EXHIBIT 7

Draft

Comments from Metolachlor RED (April 1995) and Initiation Package (Dec 2002)

RED General comments

1. The endangered species statement in the RED references the ESPP as identifying all pesticides whose use may cause adverse impacts to T&E species and to implement mitigation measures. The statement further asserts that use restrictions would be required to protect T&E species. It references future FR notices and county bulletins, and because of that future program, no label modifications are imposed through the RED document. It concludes that requirements for product use modification will occur under the ESPP. At present, NOAA Fisheries Service has numerous problems with the ESPP, as drafted, and may not consider it to be sufficient to avoid jeopardy of threatened and endangered salmonids.

In addition, based on EPA's risk categorization, the ecological exposure and risk characterization in the RED identified the following exceedances of the levels of concern (LOC):

- endangered species LOC for freshwater fish
- restricted use LOC for marine/estuarine invertebrates
- restricted use LOC for freshwater molluscs
- endangered species LOC for marine/estuarine invertebrates
- adverse effects expected to occur to non-target terrestrial and aquatic plants.

This information supports the conclusion that use of metolachlor may cause direct and/or indirect adverse effects to endangered freshwater fish and marine/estuarine invertebrates or adversely modify designated critical habitat. This conclusion can be supplemented with data on metolachlor's high mobility in sandy/loamy soils and moderate mobility in other soils (clays and sandy loams), its high persistence, and that metolachlor could be available for runoff to surface water for several months post-application. The RED states that metolachlor is "among the top five pesticides in terms of frequency of detection...and it is detected in a high percentage of surface water samples...for several months post-application."

At present, the only label statements direct applicators not to apply the product directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. There are directions not to contaminate water when disposing of equipment washwater, and not to apply where runoff is likely to occur. Lastly, the label prohibits the application when the weather conditions favor drift from the treated area. There are no restrictions or prohibitions or mention of protections for threatened and endangered species or designated critical habitat.

The draft ESPP (FRN Vol. 67, No. 231, Dec. 2, 2002, 71549-71561pp.) proposes an implementation program that captures the FIFRA responsibilities and requirements while remaining in compliance with the ESA. However, the draft ESPP does not appear to broadly protect listed species such that they could survive and recover in the wild. As an example, it does not **require** mitigative measures such as label modifications or use restriction, but rather **requests** that labels be amended. In the case of metolachlor, this approach leaves a large gap of protection for T&E species. This is an obvious oversight on EPA's part and needs to be

rectified, particularly when the RED identifies risks for T&E species.

2. The degradates appear to be fairly mobile, both subsurface and overland in a variety of agricultural soils, however no information about their toxicity has been provided. This is a significant oversight as these degradates appear fairly persistant, will be found primarily in solution as opposed to adsorbed to sediment particles, and are in the atrazine family. The toxicity of the degradates should be determined.

Questions from the RED

1. Appendix B. Appendix B identifies that there is a data gap associated with the life cycle test for invertebrates. Has that data gap been filled? Has that information been factored in to a revised risk assessment? The droplet size spectrum and drift field evaluation are identified as reserved. Has new information been incorporated into the risk assessment? Please describe how ecological effects and environmental fate tests are only driven by terrestrial food, feed and/or non-food use patterns and other tests such as toxicity are driven by all use patterns.

2. p. 5. Estimated Metolachlor usage. The regulatory history section on page 6 identifies that metolachlor was first registered for use on turf, but has now expanded to food/feed and non-food crops. The table on page 5 does not provide any turf uses for the compound. What are the estimated use amounts on turf?

1. p. 5. What does it mean to have "placed the Tier III study requirements on reserve? Have these studies been conducted? If they have been conducted, have they been incorporated into an updated risk assessment? If they have been conducted, NOAA Fisheries Service would like to obtain the data.

What Spray Drift information has been developed? NOAA Fisheries Service would like to obtain a copy of the information.

Has degradates toxcitiy been identified? If degradate toxicity information exists, NOAA Fisheries Service would like to obtain the data.

2. p. 26. Have the confirmatory early fish life-stage studies for chronic toxicity been conducted? It is unclear how EPA can register a pesticide when not all of the tests have been completed, particularly when the endangered species acute level of concern has been exceeded? Please provide all data that have been submitted since the completion of the RED.

3. p. 31. What is known about the toxicity of the degradates? If the information on toxicologic risk of degradates must be reported to EPA (40 CFR 159.179), how can EPA register the pesticide when that information has not been supplied? Please provide all data that have been submitted since the completion of the RED.

4. p. 32. Have recent (since 1996) studies shed any light on the question of the binding of metolachlor to organic matter? Please provide all data that have been submitted since the completion of the RED.

The ½ life of metolachlor appears to be under debate. Its ½ lives are described as in excess of 270 days under aerobic conditions, and 14-103 days from different crop and soil types. Has this issue been further clarified and a more definitive ½ life determined?

5. p. 35. Have recent (since 1996) studies provided additional information on the "unknowns" about bioaccumulation. The relatively high octanol/water coefficient of metolachlor (log K_{ow} = 3.46) is counter-intuitive to the low bioconcentration seen in the flow-through studies. Please provide all data that have been submitted since the completion of the RED.

6. p. 37. What are the findings of the Spray Drift Task Force regarding droplet size spectrum, droplet size evaluation and all other factors? Please provide a copy of the Task Force report.

7. p. 42. What is the basis for the 1% spray drift value? Has that value been modified since the Drift Spray Task Force has convened?

Initiation Package General Comments

1. The initiation packages do not clearly identify the scope of the action area, rather they only refer to the 26 ESUs. Consultation under section 7 of the ESA requires the identification of an action area. Please identify whether you are requesting consultation on metolachlor in Washington, Oregon, Idaho and/or California. An action area is defined as all areas to be affected directly and indirectly by the Federal action and not merely the immediate area involved in the action (50 C.F.R. 402.02). The action area could be any state in which the pesticide is registered for use, plus any waters outside of a state in which it has been registered that may be affected by its use because of downstream effects. In other words, the spatial extent of the direct and indirect effects of the action define the action area.

2. To comply with section 7 regulations [50 C.F.R. 402.14(c)], the action agency is required to include in the initiation package/biological assessment an analysis of any cumulative effects that may result from the Federal action. The cumulative effects analysis should evaluate the likely effects of future non-Federal activities in the action area that are reasonably certain to occur and that will effect salmonids. This includes but is not limited to the use of pesticides other than the ones being evaluated and how they interact with the pesticide under consultation. This requires, in turn, consideration of baseline environmental conditions in salmonid habitat (current state of relevant habitat conditions such as streamflow, temperature and other physical, chemical and biological attributes). Salmonids are exposed to many stressors other than pesticides, and this

may affect their sensitivity to exposure to specific pesticides.

From the standpoint of multiple stressors, the potential exists for a pesticide to cause additive, or synergistic toxicity when it co-occurs with other registered pesticides. As is evident from recent U.S. Geological Survey National Water Quality Assessment (NAWQA) studies in several western basins, pesticides frequently enter salmonid habitat as mixtures. The labels themselves often allow mixing. This raises the possibility of multiple effects attributed solely to pesticide mixtures.

Multiple toxicity effects can be antagonistic, additive, or synergistic. For example, if metolachlor and a second pesticide have a common mechanism of toxicity, the potential for additive effects should be evaluated if the second pesticide is also expected to occur in salmon or steelhead habitat. For example, S. Anderson, as part of an EPA grant (National Center for Environmental Research, grant # R826603), looking at the "Genetic Diversity in California Native Fish Exposed to Pesticides", has detected metolachlor, as well as other pesticides in the study sites' water. That study identified a genotoxic effect of induction of DNA strand breaks correlated with the onset of the pesticide pulse. Under the Food Quality Protection Act of 1996, EPA must assess the cumulative effects of pesticides and other chemicals that demonstrate a common mechanism of toxicity to human health. The initiation package/biological assessment for the metolachlor consultations should address these same multiple effect concerns for the health of salmonids and the aquatic food chain. EPA must conduct the search for such effects and provide them in the initiation package.

3. According to EPA's internal *Guidelines for Ecological Risk Assessment* (Federal Register 63(93):26846-26924, May 14, 1998), the first phase of an ecological risk assessment is the formulation of the problem. This provides the foundation for the entire assessment. The problem formulation phase involves the selection of assessment endpoints, or explicit expressions of the actual environmental value that is to be protected. Assessment endpoints are operationally defined by an ecological entity and its attributes. The EPA Hazard Evaluation Division Standard Evaluation Procedure Ecological Risk Assessment guidance (June 1986) does not address the topic of problem formulation. In addition, the document identifies a suite of generic tests for use in ecological risk assessment. It does not allow for variation based on species specificity or targeted effects

In the context of the ESA, the ecological entities are threatened or endangered salmonids, and the assessment endpoints are the essential biological requirements of salmon and steelhead. Thus, salmonid essential biological requirements are the environmental values that are to be protected. To be consistent with EPA's (1998) internal guidelines, assessment endpoints need to be explicitly defined before a risk assessment proceeds. If they are not defined, or if assessment endpoints are vague, the subsequent stages of a risk assessment will be compromised.

The "endangered species risk assessment" documents submitted by EPA do not clearly define the essential biological requirements of salmonids. Although the metolachlor risk assessment states

that direct effects result from exposure to a pesticide at levels that may cause harm, there is no explicit consideration of "harm", the form of assessment endpoints and risk hypotheses. Moreover, the risk assessment states that "relevant acute data are derived from standardized toxicity tests with lethality as the primary endpoint". This conveys the incorrect impression that direct mortality (*i.e.*, fish kills) is the only assessment endpoint that is relevant to the question of "harm". In fact, acute or chronic sublethal endpoints are also relevant if they have clear significance for the survival, reproductive success, recovery, or migratory success of salmon and steelhead.

To summarize, the "endangered species risk assessment" document for metolachlor submitted by EPA contains critical gaps in the problem formulation phase. This is due to the fact that the assessment is predicated on an Environmental Risk Assessment developed for another purpose (e.g. the registration of metolachlor) in the context of an entirely different federal statute (FIFRA). Therefore, for the purposes of a section 7 consultation, the problem, assessment endpoints, and risk hypotheses should be revised and re-described. If the revised endpoints are significantly different from the existing assessment, the entire risk assessment should be re-run.

4. The effect determination submitted by EPA does not adequately define the scientific basis for using the "standard endangered species criterion of the Risk Quotient exceeding 0.05". A pesticide may have multiple modes of action (or toxicity), hence, justification is needed for using LC_{50} data to as the sole means of determining toxicity, to the exclusion of essential physiological and behavioral systems of salmonids.

It is not clear whether the risk approach takes a balanced approach to "error". Despite the recognition of a high degree of uncertainty, NOAA Fisheries Service is concerned that the ecological risk assessment may conclude that a pesticide does not pose an ecological risk, when in fact, it does (a "Type II error"). The lack of information on chronic sublethal effects, or effects posed by degradates, mixtures, surfactants, adjuvants and inert (other) ingredients, can very quickly lead to Type II errors. In addition, lack of information on exposure potential (i.e., we don't know whether use occurs, so we assume that it does not occur) can also lead to Type II errors.

The philosophical approach of risk assessment, attempting to conclude that a pesticide poses an ecological risk, when it does not (a "Type I error") can pose problems when evaluating the effects to listed species and designated critical habitat. Statistically, minimizing the likelihood of Type I error increases the risk of Type II error (assuming that sample sizes are relatively small, which is appropriate for pesticides such as metolachlor). This imbalance should be identified, addressed, and eliminated.

5. The effects of an action are differentiated by three determinations. The "no effect" determination is made when the action will have no effect on the listed species or critical habitat. The "may affect" determination if further differentiated into two parts. The "may affect, not likely to adversely affect" determination is made when the action is determined to be

insignificant and discountable. The "may affect, likely to adversely affect" determination is made when the effects of the action rise to the level such that "take", which is incidental to the action, is likely to occur. The effects determinations in the conclusion of the initiation package only differentiates between "no effect" and "may affect". This needs to be clarified. **(Raise this issue verbally with Larry Turner. The main issue is to confirm that the "may affect" are LAA.)**

In addition, what is EPA's interest in regards to NOAA Fisheries Service consultation on the "no effect" determinations?

6. The data in the initiation package for metolachlor originated primarily from the RED (written in 1996). For example, in the case of use information, the data in the RED were derived from nationwide information. As a result, neither the maps nor the information on usage, such as pounds of product applied, can be readily translated to the location of this consultation. As appropriate, region-specific information should be provided, and if not available, estimated to the greatest extent.

7. Potential conservation measures have been identified in the section in the initiation package that compares the ESUs and metolachlor use area. Those potential conservation measures include buffers to minimize runoff and drift into surface waters, and/or restriction of application to the ground. Other than working with the Washington State Department of Agriculture to develop applicable protective measures for Washington State, how, when, where, and with whom does EPA propose implement these potential conservation measures? Are there other potential conservation measures proposed?

Initiation Package Specific Comments

1. p. 1. Summary. The first paragraph states that metolachlor is not likely to occur in surface waters in high enough concentrations to directly impact listed salmon. However, the RED (p. 38) states that "substantial amounts could be available for runoff to surface waters for several months post-application". This difference must be reconciled.

The summary also states that metolachlor is slightly to moderately toxic to freshwater animals. The RED identifies that the LOC for endangered freshwater fish and that estuarine/marine fish and invertebrates may be adversely impacted. In addition, the Pesticide Action Network (PAN) identified metolachlor as being a high developmental or reproductive toxin and has an average LC50 of 5.05ppb for rainbow trout (from EPA AQUIRE database). Given the potential for greater exposure than described and the higher toxicity than identified, the ESA effect calls may need to be modified.

2. p. 4, fourth paragraph. The second sentence states that very many of the inerts are in "exceedingly small amounts". That appears to be a misrepresentation as the labels for the

metolachlor products list inerts ranging from 54.95 - 58.0%. That misrepresentation should be rectified. If product formulation testing is driving by the amount of inert ingredient in the product, there could be a significant oversight in which formulations get tested.

The last sentence speaks to a "sufficient quantity" of inerts in the product to warrant concern and having OPP attempt to evaluate the potential effects. As mentioned above, there is a concern about what constitutes "sufficient quantity" if 54.95 - 58.0% is considered to be an "exceedingly small amount". How can that disparity be eliminated? In addition, are there any sequence steps or criteria to determine how formulated products get "black box" tested? Have metolachlor formulations been "black box" tested?

3. p. 4, last paragraph. What fish toxicity tests are conducted on formulated products?

4. p. 5. second paragraph. Given NOAA Fisheries Service's concern about the potential effect of inert ingredients, the lack of toxicity data from formulated products is a great concern. How can this program be revised to enhance this information which is critical for decision making?

Discussions about the GENEEC model and older models is unclear. Please explain how the exposure scenario of a 10 hectare watershed draining into a 1 hectare pond that is 2 meters deep can be compared to a stream or river where salmon spawning, rearing or migration would occur.

5. p. 9, second paragraph and Table 2. The Hazard Evaluation Division Standard Evaluation Procedure (June 1986) does not describe the risk quotient approach. Please provide more background for this approach and describe how the risk quotients were derived. It would be very helpful to provide an example using the metolachlor product.

6. p. 8. Designated critical habitat. Do any data exist to substantiate the assertion that sediment loading from destruction, due to the high toxicity of metolachlor to terrestrial plants, of low herbaceous material growing in designated critical habitat is insignificant when compared to initial cultivation of fields?

7. pp. 10-11. The section on sublethal effects references the work by Moore and Waring (1996) and Scholz et al (2000) on diazinon. This section appears to be extracted directly from the diazinon consultation initiation package. The relevance of this diazinon discussion to the sublethal effects of metolachlor is unclear. Please provide clarification.

8. p. 13. Table 3. Information about product usage within the action area should be provided or, at best, estimated from a worst case.

9. p.14. a. Aquatic toxicity of metolachlor. Has any formulated product testing (acute and chronic) been conducted on metolachlor? NOAA Fisheries Service is particularly interested in toxicity information from the formulation that contains 58.0% inert ingredients.

10. p. 16. Table 8. Have any chronic toxicity studies of metolachlor been found in the literature?

11. p. 18. b. Environmental fate and transport. first paragraph. It appears that two degradates are produced under aerobic metabolism and that OPP has conducted toxicity tests. The degradate toxicity data were not provided in the RED. Those data should be included in this initiation package.

12. p. 21. Table 12. The PAN database identified metolachlor as being a high developmental or reproductive toxin and having an average LC50 of 5.05ppb for rainbow trout (from EPA AQUIRE database). That value should be incorporated into the fate and transport modeling and the results should be reported. What are the bases for the revised risk quotients?

e. Changes in registration status. When were the SLN registrations issued for California, Oregon, and Washington? Were any specific label changes required in association with these SLNs?

13. p. 22. f. General risk conclusions. The finding that acute risk levels of concern to fish are not exceeded by the estimated exposure values may be incorrect. The lower value of 5.05ppb for rainbow trout should be incorporated into the model and it should be re-run.

According to the RED, metolachlor is "toxic to terrestrial plant species at levels significantly below the maximum label rate of 3.2 pounds active ingredient/acrea". Given the level of toxicity of this herbicide to terrestrial plants, an analysis of effects of non-target contact with riparian vegetation should be provided. In addition, the RED indicates that metolachlor is highly toxic to aquatic plants. The effects of non-target drift, surface runoff, or groundwater discharge should also be analyzed for aquatic vegetation as part of the indirect effects on the food chain.

14. p. 23. What is known about the compliance success of the county bulletins in California? What is know about the efficacy of the protective measures for keeping the pesticides out of the water?

15. p.24. 4. Listed salmon and steelhead ESUs and comparison with metolachlor use areas. Is metolachlor registered for homeowner use in Oregon, Washington or Idaho?

15. p. 24. The use of metolachlor can be estimated by current cropping patterns by county. The Washington Department of Agriculture is developing a geospatially-referenced database which includes land use and pesticide monitoring data and produces GIS-based maps and data spreadsheets. This information can be furnished upon request. If possible, that information should be provided for all states within the action area.

16. p. 37. third paragraph. The initiation package does not include cropping information when only a single grower or two occurs in a county. The lack of that information could be critical if the grower's land resides adjacent to or upstream of a salmon or steelhead spawning, rearing or migratory corridor. If that information can be obtained it should be reported.

17. pp. 67-68. Table 50. As discussed above in the general comments, EPA must differentiate their "may affect" calls between "not likely to adversely affect" and "likely to adversely affect".