Tebuthiuron
Analysis of Risks
to
Endangered and Threatened Pacific Salmon and Steelhead

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Summary

Tebuthiuron is a member of the substituted urea class of herbicides registered nationally for control of weeds, grasses, woody plants and brush on pastures, rangeland and many non-agricultural industrial sites as rights of way, railway beds, ditch banks and uncultivated areas. A Reregistration Eligibility Document (RED) that includes an ecological risk assessment for fish, aquatic invertebrates and aquatic plants was issued in 1994. Tebuthiuron is practically nontoxic to freshwater fish and invertebrates, and estuarine molluscs and crustaceans. The one exception is for estuarine shrimp, whose toxicity from exposure to tebuthiuron is in the "moderately toxic" category. Tebuthiuron is less toxic to aquatic vascular plants than to green algae and diatoms. The Estimated Environmental Concentrations (EECS) were modeled with Tier II PRZM/EXAMS models using available scenarios that represent climatic and soil conditions in the area which encompass California, Washington, Oregon, and Idaho or are suitable surrogates for the uses of the herbicide. Selected tebuthiuron use scenarios included pastureland, rangeland, rights-of-ways, ditch banks, and other general non-cropland uses. Acute and chronic risk quotients calculated from these EECS and available toxicity data indicate no direct risk to endangered fish, aquatic invertebrate populations, and aquatic vegetation. We conclude that tebuthiuron will not present a direct effect on Pacific salmon and steelhead, no indirect effects based on the loss of their aquatic invertebrate food supply and no indirect effects based on loss of aquatic plant cover.

Introduction

Problem formulation: The purpose of this analysis is to determine whether the registration of tebuthiuron as an herbicide for use on various treatment sites may affect threatened and endangered (T&E or listed) Pacific anadromous salmon and steelhead and their designated critical habitat.

Scope: Although this analysis is specific to listed Pacific anadromous salmon and steelhead and the watersheds in which they occur, it is acknowledged that tebuthiuron is registered for uses that may occur outside this geographic scope and that additional analyses may be required to address other T&E species in the Pacific states as well as across the United States.

Contents

1. Background

Under section 7 of the Endangered Species Act, the Office of Pesticide Programs (OPP) of the U. S. Environmental Protection Agency (EPA) is required to consult on actions that may affect Federally listed endangered or threatened species or that may adversely modify designated critical habitat. Situations where a pesticide may affect a fish, such as any of the salmonid species listed by the National Marine Fisheries Service (NMFS), include either direct or indirect effects on the fish. Direct effects result from exposure to a pesticide at levels that may cause harm.

Acute Toxicity - Relevant acute data are derived from standardized toxicity tests with lethality as the primary endpoint. These tests are conducted with what is generally accepted as the most sensitive life stage of fish, i.e., very young fish from 0.5-5 grams in weight, and with species that are usually among the most sensitive. These tests for pesticide registration include analysis of observable sublethal effects as well. The intent of acute tests is to statistically derive a median effect level; typically the effect is lethality in fish (LC50) or immobility in aquatic invertebrates (EC50). Typically, a standard fish acute test will include concentrations that cause no mortality, and often no observable sublethal effects, as well as concentrations that would cause 100% mortality. By looking at the effects at various test concentrations, a dose-response curve can be derived, and one can statistically predict the effects likely to occur at various pesticide concentrations; a well-done test can even be extrapolated, with caution, to concentrations below those tested (or above the test concentrations if the highest concentration did not produce 100%

mortality).

OPP typically uses qualitative descriptors to describe different levels of acute toxicity, the most likely kind of effect of modern pesticides (Table 1). These are widely used for comparative purposes, but must be associated with exposure before any conclusions can be drawn with respect to risk. Pesticides that are considered highly toxic or very highly toxic are required to have a label statement indicating that level of toxicity. The FIFRA regulations [40CFR158.490(a)] do not require calculating a specific LC50 or EC50 for pesticides that are practically non-toxic; the LC50 or EC50 would simply be expressed as >100 ppm. When no lethal or sublethal effects are observed at 100 ppm, OPP considers the pesticide will have "no effect" on the species.

Table 1. Qualitative descriptors for categories of fish and aquatic invertebrate toxicity (from Zucker, 1985)

LC50 or EC50	Category description
< 0.1 ppm	Very highly toxic
0.1- 1 ppm	Highly toxic
>1 < 10 ppm	Moderately toxic
> 10 < 100 ppm	Slightly toxic
> 100 ppm	Practically non-toxic

Comparative toxicology has demonstrated that various species of scaled fish generally have equivalent sensitivity, within an order of magnitude, to other species of scaled fish tested under the same conditions. Exceptions are known to occur for only an occasional pesticide, as based on the several dozen fish species that have been frequently tested. Sappington et al. (2001), Beyers et al. (1994) and Dwyer et al. (1999), among others, have shown that endangered and threatened fish tested to date are similarly sensitive, on an acute basis, to a variety of pesticides and other chemicals as are their non-endangered counterparts.

Chronic Toxicity - OPP evaluates the potential chronic effects of a pesticide on the basis of several types of tests. These tests are often required for registration, but not always. If a pesticide has essentially no acute toxicity at relevant concentrations, or if it degrades very rapidly in water, or if the nature of the use is such that the pesticide will not reach water, then chronic fish tests may not be required [40CFR158.490]. Chronic fish tests primarily evaluate the potential for reproductive effects and effects on the offspring. Other observed sublethal effects are also required to be reported. An abbreviated chronic test, the fish early-life stage test, is usually the first chronic test conducted and will indicate the likelihood of reproductive or chronic effects at relevant concentrations. If such effects are found, then a full fish life-cycle test will be conducted. If the nature of the chemical is such that reproductive effects are expected, the abbreviated test may be skipped in favor of the full life-cycle test. These chronic tests are designed to determine a “no observable effect level” (NOEL) and a “lowest observable effect level” (LOEL). A chronic risk requires not only chronic toxicity, but also chronic exposure, which can result from a chemical being persistent and resident in an environment (e.g., a pond) for a chronic period of time or from repeated applications that transport into any environment such that exposure would be considered “chronic”.

As with comparative toxicology efforts relative to sensitivity for acute effects, EPA, in conjunction with the U. S. Geological Survey, has a current effort to assess the comparative toxicology for chronic effects also. Preliminary information indicates, as with the acute data, that endangered and threatened fish are again of similar sensitivity to similar non-endangered species.

Metabolites and Degradates - Information must be reported to OPP regarding any pesticide metabolites or degradates that may pose a toxicological risk or that may persist in the environment [40CFR159.179]. Toxicity and/or persistence test data on such compounds may be required if, during the risk assessment, the nature of the metabolite or degradate and the amount that may occur in the environment raises a concern. If actual data or structure-activity analyses are not available, the requirement for testing is based upon best professional judgement.

Inert Ingredients - OPP does take into account the potential effects of what used to be termed “inert” ingredients, but which are beginning to be referred to as “other ingredients”. OPP has classified these ingredients into several categories. A few of these, such as nonylphenol, can no longer be used without including them on the label with a specific statement indicating the potential toxicity. Based upon our internal databases, I can find no product in which nonylphenol is now an ingredient. Many others, including such ingredients as clay, soybean oil, many polymers, and chlorophyll, have been evaluated through structure-activity analysis or data and determined to be of minimal or no toxicity. There exist also two additional lists, one for inerts with potential toxicity which are considered a testing priority, and one for inerts unlikely to be toxic, but which cannot yet be said to have negligible toxicity. Any new inert ingredients are required to undergo testing unless it can be demonstrated that testing is unnecessary.

The inerts efforts in OPP are oriented only towards toxicity at the present time, rather than risk. It should be noted, however, that very many of the inerts are in exceedingly small amounts in pesticide products. While some surfactants, solvents, and other ingredients may be present in fairly large amounts in various products, many are present only to a minor extent. These include such things as coloring agents, fragrances, and even the printers ink on water soluble bags of pesticides. Some of these could have moderate toxicity, yet still be of no consequence because of the negligible amounts present in a product. If a product contains inert ingredients in sufficient quantity to be of concern, relative to the toxicity of the active ingredient, OPP attempts to evaluate the potential effects of these inerts through data or structure-activity analysis, where necessary.

For a number of major pesticide products, testing has been conducted on the formulated end-use products that are used by the applicator. The results of fish toxicity tests with formulated products can be compared with the results of tests on the same species with the active ingredient only. A comparison of the results should indicate comparable sensitivity, relative to the percentage of active ingredient in the technical versus formulated product, if there is no extra activity due to the combination of inert ingredients. I note that the “comparable” sensitivity must take into account the natural variation in toxicity tests, which is up to 2-fold for the same species in the same laboratory under the same conditions, and which can be somewhat higher between different laboratories, especially when different stocks of test fish are used.

The comparison of formulated product and technical ingredient test results may not provide specific information on the individual inert ingredients, but rather is like a “black box” which sums up the effects of all ingredients. I consider this approach to be more appropriate than testing each individual inert and active ingredient because it incorporates any additivity, antagonism, and synergism effects that may occur and which might not be correctly evaluated from tests on the individual ingredients. I do note, however, that we do not have aquatic data on most formulated products, although we often have testing on one or perhaps two formulations of an active ingredient.

Risk - An analysis of toxicity, whether acute or chronic, lethal or sublethal, must be combined with an analysis of how much will be in the water, to determine risks to fish. Risk is a combination of exposure and toxicity. Even a very highly toxic chemical will not pose a risk if there is no exposure, or very minimal exposure relative to the toxicity. OPP uses a variety of chemical fate and transport data to develop “estimated environmental concentrations” (EECS) from a suite of established models. The development of aquatic EECS is a tiered process.

The first tier screening model for EECS is with the GENEEC program, developed within OPP, which uses a generic site (in Yazoo, MS) to stand for any site in the U. S. The site choice was intended to yield a maximum exposure, or “worst-case,” scenario applicable nationwide, particularly with respect to runoff. The model is based on a 10 hectare watershed that surrounds a one hectare pond, two meters deep. It is assumed that all of the 10 hectare area is treated with the pesticide and that any runoff would drain into the pond. The model also incorporates spray drift, the amount of which is dependent primarily upon the droplet size of the spray. OPP assumes that if this model indicates no concerns when compared with the appropriate toxicity data, then further analysis is not necessary as there would be no effect on the species.

It should be noted that prior to the development of the GENEEC model in 1995, a much more crude approach was used to determining EECS. Older reviews and Reregistration Eligibility Decisions (REDs) may use this approach, but it was excessively conservative and does not provide a sound basis for modern risk assessments. For the purposes of endangered species consultations, we will attempt to revise this old approach with the GENEEC model, where the old screening level raised risk concerns.

When there is a concern with the comparison of toxicity with the EECS identified in GENEEC model, a more sophisticated PRZM-EXAMS model is run to refine the EECS if a suitable scenario has been developed and validated. The PRZM-EXAMS model was developed with widespread collaboration and review by chemical fate and transport experts, soil scientists, and agronomists throughout academia, government, and industry, where it is in common use. As with the GENEEC model, the basic model remains as a 10 hectare field surrounding and draining into a 1 hectare pond. Crop scenarios have been developed by OPP for specific sites, and the model uses site-specific data on soils, climate (especially precipitation), and the crop or site. Typically, site-scenarios are developed to provide for a worst-case analysis for a particular crop in a particular geographic region. The development of site scenarios is very time consuming; scenarios have not yet been developed for a number of crops and locations. OPP attempts to match the crop(s) under consideration with the most appropriate scenario. For some of the older OPP analyses, a very limited number of scenarios were available. As more scenarios become available and are geographically appropriate to selected T&E species, older models used in previous analyses may be updated.

One area of significant weakness in modeling EECS relates to residential uses, especially by homeowners, but also to an extent by commercial applicators. There are no usage data in OPP that relate to pesticide use by homeowners on a geographic scale that would be appropriate for an assessment of risks to listed species. For example, we may know the maximum application rate for a lawn pesticide, but we do not know the size of the lawns, the proportion of the area in lawns, or the percentage of lawns that may be treated in a given geographic area. There is limited information on soil types, slopes, watering practices, and other aspects that relate to transport and fate of pesticides. We do know that some homeowners will attempt to control pests with chemicals and that others will not control pests at all or will use non-chemical methods. We would expect that in some areas, few homeowners will use pesticides, but in other areas, a high percentage could. As a result, OPP has insufficient information to develop a scenario or address the extent of pesticide use in a residential area.

It is, however, quite necessary to address the potential that home and garden pesticides may affect T&E species, even in the absence of reliable data. Therefore, I have developed a hypothetical scenario, by adapting an existing scenario, to address pesticide use on home lawns where it is most likely that residential pesticides will be used outdoors. It is exceedingly important to note that there is no quantitative, scientifically valid support for this modified scenario; rather, it is based on my best professional judgement. I do note that the original scenario, based on golf course use, does have a sound technical basis, and the home lawn scenario is effectively the same as the golf course scenario. Three approaches will be used. First, the treatment of fairways, greens, and tees will represent situations where a high proportion of homeowners may use a pesticide. Second, I will use a 10% treatment to represent situations where only some homeowners may use a pesticide. Even if OPP cannot reliably determine the percentage of homeowners using a pesticide in a given area, this will provide two estimates. Third, where the risks from lawn use could exceed our criteria by only a modest amount, I can back-calculate the percentage of land that would need to be treated to exceed our criteria. If a smaller percentage is treated, this would then be below our criteria of concern. The percentage here would be not just of lawns, but of all of the treatable area under consideration; but in urban and highly populated suburban areas, it would be similar to a percentage of lawns. Should reliable data or other information become available, the approach will be altered appropriately.

It is also important to note that pesticides used in urban areas can be expected to transport considerable distances if they should run off on to concrete or asphalt, such as with streets (e.g., TDK Environmental, 2001). This makes any quantitative analysis very difficult to address aquatic exposure from home use. It also indicates that a no-use or no-spray buffer approach for protection, which we consider quite viable for agricultural areas, may not be particularly useful for urban areas.

Finally, the applicability of the overall EEC scenario, i.e., the 10 hectare watershed draining into a one hectare farm pond, may not be appropriate for a number of T&E species living in rivers or lakes. This scenario is intended to provide a "worst-case" assessment of EECS, but very many T&E fish do not live in ponds, and very many T&E fish do not have all of the habitat surrounding their environment treated with a pesticide. OPP does believe that the EECS from the farm pond model do represent first order streams, such as those in headwaters areas (Effland, et al. 1999). In many agricultural areas, those first order streams may be upstream from pesticide use, but in other areas, or for some non-agricultural uses such as forestry, the first order streams may receive pesticide runoff and drift. However, larger streams and lakes will very likely have lower, often considerably lower, concentrations of pesticides due to more dilution by the receiving waters. In addition, where persistence is a factor, streams will tend to carry pesticides away from where they enter into the streams, and the models do not allow for this. The variables in size of streams, rivers, and lakes, along with flow rates in the lentic waters and seasonal variation, are large enough to preclude the development of applicable models to represent the diversity of T&E species' habitats. We can simply qualitatively note that the farm pond model is expected to overestimate EECS in larger bodies of water.

Indirect Effects - We also attempt to protect listed species from indirect effects of pesticides. We note that there is often not a clear distinction between indirect effects on a listed species and adverse modification of critical habitat (discussed below). By considering indirect effects first, we can provide appropriate protection to listed species even where critical habitat has not been designated. In the case of fish, the indirect concerns are routinely assessed for food and cover.

The primary indirect effect of concern would be for the food source for listed fish. These are best represented by potential effects on aquatic invertebrates, although aquatic plants or plankton may be relevant food sources for some fish species. However, it is not necessary to protect individual organisms that serve as food for listed fish. Thus, our goal is to ensure that pesticides will not impair populations of these aquatic arthropods. In some cases, listed fish may feed on other fish. Because our criteria for protecting the listed fish species is based upon the most sensitive species of fish tested, then by protecting the listed fish species, we are also protecting the species used as prey.

In general, but with some exceptions, pesticides applied in terrestrial environments will not affect the plant material in the water that provides aquatic cover for listed fish. Application rates for herbicides are intended to be efficacious, but are not intended to be excessive. Because only a portion of the effective application rate of an herbicide applied to land will reach water through runoff or drift, the amount is very likely to be below effect levels for aquatic plants.

Some of the applied herbicides will degrade through photolysis, hydrolysis, or other processes. In addition, terrestrial herbicide applications are efficacious in part, due to the fact that the product will tend to stay in contact with the foliage or the roots and/or germinating plant parts, when soil applied. With aquatic exposures resulting from terrestrial applications, the pesticide is not placed in immediate contact with the aquatic plant, but rather reaches the plant indirectly after entering the water and being diluted. Aquatic exposure is likely to be transient in flowing waters. However, because of the exceptions where terrestrially applied herbicides could have effects on aquatic plants, OPP does evaluate the sensitivity of aquatic macrophytes to these herbicides to determine if populations of aquatic macrophytes that would serve as cover for T&E fish would be affected.

For most pesticides applied to terrestrial environment, the effects in water, even lentic water, will be relatively transient. Therefore, it is only with very persistent pesticides that any effects would be expected to last into the year following their application. As a result, and excepting those very persistent pesticides, we would not expect that pesticidal modification of the food and cover aspects of critical habitat would be adverse beyond the year of application. Therefore, if a listed salmon or steelhead is not present during the year of application, there would be no concern. If the listed fish is present during the year of application, the effects on food and cover are considered as indirect effects on the fish, rather than as adverse modification of critical habitat.

Designated Critical Habitat - OPP is also required to consult if a pesticide may adversely modify designated critical habitat. In addition to the indirect effects on the fish, we consider that the use of pesticides on land could have such an effect on the critical habitat of aquatic species in a few circumstances. For example, use of herbicides in riparian areas could affect riparian vegetation, especially woody riparian vegetation, which possibly could be an indirect effect on a listed fish. However, there are very few pesticides that are registered for use on riparian vegetation, and the specific uses that may be of concern have to be analyzed on a pesticide by pesticide basis. In considering the general effects that could occur and that could be a problem for listed salmonids, the primary concern would be for the destruction of vegetation near the stream, particularly vegetation that provides cover or temperature control, or that contributes woody debris to the aquatic environment. Destruction of low growing herbaceous material would be a concern if that destruction resulted in excessive sediment loads getting into the stream, but such increased sediment loads are insignificant from cultivated fields relative to those resulting from the initial cultivation itself. Increased sediment loads from destruction of vegetation could be a concern in uncultivated areas. Any increased pesticide load as a result of destruction of terrestrial herbaceous vegetation would be considered a direct effect and would be addressed through the modeling of estimated environmental concentrations. Such modeling can and does take into account the presence and nature of riparian vegetation on pesticide transport to a body of water.

Risk Assessment Processes - All of our risk assessment procedures, toxicity test methods, and EEC models have been peer-reviewed by OPP's Science Advisory Panel. The data from toxicity tests and environmental fate and transport studies undergo a stringent review and validation process in accordance with "Standard Evaluation Procedures" published for each type of test. In addition, all test data on toxicity or environmental fate and transport are conducted in accordance with Good Laboratory Practice (GLP) regulations (40 CFR Part 160) at least since the GLPs were promulgated in 1989.

The risk assessment process is described in "Hazard Evaluation Division - Standard Evaluation Procedure - Ecological Risk Assessment" by Urban and Cook (1986) (termed Ecological Risk Assessment SEP below), which has been separately provided to National Marine Fisheries Service staff. Although certain aspects and procedures have been updated throughout the years, the basic process and criteria still apply. In a very brief summary: the toxicity information for various taxonomic groups of species is quantitatively compared with the potential exposure information from the different uses and application rates and methods. A risk quotient of toxicity divided by exposure is developed and compared with criteria of concern. The criteria of concern presented by Urban and Cook (1986) are presented in Table 2.

Table 2. Risk quotient criteria for direct and indirect effects on T&E fish

Test data	Risk quotient	Presumption
Acute LC_{50}	>0.5	Potentially high acute risk
Acute LC_{50}	>0.1	Risk that may be mitigated through restricted use classification
Acute LC_{50}	>0.05	Endangered species may be affected acutely, including sublethal effects
Chronic NOEC	>1	Chronic risk; endangered species may be affected chronically, including reproduction and effects on progeny
Acute invertebrate LC_{50}[a]	>0.5	May be indirect effects on T&E fish through food supply reduction
Aquatic plant acute EC_{50}[a]	>1[b]	May be indirect effects on aquatic vegetative cover for T&E fish

a. Indirect effects criteria for T&E species are not in Urban and Cook (1986); they were developed subsequently.
b. This criterion has been changed from our earlier requests. The basis is to bring the endangered species criterion for indirect effects on aquatic plant populations in line with EFED's concern levels for these populations.

The Ecological Risk Assessment SEP (pages 2-6) discusses the quantitative estimates of how the acute toxicity data, in combination with the slope of the dose-response curve, can be used to predict the percentage mortality that would occur at the various risk quotients. The discussion indicates that using a "safety factor" of 10, as applies for restricted use classification, one individual in 30,000,000 exposed to the concentration would be likely to die. Using a "safety factor" of 20, as applies to aquatic T&E species, would exponentially increase the margin of safety. It has been calculated by one pesticide registrant (without sufficient information for OPP to validate that number), that the probability of mortality occurring when the LC50 is 1/20th of the EEC is 2.39×10^{-9}, or less than one individual in ten billion. It should be noted that the discussion (originally part of the 1975 regulations for FIFRA) is based upon slopes of primarily organochlorine pesticides, stated to be 4.5 probits per log cycle at that time. As organochlorine pesticides were phased out, OPP undertook an analysis of more current pesticides based on data reported by Johnson and Finley (1980), and determined that the "typical" slope for aquatic toxicity tests for the "more current" pesticides was 9.95. Because the slopes are based upon logarithmically transformed data, the probability of mortality for a pesticide with a 9.95 slope is again exponentially less than for the originally analyzed slope of 4.5.

The above discussion focuses on mortality from acute toxicity. OPP is concerned about other direct effects as well. For chronic and reproductive effects, our criteria ensures that the EEC is below the no-observed-effect-level, where the "effects" include any observable sublethal effects. Because our EEC values are based upon "worst-case" chemical fate and transport data and a small farm pond scenario, it is rare that a non-target organism would be exposed to such concentrations over a period of time, especially for fish that live in lakes or in streams (best professional judgement). Thus, there is no additional safety factor used for the no-observed-effect-concentration, in contrast to the acute data where a safety factor is warranted because the endpoints are a median probability rather than no effect.

Sublethal Effects - With respect to sublethal effects, Tucker and Leitzke (1979) did an extensive review of existing ecotoxicological data on pesticides. Among their findings was that sublethal effects as reported in the literature did not occur at concentrations below one-fourth to one-sixth of the lethal concentrations, when taking into account the same percentages or numbers affected, test system, duration, species, and other factors. This was termed the "6x hypothesis". Their review included cholinesterase inhibition, but was largely oriented towards externally observable parameters such as growth, food consumption, behavioral signs of intoxication, avoidance and repellency, and similar parameters. Even reproductive parameters fit into the hypothesis when the duration of the test was considered. This hypothesis supported the use of lethality tests for use in assessing acute ecotoxicological risk, and the lethality tests are well enough established and understood to provide strong statistical confidence, which can not always be achieved with sublethal effects. By providing an appropriate safety factor, the concentrations found in lethality tests can therefore generally be used to protect from sublethal effects. As discussed earlier, the entire focus of the early-life-stage and life-cycle chronic tests is on sublethal effects.

In recent years, Moore and Waring (1996) challenged Atlantic salmon with diazinon and observed effects on olfaction as relates to reproductive physiology and behavior. Their work indicated that diazinon could have sublethal effects of concern for salmon reproduction. However, the nature of their test system, direct exposure of olfactory rosettes, could not be quantitatively related to exposures in the natural environment. Subsequently, Scholz et al. (2000) conducted a non-reproductive behavioral study using whole Chinook salmon in a model stream system that mimicked a natural exposure that is far more relevant to ecological risk assessment than the system used by Moore and Waring (1996). The Scholz et al. (2000) data indicate potential effects of diazinon on Chinook salmon behavior at very low levels, with statistically significant effects at nominal diazinon exposures of 1 ppb, with apparent, but non-significant effects at 0.1 ppb.

It would appear that the Scholz et al (2000) work contradicts the 6x hypothesis for acute effects. The research design, especially the nature and duration of exposure, of the test system used by Scholz et al (2000), along with a lack of dose-response, precludes comparisons with lethal levels in accordance with the 6x hypothesis as used by Tucker and Leitzke (1979). Nevertheless, it is known that olfaction is an exquisitely sensitive sense. And this sense may be particularly well developed in salmon, as would be consistent with its use by salmon in homing (Hasler and Scholz, 1983). So the contradiction of the 6x hypothesis is not surprising. As a result of these findings, the 6x hypothesis needs to be re-evaluated with respect to olfaction. At the same time, because of the sensitivity of olfaction and because the 6x hypothesis has generally stood the test of time otherwise, it would be premature to abandon the hypothesis for other acute sublethal effects until there are additional data.

2. Description of Tebuthiuron:

A. Chemical History: Tebuthiuron is a member of the substituted urea class of herbicides and was first registered in 1974. It is used to control broadleaf and woody weeds, grasses, woody plants and brush on feed crop sites and non-food crop sites. It is a relatively nonselective, soil activated herbicide that acts by inhibiting photosynthesis via absorption through plant roots. It requires rain to move into the root zone. It is considered a "specialty herbicide" as its use sites are limited to specific nonagricultural sites, and it is not marketed for the homeowner. It provides total vegetation control in that it will kill, over time all vegetation in the area being treated. Treatment sites include pasture and rangeland, and outdoor industrial areas such as: airports and landing fields; utility substations; rights of way; tank farms; railway roadbeds and ballast; railroad rights of way; road shoulders where no vegetation is desired; at base of highway guardrails; signposts and markers at the base of transmission towers and poles; around industrial buildings; lumberyards; ditch banks; railroad yards; firebreaks; fencerows; hedgerows; uncultivated areas and soils; and under paved roads and sidewalks where no future landscaping is planned. The industrial treatment sites are referred to as "industrial vegetation management". The primary uses include rangeland and pastureland, railroad and electrical utility rights of way, industrial facilities and pipelines.

The treated plants go through several defoliation cycles before they die. The time required to achieve control of woody vegetation may vary from one to several years; it typically takes one to three years to completely eliminate vegetation in the treated area.

It is formulated as granular pelleted/tableted (20% active ingredient), wettable powder [80% active ingredient (a.i.)], water dispersible granules (80% a.i.) and granular products (1%, 2% and 5% a.i.). The 1% and 2% granular formulations contain 3% diuron and 6% diuron, respectively. The 20% pelleted formulation (Spike 20P®) is the only one registered for use on pastureland and rangeland. All formulations, including Spike 20P®, are registered for use on many industrial sites and noncrop areas. It can be applied by aircraft (Spike 20P® only), backpack sprayer, hand-held sprayer, mechanical granule applicator, shaker can, spreader, tank-type sprayer. Methods of application include band, broadcast, soil band, soil broadcast, and spot treatments. Manufacture of the 40% pelleted formulation was discontinued in 1996/1997. The records from OPP's Registration Division still list it as an active product, but it is not listed by Dow AgroSciences on their website (www.Dow AgroSciences.com) as a currently registered product.

B: Chemical Description:

- ❏ Common Name: Tebuthiuron
- ❏ Chemical Name: N-[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-N,N'dimethylurea
- ❏ Chemical Family: Substituted urea
- ❏ Case Number: 0054
- ❏ CAS Registry Number: 34014-18-1

C. Summary of Labeled Uses:

General directions – Treatments become effective after sufficient rainfall has occurred to move the active ingredient into the root zone. It can be applied at any time when the ground is not frozen or saturated with water. For best brush control results, do not disturb intact plants by such practices as wood cutting, chaining or burning for two years after application. Dormant season application is recommended to minimize herbicidal effects on grasses and other herbaceous plants.

Do not apply to any portion of ditch banks that will come into direct contact with water as movement of tebuthiuron products into the water may result in injury or death of nontarget plant species or to ditches used to transport irrigation or potable water.

Limitations on application rates are placed on the use of tebuthiuron products in "vulnerable areas" that are defined as areas where the soils are sandy and the depth of the water table is shallow".

Nongranular Products

Rangeland and pastureland - In vulnerable sites, apply no more than 1 lb a.i./A in areas with less than 20 inches annual rainfall, and no more than 2 lb a.i./A in areas with more than 20 inches annual rainfall. Do not apply more than once per year when treating herbaceous vegetation. The maximum use rate is 1 to 2 lb a.i./a once every 3 years for broadcast applications for vulnerable sites.

In non-vulnerable sites apply no more than 2 lb a.i./A in areas with less than 20 inches annual rainfall, and no more than 4 lb a.i./A in areas with more than 20 inches annual rainfall. The maximum use rate is up to 4 lb a.i./A once every 3 years and no more than 2 treatments totaling 6 lb a.i./A in any 6-year period.

It can be applied by air or ground equipment for broadcast treatments or by hand for treatment of individual plants or clumps of plants.

To control woody plants on rangeland and pastureland, apply from 0.75 to 4 lb a.i./A, depending on the species of plant being controlled.

Noncropland, including industrial sites – In vulnerable sites, apply no more than 1 lb a.i./A in areas with less than 20 inches annual rainfall, and no more than 2 lb a.i./A in areas with more than 20 inches annual rainfall. Do not apply more than once per year when treating herbaceous vegetation. The maximum use rate is 1 to 2 lb a.i./a once every 3 years for broadcast applications for vulnerable sites.

In non-vulnerable sites apply no more than 2 lb a.i./A in areas with less than 20 inches annual rainfall, and no more than 4 lb a.i./A in areas with more than 20 inches annual rainfall. The maximum use rate is up to 4 lb a.i./A once every 3 years and no more than 2 treatments totaling 6 lb a.i./A in any 6-year period.

Broadcast applications can be done with aerial equipment with the Spike 20P® formulation only. The maximum use rate and frequency by ground broadcast application to achieve total vegetation control and maintenance of bare ground is a rate up to 4 lb a.i./A allied only once per year, with no more than 6 lb a.i./a being applied in any 3-year period. Spot treatments by hand-held equipment may occur at rates up to 6 lb a.i./A when needed.

Woody plants may also be controlled by banded methods, in addition to broadcast and spot treatments. Apply from 0.75 to 4 lb a.i./A, depending on the species of plant being controlled.

There are two 2(ee) registrations for Spike 20P®. The first is for control of pinyon pine and oneseed, Utah and Rocky Mountain juniper in Arizona, California, Colorado, Idaho Nevada, New Mexico, Oregon, Utah and Wyoming. The product can be applied by air or ground equipment at 1 to 2 lb a.i./A prior to seasonal rainfall. The second is a reduced rate application for big sagebrush canopy cover reduction in Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Oregon, South Dakota, Utah, Washington and Wyoming. It may be applied at 0.2 to 0.5 lb a.i./A to thin, but not eliminate, sagebrush cover in pasture and rangelands.

Granular Products

Railroad rights of way, under paved surfaces, ditch banks, industrial areas (unspecified) – The granules are applied with a seed or fertilizer spreader, or a shaker type applicator. It is applied at 2 to 6 lb a.i./A or 1.5 to 4 lb a.i./A as a spot treatment directly to the ground. Treatment can be repeated if deep-rooted perennial weeds are present.

For broadcast and banded treatments the maximum label rate is 2 lb a.i./A once every 3 years in vulnerable areas. For all other areas apply one time in a 3-year period at rates up to 4 lb a.i./A. However, no more than 6 lb a.i./A may be applied in 2 consecutive treatments in any 6-year period.

Woody plants in industrial areas – Treated area-wide or by individual plants. Individual (spot) treatment – hand toss 2 oz. of granules around the base of each unwanted woody stem. Broadcast – with a mechanical spreader– at rates equivalent to 2 to 6 lb a.i./A. The broadcast rate depends on the species of woody plant(s) being removed.

General weed control and buried cable closures, telephone booths, cross-connect boxes, transformer pads and fire plugs – The granules are applied with a seed or fertilizer spreader, or a shaker type applicator. It is applied at 2 to 6 lb a.i./A or 1.5 to 4 lb a.i./A as a spot treatment directly to the ground. Treatment can be repeated if deep-rooted perennial weeds are present.

D. Estimated Usage of Tebuthiuron

We have no recent national data on the amount of tebuthiuron applied annually in the U.S. The 1994 RED provided national usage data for tebuthiuron. The use information was updated in 2001 and 2002 by the Biological and Economic Analysis Division (BEAD) for the 2002 TRED (Tolerance Reregistration Eligibility Document), but this newer information is based on data from 1999. Dow AgroSciences supplied Confidential Business Information (CBI) to OPP for use in development of the TRED along with non-CBI information on the typical use rates and areas of use of the several tebuthiuron formulations. These data are also from 1999. The CBI data are proprietary and are protected by FIFRA definitions of Confidential Business Information (CBI) under Section 10 (d)(1)(A), (B) and (C).

The information from the registrant indicates that tebuthiuron is used on pasture lands and rangelands to provide long-term control of tough woody brush species. It is used for rangeland improvement and reclamation and for enhancement of wildlife habitat. Its primary use on these sites is in the states of Texas, Oklahoma and New Mexico. It is generally broadcast via aerial applications to these sites during the growing season of April to October.

The use of tebuthiuron for industrial vegetation management (IVM) is to provide extended control of woody brush or achieve total bare ground, and to enhance public safety and access along roadsides, utility rights of way and several industrial sites. The railroad sites are treated annually, commonly by ground boom sprayer. Approximately every three years these sites are rotated to other herbicide products as part of a resistance management program. For other industrial sites, it is generally applied annually for two to three years followed by rotation to other products. Applications occur via ground boom, handgun or backpack sprayer. Woody plant control in industrial sites occurs generally once each maintenance cycle which is typically every three to eight years.

The CBI data, in general terms, indicates that relatively little tebuthiuron is used in California and the PNW on pasture and range lands in terms of pounds of active ingredient sold or acres treated. Slightly more is used in Idaho than California, and relatively none is used in Oregon and Washington. With regard to IVM, the four states rank in use by California, Idaho, Washington and Oregon. California uses significantly more than the other three states which use relatively little on these sites.

The Quantitative Usage Analysis (BEAD, 2/28/02), that is based on data available to EPA and on expert opinion, states that the total number of pounds of tebuthiuron declined between the years 1996 through 1999 by approximately 40 percent from an estimated 230,000 pound a.i. per year to less than 195,000 pounds a.i. per year. In 1999, the distribution of the total annual pounds of tebuthiuron applied was 37 percent for pasture and rangeland, 29% for railroad rights of way and 28 percent for electric utilities. Industrial facilities and pipelines accounted for only 5.5 percent of the total pounds of tebuthiuron applied. In terms of the percentage of the acres for treated in 1999, an average of less than one percent of rangeland and pasture land acreage was treated up to an estimated maximum two percent of acres treated annually. For the miles of railroad and utility rights of way treated annually, the average percentage of miles treated was less than one percent. For rangeland and railroad applications rates averaged about 2 lb a.i./A for each. Application of tebuthiuron to rangeland and railroads typically occur once every ten to twenty years for rangeland, once every two to three years for weed control and once every three to eight years for woody plant control on railroads.

Some additional data from the 1990s also are available from the U.S. Geological Survey (USGS) (http://ca.water.usgs.gov/cgi-bin/pnsp/pesticide_use_maps_1997.pl?map=W1963). The USGS estimated county pesticide use for the conterminous United States by combining (1) state-level information on pesticide use rates available from the National Center for Food and Agricultural Policy from pesticide use information collected by state and federal agencies over a 4-year period (1995 - 1998), and (2) on 1997 Census of Agriculture county crop acreage. This map is included here as a quick and easy visual depiction of where tebuthiuron may have been used. However, it should not be used for any quantitative analysis, as it does not include noncropland sites or sites for industrial vegetation management. Refer to the attached map from The map indicates that the use of tebuthiuron on pastureland occurs in Oklahoma and Pennsylvania only. California and the three Pacific Northwest (PNW) states, Washington, Oregon and Idaho do not use tebuthiuron on pastures according to these data.

We are not aware of any comprehensive sources of annual pesticide use information for Oregon, Washington or Idaho. Oregon is attempting to implement full pesticide-use reporting but has not yet done so. However, Washington State Department of Agriculture (WSDA, unpublished report, 2004) provided us with information regarding the present use of tebuthiuron in that state.

Tebuthiuron is a restricted use pesticide in Washington. It is typically sprayed or spread dry on the soil surface preferably just before or during the time of active weed growth. A single application is normally effective for several years. Washington State Department of Transportation (WSDOT) has not used tebuthiuron for roadside weed management in the past three years, and have no plans to include the herbicide in the pest management program in the future. If it is used on non-cropland sites and rights of way, it is typically used in the fall east of the Cascades and in the spring west of the Cascades. Neither is tebuthiuron used on irrigated pasture in Washington. Typically, non-irrigated pasture and rangeland is not treated with herbicides. If used on pasture and rangeland, it is applied before seasonal rains to get the most rapid response. A single application is normally effective for several years.

We found additional information that seems to corroborate the information we received from WSDA. A report published by Washington State University Extension (Howard and Parker, http://cru.cahe.wsu.edu/CEPublications/eb1551/eb1551.html) states that tebuthiuron should not be used to control woody plants in western Washington due to the presence of shallow water tables there.

At the state and county level, more data are available for tebuthiuron use in California than in Oregon, Washington, and Idaho. California requires full pesticide-use reporting by most applicators (excluding homeowners), and the California Department of Pesticide Regulation (DPR) provides the information at the county level (www.cdpr.ca.gov/docs/pur/purmain.htm).

DPR reports annual use trends of the more commonly used pesticides in the state. The Annual reports for California indicate that only were applied throughout the state. Table 3 present the uses and amounts of active ingredient applied in 2001 and 2002. Approximately 8600 to 12,000 pounds of tebuthiuron were used in both years. As a comparison, 48,000 to 55,000 pounds of diuron, the herbicide that is formulated in two of the granular products with tebuthiuron, was used for landscape maintenance in California the same years.

Table 3. Uses of tebuthiuron in California in 2001 and 2002 (Source: California DPR Pesticide Use Report)

2001			2002		
Commodity	**lb a.i.**	**Amount treated[1]**	**Commodity**	**lb a.i.**	**Amount treated[1]**
Animal premises	16	11			
Landscape maintenance	3413	NA	Landscape maintenance	1715	NA
Rights of way	4987	NA	Rights of way	10,042	NA
Structural pest control	6	NA	Structural pest control	3	NA
Uncultivated ag	1	7	Uncultivated ag	10	12

Uncultivated non-ag	218	226	Uncultivated non-ag	43	56
Chemical total	8,639		Chemical total	11,813	

[1]Amount treated = cumulative areas or units treated over time with the active ingredient.
[2]NA = Not available

3. General Aquatic Risk Assessment for Endangered and Threatened Salmon and Steelhead

A. Aquatic Toxicity

The acute toxicity data indicate that technical grade tebuthiuron is practically nontoxic to freshwater fish and invertebrates, and estuarine molluscs and crustaceans. The one exception is for estuarine shrimp, whose toxicity from exposure to tebuthiuron is in the "moderately toxic" category. Tests of fish conducted with a 20% pelleted formulation and an 80% water - soluble formulation indicated they are also practically nontoxic to this group of animals. Adverse chronic effects on survival and growth of freshwater fish occurred at exposure concentrations of 18 ppm for fathead minnow and 52 ppm for rainbow trout. Growth and fecundity of freshwater invertebrates occurred at an exposure concentration of 44.2 ppm tebuthiuron.

The data from the RED and the EFED database are presented in Tables 4 through 8, and the data from the AQUIRE database are presented in Table 9.

Table 4. Acute toxicity of tebuthiuron to freshwater fish (source: EFED Pesticide Ecotoxicity Database and RED)

Species	Scientific Name	% ai	96-h LC 50 (ppm)	Toxicity Category
Rainbow trout	*Oncorhynchus mykiss*	98	143	Practically nontoxic
Bluegill sunfish	*Lepomis macrochirus*	98	106	Practically nontoxic
Fathead minnow	*Pimephales promelas*	98	> 180	Practically nontoxic
Fathead minnow	*Pimephales promelas*	80	> 180	Practically nontoxic
Fathead minnow	*Pimephales promelas*	20	> 180	Practically nontoxic
Goldfish	*Carassius auratus*	98	> 160	Practically nontoxic

Table 5. Acute toxicity of tebuthiuron to freshwater invertebrates (source: EFED Pesticide Ecotoxicity Database and RED)

Species	Scientific Name	% ai	48-h LC 50 (ppm)	Toxicity Category
Waterflea	*Daphnia magna*	99.2	297	Practically nontoxic

Table 6. Acute toxicity of tebuthiuron to estuarine fish and invertebrates (source: EFED Pesticide Ecotoxicity Database and RED)

Species	Scientific Name	% ai	96-h LC 50 (ppm)	Toxicity Category
Pink shrimp	*Panaeus duorarum*	98	62	Moderately toxic
Eastern oyster	*Crassostrea virginica*	98	>180<320	Practically nontoxic
Fiddler crab	*Uca pugilator*	98	>100	Practically nontoxic

Table 7. Chronic toxicity of tebuthiuron to fish and invertebrates (source: EFED Pesticide Ecotoxicity Database and RED)

Species	Scientific Name	% ai	Duration	Endpoints affected	NOEC (ppm)	LOEC (ppm)
Fathead minnow	*Pimephales promelas*	98	28 days	growth	9.3	18
Rainbow trout	*Oncorhynchus mykiss*	98	45 days	growth and survival	26	52
Waterflea	*Daphnia magna*	97.4	21 days	growth and fecundity	21.8	44.2

OPP does not categorize toxicity to plants. However, the data indicate that tebuthiuron is less toxic to aquatic vascular plants than to green algae and diatoms.

Table 8. Acute toxicity of tebuthiuron to aquatic plants (source: EFED Pesticide Ecotoxicity Database and RED)

Species	Scientific Name	% ai	NOEC (ppm)	EC50 (ppm)
Duckweed	*Lemna gibba*	99.08	<0.066	0.135 (14-D)
Freshwater diatom	*Navicula pelliculosa*	99.08	0.056	0.081 (5-D)
Green algae	*Selenastrum capricornutum*	98.0	0.013	0.05 (5-D)
Blue-green algae	*Anabaena flos-aquae*	99.08	0.31	4.06 (5-D)
Marine diatom	*Skeletonema costatum*	99.08	0.031	0.05 (5-D)

There are some aquatic toxicity data for tebuthiuron from EPA's AQUIRE database (http://www.epa.gov/ecotox/). We did not look at the original papers but report the toxicity values for the toxicity test periods that are analogous to the those required by OPP testing requirements as a means of comparison. The AQUIRE reference numbers for each reported value are provided. There were only two data values reported in AQUIRE for tebuthiuron that are analogous in the endpoints measured

The AQUIRE database is not always reliable regarding the test being with the formulation or the active ingredient; unless the test indicates an active ingredient, it is inputted into AQUIRE as formulation testing. However, we have seen values reported for the technical material in Mayer & Ellersieck (1986) to be reported in AQUIRE as a formulation test We report the information on formulation versus active ingredient, but we need to note that it is not completely reliable.

Table 9. Summary of acute toxicity data from the EPA AQUIRE database.

Species	Scientific Name	Test Chemical*	96-h LC 50 (ppm)	Reference
Freshwater Fish				
Japanese eel	*Anguilla japonica*	Form.	> 40 (48-h)	8570
Freshwater Plants				
Green algae	*Selenastrum capricornutum*	Active	0.307 (14-d)	2576

* Form. = Test was conducted with formulated products. The product composition and percent active ingredient were not given.
Active = Test was conducted with the active ingredient, but the percent dichlobenil was not given.

There are two granular formulations of tebuthiuron that also contain diuron. The risks of diuron to Pacific salmonids were addressed in an earlier consultation (Diuron, Analysis of Risks to Endangered and Threatened Pacific Salmon and Steelhead, Larry Turner, July 31, 2003; http://www.epa.gov The toxicity data indicate that diuron is moderately toxic to fish and highly toxic to invertebrates.

B. Environmental Fate (This information comes from pages 18 to 21 of the RED.)

Tebuthiuron is persistent and mobile and can leach to ground water. Tebuthiuron is stable to hydrolysis and photodegradation in water with these half-lives greater than 30 days. It is also stable to aerobic and anaerobic metabolism in soil and water. It is highly soluble in water, and it has a low potential to adsorb to soil. The principal route of dissipation appears to be transport to ground water through leaching and to surface water by solubilizing in the runoff. Therefore, tebuthiuron is likely to persist in the soil at the site of application, in water and in sediment.

An interim terrestrial field dissipation study supports the results of the laboratory data. In California, Nebraska and Florida field half-lives were estimated at one to 2two years. In California tebuthiuron moved into the six to twelve inch soil depth.

The bioaccumulation study done with bluegill fish exposed the fish to a nominal concentration of 5.0 ppm for 28 days. The bioconcentration factors (BCFs) for edible tissue, nonedible tissue and whole fish were 1.98, 3.40 and 2.63, respectively.

C. Field Monitoring Studies (This information comes from pages 27 to 28 of the RED.)

Field monitoring studies may be required on a case-by-case basis depending on the intended use pattern of the chemical, the toxicity to non-target organisms, and pertinent environmental fate characteristics. Tebuthiuron is extremely persistent in the soil. especially in areas of low precipitation. Tebuthiuron is also highly soluble in water, suggesting a high potential for transport from the application site. When applied over extensive areas, as in the case of rangeland brush control, tebuthiuron would seem to have a high potential for contamination of aquatic systems within the watershed. For these reasons, monitoring studies measuring residues in runoff waters, hydrosoil, and catchment ponds were required. Instead of a single monitoring study, several studies were submitted by the registrant.

The initial monitoring studies show that tebuthiuron moves from the application site through runoff. It is detectable in the runoff water and in ponds receiving runoff from the treated watershed. Maximum residue levels in catchment ponds ranged from 12 ppb to 70 ppb under conditions of normal rainfall. After a single rainfall event of 7 inches, tebuthiuron levels of 180 ppb were detected m one pond. Maximum levels in hydrosoil ranged from 70 ppb - 140 ppb. The acceptable field monitoring studies are summarized in the following table:

Table 10. Summary of Four Field Monitoring Studies for Tebuthiuron Conducted from 1981 to 1984.

Location	Application Rate (one appl)	Maximum Residues of Tebuthiuron	Calculated % Lost from the Watershed
Boise, Idaho	1.0 lb ai/A	Catchment pond = 12 ppb. Weir (runoff from entire watershed) = 14 ppb. Spring = 7 ppb.	1.9%
Arizona	3.0 lb ai/A	Weir pond = 33 ppb. Weir (runoff from entire watershed) = 54 ppb.	0.05%
Hondo. Texas	2.0 lb ai/A	Catchment pond = 70 ppb. Hydrosoil = 70 ppb.	0.08%
Marietta, Oklahoma	2.0 lb ai/A	Catchment pond = 180 ppb (following a 7" rainfall event). Hydrosoil = 140 ppb.	4.53%

In 1982, the registrant was requested to continue monitoring water and hydrosoil at the various study sites, especially in the catchment pond at the Marietta, Oklahoma site. This information was considered essential in order to better determine the long-term availability of tebuthiuron for runoff into aquatic systems and the likelihood of long-term buildup of tebuthiuron in the hydrosoil. The supplemental information indicated that following the single application to each site in 1981 (1980 for Idaho) tebuthiuron is lost over time (three years) such that the concentrations decrease to a very low level of 0.0003 ppm (0.3 ppb) to undetectable levels. However, residues may remain in the soil surrounding the catchments, particularly the lower soil layers.

D. Incidents

OPP maintains two databases of reported incidents. The Ecological Incident Information System (EIIS) contains information on environmental incidents which are provided voluntarily to OPP by state and federal agencies and others. There have been periodic solicitations for such information to the states and the U. S. Fish and Wildlife Service. The second database is a compilation of incident information known to pesticide registrants and any data conducted by them that shows results differing from those contained in studies provided to support registration. These data and studies (together termed incidents) are required to be submitted to OPP under regulations implementing FIFRA section 6(a)(2).

We are aware of only three incident reports for tebuthiuron , and all involved terrestrial plants in Florida, New Mexico and Oregon.

E. Actual and Estimated Concentrations of Tebuthiuron in Water

Measured concentrations in water

There is a limited amount of water monitoring data for tebuthiuron.

The U.S. Geological Survey (USGS) summarized NAWQA (National Water Quality Assessment) data for several river basin study units and compared those findings with the NAWQA national range for each compound detected. Circular 1160 for Water Quality in the Upper Snake River Basin, Idaho and Wyoming, 1992 - 1995, indicates that tebuthiuron was detected in 1% of the surface water samples in the range of ~0.0.01 ppb to ~0.1 ppb. Circular 1144 for Central Columbia Plateau, Washington and Idaho, 1992 - 1995 indicates that tebuthiuron was detected in 7% of the surface water samples in the range of ~0.005 ppb to ~0.09 ppb. Circular 1159 for the San Joaquin-Tulare Basins, 1992 - 1995, indicates that tebuthiuron was detected in 2% of the surface water samples in the range of ~0.001 ppb to ~0.2 ppb. Circular 1161 for the Willamette Basin, Oregon, 1991 - 1995, indicates that tebuthiuron was detected in 15% of the surface water samples in the range of ~0.002 ppb to ~0.2 ppb. The USGS freshwater-chronic criterion for the protection of aquatic life for tebuthiuron is ~2 ppb. All of the detections were below this criterion.

We must note that the NAWQA sampling data, while considered high quality, are not targeted to sites and times where tebuthiuron is used. Even regular sampling according to a predetermined schedule may not detect peak residues unless the samples happen to be taken shortly afterwards and adjacent to sites treated with tebuthiuron . It seems likely, but may not be correct, that when samples are taken, the highest NAWQA residues may actually represent peaks that occur in natural waters.

The California DPR Surface Water Database summary data was surveyed for any detections of tebuthiuron. These data were last updated April 2003. There were relatively few detections of tebuthiuron. Sacramento County had ten measurable detections in the period from January 29, 1997 to February 16, 2000 that ranged from 0.013 ppb in January 1998 to 3.00 ppb in July 1999. Yolo County had only one measurable detection of 0.023 ppb in January 1994. The only other county with measurable detections was Sutter County with eleven detections in the period from January 25, 1994 to February 20, 1994. The residue concentrations ranged from 0.025 ppb to 1.00 ppb.

WSDA provided us with maps depicting sampling sites and measurable detections of tebuthiuron in surface water from 1995 to 2004 for steelhead, chinook, chum and sockeye ESUs. The maps indicate that the highest range of residues measured in these ESUs was 0.041 to 0.095 ppb.

Estimated environmental concentrations(EECS)

In the environmental risk assessment in the 1994 RED, OPP's Environmental Fate and Effects Division (EFED) used an earlier version of the PRZM and EXAMS models used by EFED than is currently used. They used New York to represent a pastureland scenario receiving more than 20 inches of rain per year, with an application rate of 6 lb a.i./A, and Oklahoma to represent a rangeland scenario receiving less than 20 inches of rain per year, with an application rate of 2 lb a.i./A. These two states are not representative of the soils found in California and the PNW states. Also the 6 lb/A rate is only used as a spot treatment and not a broadcast treatment. Broadcast treatments, even if applied at lower rates than spot treatments, are more likely to enter aquatic habitats than are spot treatments. As the EECS in the RED were not adequate for this consultation, EFED provided us with new EEC calculations based on PRZM/EXAMS models specific for this consultation.

Tier II PRZM/EXAMS modeling was conducted to estimated the impacts of runoff and spray drift of tebuthiuron from a 10 ha field on estimated environmental concentrations in a small, static water body. Standard PRZM/EXAMS exposure scenarios were selected to best represent specific crops in the area of the consultation. Selected scenarios for tebuthiuron are shown in Table 11. The available scenarios represent climatic and soil conditions in the area which encompass California, Washington, Oregon, and Idaho or are suitable surrogates for the uses requested under this action. Selected tebuthiuron use scenarios included pastureland, rangeland, rights-of-ways, ditch banks, and other general non-cropland uses.

Table 11. Requested and Available Modeling Scenarios Used in Tier II Modeling

Requested Exposure Scenario		Best Available Standard Modeling Scenarios		
State	**Crop**	**State**	**Crop**	**MLRA**
California, Oregon, Washington, Idaho	Pastures Rangeland, and other Non-Crop land	California	Alfalfa	17
		Minnesota	Alfalfa	56
		Oregon	Grass Grown for Seed	2

		Pennsylvania	Alfalfa	148
		Texas	Alfalfa	86

Surrogate agricultural exposure scenarios were selected to represent pastureland, rangeland, and other non-crop land uses because readily available peer reviewed scenarios for pastureland and rangeland do not exist and the remaining non-crop land uses (e.g., ditch banks, railroad and highway rights-of-ways) require modeling approaches which have yet to be developed. Where scenarios were within major land resource areas (MLRA) that match requested regions of the action area, these scenarios were used as surrogates for the requested crops (Austin, 1972). The MLRA represents land resource mapping units which are based on agricultural production and land resources within states and regions. They were designed to allow for regional agricultural planning.

All EECS are based on one yearly aerial application of a granular formulation at 4 lb a.i./A with no soil incorporation. Estimated environmental concentrations of tebuthiuron are shown in Table 12. Peak concentrations of tebuthiuron ranged from 0.54 to 7.0 µg/L. The concentrations estimated based on surrogate scenarios are expected to be high-end exposures for these use site. However, it is important to note that under certain conditions, high runoff producing rain events following application, extensive hydrologic group D soils or alternative field to water body ratios may result in concentrations higher than those estimated using an agricultural model. Alternatively, the PRZM-EXAMS models are based on runoff into a one-acre farm pond, which is very different from the flowing river habitats of endangered and threatened salmon and steelhead. If a validated model for flowing rives were available, the EEC values would be lower than those reported here, but currently the difference cannot be quantified.

Table 12: **1 in 10 year Estimated Environmental Concentrations of Tebuthiuron for Non-Crop Land Uses**

Scenario	Location	Estimated Environmental Concentration (µg/L)			
		Peak	4 day average	21 day average	60 day average
Grass Grown for Seed	Oregon	0.54	0.53	0.47	0.36
Alfalfa	Minnesota	0.73	0.70	0.62	0.46
Alfalfa	Pennsylvania	1.8	1.7	1.5	1.1
Alfalfa	California	2.0	2.0	1.8	1.4
Alfalfa	Texas	7.0	6.7	5.5	3.5

F. General Risk Conclusions

Our risk conclusions are based on risk quotients (RQS) derived from the available toxicity data (Tables 4 to 8) and EECS from the PRZM/EXAMS model listed in Table12 above.

Table 13. Acute and Chronic Risk Quotients for Freshwater and Estuarine Fish and Aquatic Invertebrates, Based on Toxicity for the Most Sensitive Species (Tables 4 to 8) and EECS Modeled from PRZM/EXAMS (Table 12)

Use Site	Acute Risk Quotients[g]				Chronic Risk Quotients[h]	
	freshwater fish[a]	freshwater invertebrate[b]	estuarine invertebrate[c]	rooted aquatic plants[d]	freshwater fish[e]	freshwater invertebrate[f]
Grass grown for seed (OR)	<0.0001	<0.0001	<0.0001	0.004	<0.001	<0.001
Alfalfa (MN)	<0.0001	<0.0001	<0.0001	0.005	<0.001	<0.001
Alfalfa (PA)	<0.0001	<0.0001	<0.0001	0.013	<0.001	<0.001
Alfalfa (CA)	<0.0001	<0.0001	<0.0001	0.015	<0.001	<0.001
Alfalfa (TX)	<0.0001	<0.0001	<0.0001	0.052	<0.001	<0.001

[a] bluegill acute LC50 =106 ppm.
[b] Daphnia acute LC50 = 297 ppm.
[c] pink shrimp LC50 = 62 ppm..
[d] Lemna EC50 = 135 ppb.
[e] fathead minnow chronic NOEC = 9.3 ppm.
[f] Daphnia chronic NOEC = 21.8 ppm.
[g] Peak EEC/LC50 or EC50; The acute LOC is >0.05 for endangered fish; >0.5 for aquatic invertebrate populations; and >1 for rooted aquatic plants.
[h]21-day-avg EEC/NOEC for invertebrates and the 90-day-avg EEC/NOEC for fathead minnow; the chronic LOC is 1for fish and invertebrates.

OPP uses an RQ > 0.05 (LOC > 0.05) to indicate there is a potential direct acute risk to endangered aquatic species and an RQ > 1.0 (LOC > 1.0) for direct chronic risks to endangered aquatic species. The LOC for determining indirect effects to endangered salmonids through loss of their food supply is RQ > 0.5 for acute effects on freshwater and estuarine invertebrates. The LOC for determining indirect effects to endangered salmonids through loss of cover is RQ > 1.0 for acute effects on aquatic rooted plants. Table 13 indicates that all RQ values are significantly below their respective LOC values. Tebuthiuron does not present direct acute or chronic risks to endangered and threatened Pacific salmon and steelhead. It also does not present any indirect risks through either loss of food supply or loss of cover.

The RED also concluded that tebuthiuron is not a risk to fish and aquatic invertebrates. This conclusion was based on the chemical's classification as "practically nontoxic". "Since tebuthiuron is practically nontoxic on an acute basis to fish and invertebrates, none of the registered uses would result in acute effects or direct mortality to these organisms." (1994 RED, page 31). The RED also concluded that chronic risks to theses organisms were also not expected as the EECS calculated for the RED were also below the chronic LOC.

The RED, however, concluded that aquatic plants were at risk. There is a simple explanation for the difference in conclusion between our assessment and that of the RED. As stated earlier, the EEC calculations in the RED were based on a relatively primitive model that did not use the currently highest labeled rate for broadcast applications. In addition, the RED addresses all non-target organisms, endangered/threatened and non-endangered organisms. For this reason, EFED's policy is to use the most sensitive plant EC50 value to calculate risks to this group of organisms. In the case of tebuthiuron the most sensitive plant is the freshwater green algae, *Selenastrum capricornutum*. However, as we use aquatic plant data to determine indirect effects on endangered fish through loss of cover, the rooted duckweed, *Lemna gibba* is the recognized surrogate test species for all species of rooted aquatic vegetation. The duckweed is 2.7 times less sensitive to tebuthiuron than is *Selenastrum*. Also all models, whether the early generic model or the current PRZM/EXAMS model consider that a 10-hectare watershed will all be treated with the maximum rate. Runoff and drift from this 10-hectare watershed will go into a 1-hectare pond, 2-meters deep. This is a conservative model for salmon and steelhead. While residues in first-order streams may be reasonably predicted for a single application, salmon and steelhead, except sockeye, occur primarily in streams and rivers where natural flow of water, and any contaminants in the water column, will move downstream and preclude continued exposure from a single application. Therefore, the conclusion of this consultation document, that there is no effect on endangered salmon and steelhead from tebuthiuron from loss of cover is justifiable.

G. Existing Protections

Nationally, there are no specific protective measures for endangered and threatened species beyond the generic statements on the current tebuthiuron labels. As stated on product labels, it is a violation of Federal law to use a product in a manner inconsistent with its labeling. All tebuthiuron products have use restrictions for protection of ground water due to the chemical's ability to leach into ground water. These limitations include rate limitations in areas with more than 20 inches of rainfall per year. Because tebuthiuron is a nonselective herbicide that will completely defoliate all terrestrial plants in the applications site, there are many label restrictions specific to reducing or preventing damage of nontarget plants. As these statement do not impact aquatic systems, they will not be discussed here.

The granular products have the Environmental Hazard Statement:

> In case of spills, collect, cover or incorporate granules/pellets spilled on the soil surfaces to prevent contamination to water. Do not apply to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash waters or rinsate.

The nongranular products have the Environmental Hazard Statement:

> Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwaters.

Tebuthiuron is included in EPA county bulletins but only for risks to terrestrial plants.

OPP currently has proposed (67*Federl Register* 231, 71549-71561, December 2, 2002) a final implementation program that includes labeling pesticide products to require pesticide applicators to follow provisions in county bulletins. The comment period has closed, and a final *Federal Register* Notice is under development and is anticipated to be published in 2004. After this notice becomes final, it is expected that pesticide registrants will be required, as appropriate, to put on their products label statements mandating that applicators follow the label and county bulletins. It is also anticipated that these will be enforceable under FIFRA, including the California bulletins. Any anticipated measures necessary to protect T&E salmon and steelhead would most likely be promulgated through this system. However, based on the current labels and uses in California and the PNW, and the conclusion of this consultation that there is "no effect" either directly or indirectly on endangered salmon and steelhead from tebuthiuron, precludes the need for labeling tebuthiuron products with statements to protect T& E salmonids.

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