similar to the UC Davis proposal (#192)and the technical review committee should evaluate and compare these two proposals and determine which has more merit.

External Scientific: #1

Research and Restoration External Scientific Review Form

Proposal Number: **6**

Applicant Organization: **Applied Marine Sciences, Inc.**

Proposal Title: **A survey of endocrine disrupting chemicals and occurrence of fish reproductive dysfunction in the CalFed solution area**

Conflict of Interest Statements:
I have no financial interest in this proposal.
XCorrect
-Incorrect

In the blank below please explain any connection to proposal, to applicant, co-applicant or subcontractor or to submitting institution (write "none" if no connection):

None.

Review:

Please provide an overall evaluation summary rating:

Excellent: outstanding in all respects;
Good: quality but some deficiencies;
Poor: serious deficiencies.

Overall Evaluation Summary Rating	**Provide a brief explanation of your summary rating**
-Excellent	**see Miscellaneous comments**
XGood	
-Poor	

1. **Goals.** Are the goals, objectives and hypotheses clearly stated and internally consistent? Is the concept timely and important?

   The goals are well in keeping with CALFED's stated needs in this area and are likely an almost direct response to those stated goals. But basically The stated hypotheses basically ask the questions: are the levels of EDCs found in the CALFED ZONE high enought to be of concern (through laboratory assays), so that we can predict that fish in the system (objects of restoration activities) are likely affected by these same levels. And the rest is basically left to our faith that more specific hypotheses will be developed as we go along. This is an adaptive approach, which is desirable (because it builds on previous work), but I get the impression on reading through the proposal as to what will be done from start to finish is that we are basically starting from "square 1" (a complete literature summary) through to sampling and testing, and then finally to predicting effects in wild individuals of restoration concern. A basic question in the beginning is stated in the proposal as: "The information base is simply too limited to know whether there is a needed or justified restoration action for improving

water quality for reproductive toxicants." I disagree and would put a bit more faith in previous work, not only in the CALFED zone but worldwide. The information base that is used to justify this study in the first place is in the very basis of the study being strong enough to suggest that indeed it is likely--otherwise why would a study like this be justified in the first place? I happen to think it IS highly justified, based on the information available "out-there", and I believe that more detailed work is needed. That's why CALFED planners came to this same conclusion and stated this as an important goal in the first place. It is stated in the proposal that these are the goals of the study. It is all somewhat circular in how this came about.

2. **Justification.** Is the study justified relative to existing knowledge? Is a conceptual model clearly stated in the proposal and does it explain the underlying basis for the proposed work? Is the selection of research, pilot or demonstration project, or a full-scale implementation project justified?

   This gets back to the comments above. The long and almost too drawn-out basic explanations in the proposal itself, as to the mechanisms and likely endpoints of ecological significance are used to strongly justify why a study of some type like this is needed. The basic question becomes whether this specific approach and the costs involved will address the basic question. And I think it will. Yet much of the justification is also based on the stated needs (as I read them here) outlined in the RFP. I would therefore predict that other research teams will be proposing much the same thing (in fact, I recall at least one more similar study listed in the hundreds of proposals on the web--and there may be more). Then a major dimension is also added that requires asking questions about the costs and cost-effectiveness of any proposed project to evaluate EDCs.

3. **Approach.** Is the approach well designed and appropriate for meeting the objectives of the project? Are results likely to add to the base of knowledge? Is the project likely to generate novel information, methodology or approaches? Will the information ultimately be useful to decision-makers?

   The approach is appropriate but predictable. It is fairly routine risk-assessment and follows well-established procedures with good QAQC, etc. These people know what they are doing. The extensive literature review in Phase I, however, seems a bit basic and one would have thought that this has basically already been done by various agencys involved in the initial work relating EDCs to environmental risk in the CALFED zone of interest, and I believe the current data-base is extensive enough to provide a strong basis for future and more definitive specific evaluations of EDCs in relation to eventual fish restoration programs--which is apparently a justified goal of this project. In that case, I would have liked seeing some development and synthesis of all this work in the final phases of study oriented toward more specific risk-assessment modeling (predictions) and population modeling (predictions). The toxicology is there in high-quality force, but there is very little field ecology and demography--despite the fact that this is a vital element in the conceptual model even as stated as the basic concept in this specific proposal (Fig. 2). Additionally, the proposal should contain more information on the outreach portion of the study (although this is implied at least partially in their proposal to establish a website on the data-base--it should be emphasized more), where the extensive toxicological information gathered from this study will finally be put to use in helping to make decisions about restoration. The initial information generated by this project will be much needed, and perhaps the approach will provide some novel new ways to evaluate EDCs from a toxicological viewpoint (but not much from the ecological or demographic viewpoint. And I would see this a a weakness in the proposal--at least that it is not more clearly stated and applied in the final phases of the study. In fact, I was kind of left feeling that after Phase III, people would be thinking "now what?"

Getting back to Phase I, in defense of a strong literature review. If it is in the goals of CALFED (I have not had time to study in detail the approaches asked for in the RFP) to produce a synthesis document on EDC data and studies from the area, and to relate these to other studies around the world, for example, in a document such as was done in the SNEP projects, then indeed this is what the project here proposes to do. And they will ge going to all the agencies and organizations to synthesize the published and unpublished data and to bring it together into one huge document--it will be useful. In that light, it will be a good idea to synthesize at least all the agency data on EDCs of the CALFED area of interest , as much of that is likely to remain in the "gray zone". So overall, I am somewhat ambivalent on an extensive literature review. On the other hand, if EDC field assays and monitoring are necessary soon, the first part of the study, Phase I, the literature review and planning period, will put EDC studies a year or two behind other environmental evaluation goals. It seems that the techniques and ecology of the area are developed enough so that EDC investiagors can "hit the ground running" in an extensive, expensive study like proposed here.

Aquatic toxicology almost always speaks to fish or aquatic invertebrates, and this proposal does just that. Yet, implications for warm-blooded vertebrates are also high, especially those that consume fish. And this is one aspect of ecotoxicological risk-assessment that is not addressed in this proposal, other than some hintings of bioaccumulation or food-web effects. This seems entirely justifiable and approachable. Perhaps the aquatic toxicology compendium of all this information will be of some use and direction to others who will attempt to identify potential problems of ECDs in other ecosystem components of the SF Bay Delta watershed in future studies.

4. **Feasibility.** Is the approach fully documented and technically feasible? What is the likelihood of success? Is the scale of the project consistent with the objectives?

   The approach is feasable (as I said before, it is pretty much SOP) and likely to produce what the authors promise. The adaptive approach of later phases, although leaving questions open in the minds of reviewers, may be useful, but it is my impression from what I know in the field of EDCs that other researchers may already be a step ahead in their thinking to end up at the final stage: to produce a data set on EDCs that is synthesized, and relates to the ecotoxicological questions that need to be understood (ecological and demographic end-points in fish and wildlife populations that will affect restoration or management strategies). It might be there, but I don't see it.

5. **Project-Specific Performance Measures.** Does the project include appropriate performance measures to measure success relative to the project's goals and objectives? Is there enough detail as to how the performance measures will be quantified? For restoration projects, are monitoring plans explicit and detailed enough to determine if performance measures will be adequately assessed?

   The time line presented and the final "products" are clearly stated and reachable. Yet, as I implied above, there are not clear directions to the endpoints of ecological restoration, if even there are to be any, are left for the future. As I understand it, CALFED is basically an ecological restoration project as far as aquatic ecosystems are concerned and I would like to see the extension of this extensive proposed project toward that end.

6. **Products.** Are products of value likely from the project? Specifically for restoration projects, are products of value also likely from the monitoring component? Are interpretative outcomes likely from the project?

Theoretically, if the EDC problems are as huge as is implied even in the current literature, then projects like this have the potential to contribute in a significant way to future decisions on management and restoration in the system. Either way, we have to know. But it is hard to imagine a situation where restoration decisions will be made based entirely on these sorts of data. They will instead end-up being contributory along with many other non-EDC data on contaminants and other environmental variables.

7. **Capabilities.** What is the track record of applicants in terms of past projects? Is the project team qualified to efficiently and effectively implement the proposed project? Do they have available the infrastructure and other aspects of support necessary to accomplish the project?

   The co-investigators listed in the project (there were actually two lists, the first listed co-PIs and then the PIs or investigators listed in the "qualifications" section of the proposal--they did not match). One of the PI's listed on the cover sheet, G. Marty, did not make the qualifications list, but the remainder (and Dr. Marty, too) do make up an extremely qualified and impressive group of investigators. The only place it might be considered lacking is in the area of demography, fish ecology, or even just ecology.

   Their format of Table 3 and summaries like in Tables 1 and 2 were highly useful and the format of Table 3 should actually be included in every proposal. This was a nicely written, clear and concise proposal that indicates the authors put a lot of thought and effort into it. Nicely done!

8. **Cost/Benefit Comments.** Is the budget reasonable and adequate for the work proposed?

   The budget is certainly adequate, but I am concerned that 2.8 million will be looked-upon as just too high a price. Analytical chemistry is always expensive an that is a large part of this study. The authors have developed and will probably continue to refine and devleop very useful analytical techniques as well as assays of EDC effects in fish and this could in the future contribute significantly to reductions in the costs of future EDC-related studies CALFED might want to pursue.

   When you look at the budget, it can be seen that by far the major cost (as is typical in studies like this that require very sophisticated analytical chemistry), is services, which is basically and mostly analytical chemistry. It's an ecotoxicological fact of life: acceptable lab work is expensive.

Miscellaneous comments:

I was most concerned with this proposal, although it directly addresses a stated CALFED need, that it pretty much represents a typical risk-assessment approach (but which has been developed over time by people who do this kind of work); but it lacks the final step of extending the findings and data to operating, working ecosystems. Perhaps this is something to think about in future studies.

Yet, as proposed, the work has a high probability to answer, or help answer, the simple questions and objectives posed. I am not real excited about this study nor am I particularly negative on it. Other than the bio-assay work, which I see as of high potential future benefit to population ecologists who will need to come in and project information like this to future studies of field populations and ecosystems, I think this is a standard, routine, though well-established and tested, approach to risk assessment. If something better does not come along, it will work.

External Scientific: #2

Research and Restoration External Scientific Review Form

Proposal Number: **6**

Applicant Organization: **Applied Marine Sciences, Inc.**

Proposal Title: **A survey of endocrine disrupting chemicals and occurrence of fish reproductive dysfunction in the CalFed solution area**

Conflict of Interest Statements:
I have no financial interest in this proposal.
XCorrect
-Incorrect

In the blank below please explain any connection to proposal, to applicant, co-applicant or subcontractor or to submitting institution (write "none" if no connection):

none

Review:

Please provide an overall evaluation summary rating:

Excellent: outstanding in all respects;
Good: quality but some deficiencies;
Poor: serious deficiencies.

Overall Evaluation Summary Rating	**Provide a brief explanation of your summary rating**
-Excellent	**Good-The theme has merit for addressing CALFED goals. Costs are very high for a questionable potential return.**
XGood	
-Poor	

1. **Goals.** Are the goals, objectives and hypotheses clearly stated and internally consistent? Is the concept timely and important?

   The goals are clearly stated in the problem statement, namely to identify potential endocrine disruption problems and reproductive dysfunction in the CALFED solution area in order to determine if the recovery of resident fish populations could be limited by water quality. This is probably a significant issue for the Bay-Delta system.

2. **Justification.** Is the study justified relative to existing knowledge? Is a conceptual model clearly stated in the proposal and does it explain the underlying basis for the proposed work? Is the selection of research, pilot or demonstration project, or a full-scale implementation project justified?

A conceptual model is outlined in the text and as a figure (2). The figure serves as a conceptual model for the potential effects of endocrine disruption in fishes. Like many of the other contaminant proposals this ones shortcoming is that it offers no clear resolution to the contaminant problem. It only offers to determine if there might be a problem of significant magnitude to affect reproduction of fishes. Given the magnitude of known chemicals in the system it is likely that some reproductive impairment is going on for some species. It is unlikely that this reproductive impairment is the same for all species or for all individuals within a given population. It fails to offer an assessment of whether there are likely to be population level effects from reproductive dysfunction.

3. **Approach.** Is the approach well designed and appropriate for meeting the objectives of the project? Are results likely to add to the base of knowledge? Is the project likely to generate novel information, methodology or approaches? Will the information ultimately be useful to decision-makers?

   There is little doubt that some studies of contaminant effects on fishes is warranted for the CALFED area. I have some concerns about this particular proposal and the approach, specifically about the exposure studies. Why use fathead minnows to look at effects on fishes in the CALFED area. I understand the appeal in terms of ease of culture and experience. The drawback is that if you just want to gain general knowledge of endocrine disrupting effects, why not seek EPA funding for this project. CALFED needs to know if and how much specific contaminants or mixtures of contaminants are impeding reproductive success of fishes in this system. I believe these investigators could have come up with a more management oriented project that could offer some specific recommendation and understanding of contaminant effects on fish reproduction that would be applicable directly to this system without the need to extrapolate.

4. **Feasibility.** Is the approach fully documented and technically feasible? What is the likelihood of success? Is the scale of the project consistent with the objectives?

   The technical feasibility of the study is high (literature survey, assay development, exposure studies) but the probability of clearly determining the population level effects of contaminants on populations of fishes in the CALFED solution area, even in a relative sense, seems unlikely.

5. **Project-Specific Performance Measures.** Does the project include appropriate performance measures to measure success relative to the project's goals and objectives? Is there enough detail as to how the performance measures will be quantified? For restoration projects, are monitoring plans explicit and detailed enough to determine if performance measures will be adequately assessed?

   Some performance measures are listed.

6. **Products.** Are products of value likely from the project? Specifically for restoration projects, are products of value also likely from the monitoring component? Are interpretative outcomes likely from the project?

   Several of the typical products are listed. Results from this project could help understand the scope of the problem with endocrine disruption in the CALFED area, but interpretive outcomes could prove elusive in terms of understanding population level effects and setting management standards for contaminants.

7. **Capabilities.** What is the track record of applicants in terms of past projects? Is the project team qualified to efficiently and effectively implement the proposed project? Do they have available the infrastructure and other aspects of support necessary to accomplish the project?

   The team definitely has the background to conduct the proposed studies and the infrastructure is available for the analyses.

8. **Cost/Benefit Comments.** Is the budget reasonable and adequate for the work proposed?

   The budget is very high, especially given some of the components such as a literature search. I understand that analytical costs for these kinds of studies are high but they take it to a new high. I am also not sure that the benefits derived from this study will truly put CALFED in a better position to make decisions regarding contaminants.

Miscellaneous comments:

External Scientific: #3

Research and Restoration External Scientific Review Form

Proposal Number: **6**

Applicant Organization: **Applied Marine Sciences, Inc.**

Proposal Title: **A survey of endocrine disrupting chemicals and occurrence of fish reproductive dysfunction in the CalFed solution area**

Conflict of Interest Statements:
I have no financial interest in this proposal.
XCorrect
-Incorrect

In the blank below please explain any connection to proposal, to applicant, co-applicant or subcontractor or to submitting institution (write "none" if no connection):

None

Review:

Please provide an overall evaluation summary rating:

Excellent: outstanding in all respects;
Good: quality but some deficiencies;
Poor: serious deficiencies.

Overall Evaluation Summary Rating	**Provide a brief explanation of your summary rating**
-Excellent	**While overall the proposed work is interesting and reasonably well supported by existing literature, some of the methods are sketchy at best, and the requested budget seems extraordinarily excessive. While the proponents have excellent credentials, the overall proposal is lacking in merit.**
XGood	
-Poor	

1. **Goals.** Are the goals, objectives and hypotheses clearly stated and internally consistent? Is the concept timely and important?

   The goal of this project is to identify potential endocrine disruption problems and reproductive dysfunction in the CALFED region in order to determine if the recovery of resident fish populations could be limited by water quality. This is a timely and important project, because of the existence of a number of listed species in this area, and because of strong evidence for the presence of endocrine-disrupting compounds in these waters.

   Hypotheses are clearly stated and consistent with the goal, i.e. that 1) reproductive toxicants present in the CALFED area occur in high enough concentrations to cause reproductive dysfunction in laboratory assays of fish and positive results in receptor-based assays and 2) resident species of fish that might benefit from restoration actions are significantly affected

by these chemicals.

Objectives for each year of the project are clearly outlined and consistent with goal and hypotheses:

1. Survey the literature and other existing data for available information on concentrations and spatial distributions of EDCs in the CALFED area and their potential to induce toxic effects. 2. Select sampling sites based on results; measure EDCs in water from these sites, and test for activity in receptor binding assays and fish bioassay. 3. Assess effects in resident fish, initially with waterborne exposure, and subsequently with sediment, diet, and in situ exposures.

Rating: Excellent

2. **Justification.** Is the study justified relative to existing knowledge? Is a conceptual model clearly stated in the proposal and does it explain the underlying basis for the proposed work? Is the selection of research, pilot or demonstration project, or a full-scale implementation project justified?

   The study is justified by existing knowledge. There is evidence of the presence of endocrine disrupting compounds in the CALFED areas, but limited information on their impacts, especially on protected species. The authors do a good job of presenting background information that explains the need for such a project, and presenting a conceptual model explaining the basis for the work.

   Rating: Very good

3. **Approach.** Is the approach well designed and appropriate for meeting the objectives of the project? Are results likely to add to the base of knowledge? Is the project likely to generate novel information, methodology or approaches? Will the information ultimately be useful to decision-makers?

   The authors propose a 3-phase approach to this study. Phase I will consist of a review of existing literature and available data on concentrations and spatial distributions of EDCs in the CALFED area; along with optimization of screening assays (i.e., small fish bioassay and receptor finding assays). Phase II will consist of a survey of local waters, with sites chosen on the basis of the results of the literature review, for concentrations of EDCs and for activity in the fish exposure and receptor binding assays. Phase III would involve field and laboratory studies with resident species to test for exposure to EDCs and reproductive dysfunction.

   Basically this approach is thoughtful and well-designed to achieve the goal of the project. It would generate considerable information on the extent to which estrogenic/androgenic substances are present in the aquatic environment in the CALFED area, as well as some new data on biological effects of these compounds on laboratory and native fishes. The approaches to be used are not really novel, but could be usefully applied to this area. The information should be useful to decision-makers because it would give them a better understanding of the extent to which these types of contaminants are a problem in CALFED waters, and the concentrations of these compounds that are associated with adverse effects.

   Rating: Very good

4. **Feasibility.** Is the approach fully documented and technically feasible? What is the likelihood of success? Is the scale of the project consistent with the objectives?

The proposed approach is generally well-documented and technically feasible, and the grasp of the authors, and the likelihood of producing useful results is high. However, there are some inconsistencies, omissions, and deficiencies in the project approach as it is described. For example:

For the fathead minnow bioassay.

*** The focus seemed to be on subadult animals and effects during gonadal development and spawning. Is there a component that would look at changes in sexual differentiation due to exposure at an early life stage (e.g., exposure of embryos?). How long will larvae be followed after spawning? It didnt sound as if this period would be long enough to check for abnormalities in sexual development or sex ratio.**

*** Exactly what will be done to set up and validate the bioassay during phase I is not described.**

*** It is not clear how the 3- month flow-through exposure assay will be conducted to test for effects of local waters. Would a model mixture be used based on the results of chemical analyses of water samples from the site? It doesnt seem like it would be feasible to use actual water from the sampling areas.**

For the receptor binding assays:

*** Estrogen and androgen receptor binding are definitely useful approaches but this type of screening could exclude compounds that exert effects through non-receptor mediated mechanisms. Also, for a study of this magnitude, would it also make sense to include other assays, e.g., binding to progesterone or thyroid receptors?**

For studies with resident fish:

*** The proposal was very vague about methodology for sediment/food chain exposures proposed for Phase III**

*** The proposal was vague about the investigators ability to identify and successfully conduct laboratory exposure studies with field-collected resident species, and included very limited information about potential target species.**

*** The list of endpoints to be measured in field-collected fish did not seem to include any measures of exposure except for P450 induction, which could be due to a number of chemicals, and not necessarily those that would interact directly with estrogen or androgen receptor. Aside from that there will be gonad histology and laboratory spawning studies for egg and larval viability. It seems that other measurements, such as plasma hormone measurements, or measurment of vitellogenin or zona radiata proteins as indicators of exposure xenoestrogens, could have been included as well for a study of this magnitude.**

Rating: Good

5. **Project-Specific Performance Measures.** Does the project include appropriate performance measures to measure success relative to the project's goals and objectives? Is there enough detail as to how the performance measures will be quantified? For restoration projects, are monitoring plans explicit and detailed enough to determine if performance measures will be adequately assessed?

Tasks, milestones, and deliverables are outlined clearly and should be adequate to assess the progress of the project. Quantification is basically whether or not these items are completed.

Rating: Very Good

6. **Products.** Are products of value likely from the project? Specifically for restoration projects, are products of value also likely from the monitoring component? Are interpretative outcomes likely from the project?

   The anticipated products from this project are journal articles and a final report. These should certainly be produced, and should contain useful information on concentrations of EDCs and their effects on some fish species in the CALFED region. It should be possible to identify areas where the presence of these substances in the aquatic environment could impede recovery of protected species. The authors also indicate that data will be available upon request for incorporation into regional database systems.

   Rating: Very good

7. **Capabilities.** What is the track record of applicants in terms of past projects? Is the project team qualified to efficiently and effectively implement the proposed project? Do they have available the infrastructure and other aspects of support necessary to accomplish the project?

   This team of investigators is very well qualified and have infrastructure and facilities to complete the project. They have done extensive work of similar type which has been successful.

   Rating: Excellent

8. **Cost/Benefit Comments.** Is the budget reasonable and adequate for the work proposed?

   This project request ~$3KK over three years, which seems excessive for the work to be accomplished. For example, in Year 1, the budget includes 236K simply for a review of existing literature and chemistry data. For slide reading, without any tissues collection or processing, 134K is requested. Similarly, 154 K is requested for set up of the small fish bioassay which appears to be all for salary and consulting fees, with nothing for supplies or equipment.

   Also, it is not clear why salary support is requested for the primary investigators, while at the same time, the same people are receiving additional funds as consulting fees.

   Rating: Poor

Miscellaneous comments:

Environmental Compliance:

Proposal Number: 6

Applicant Organization: Applied Marine Sciences, Inc.

Proposal Title: A survey of endocrine disrupting chemicals and occurrence of fish reproductive dysfunction in the CalFed solution area

1. Are the legal or regulatory issues that affect the proposal identified adequately in the proposal?

   -Yes **X**No

   If no, please explain:

   It is unclear whether fathead minnows will be collected in the field or are already reared in the laboratory. If they will be collected, a scientific collecting permit from CDFG will be required. A 1601 will be required for grab sampling. If phase II and III are to be funded, a scientific collecting permit will be required. I can not determine other permits that may be required because no species or sampling sites were listed in the proposal.

2. Does the project's timeline and budget reflect adequate planning to address legal and regulatory issues that affect the proposal?

   -Yes **X**No

   If no, please explain:

   The applicant did not budget time or money for permit fees.

3. Do the legal and regulatory issues that affect the proposal significantly impair the project's feasibility?

   XYes **-**No

   If yes, please explain:

   If the applicant consults with CDFG to determine which permits are required, and obtains those permits, then the project is feasible.

Other Comments:

Budget:

Proposal Number: 6

Applicant Organization: Applied Marine Sciences, Inc.

Proposal Title: A survey of endocrine disrupting chemicals and occurrence of fish reproductive dysfunction in the CalFed solution area

1. Does the proposal include a detailed budget for each year of requested support?

   XYes **-**No

   If no, please explain:

2. Does the proposal include a detailed budget for each task identified?

   XYes **-**No

   If no, please explain:

3. Does the proposal clearly state the type of expenses encompassed in indirect rates or overhead costs?

   XYes **-**No

   If no, please explain:

4. Are appropriate project management costs clearly identified?

   XYes **-**No

   If no, please explain:

5. Do the total funds requested (Form I, Question 17A) equal the combined total annual costs in the budget summary?

   -Yes **X**No

   If no, please explain (for example, are costs to be reimbursed by cost share funds included in the budget summary).

   There is approximately a $53,000 difference between their budget and 17A and no cost share indicated

6. Does the budget justification adequately explain major expenses?

   XYes **-**No

If no, please explain:

7. Are there other budget issues that warrant consideration?

   -Yes **X**No

   If yes, please explain:

Other Comments: