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16. Abstract (Limit: 200 words)

This Position Document addresses the risks and benefits of pesticide products containing the subject active ingredient. The Agency has determined that the use of products containing the subject active ingredient may meet or exceed a risk criterion described in 40 CFR Part 154. Potential hazards will be examined further to determine the nature and extent of the risk, and considering the benefits of the subject active ingredient, whether such risks cause unreasonable adverse effects on the environment.

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b. Identifiers/Open-Ended Terms

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Part III

Environmental Protection Agency

Tributyltin Antifoulants; Notice of Intent to Cancel; Denial of Applications for Registration; Partial Conclusion of Special Review

ENVIRONMENTAL PROTECTION AGENCY

[OPP-30000/49B; FRL 3458-7]

Tributyltin Antifoulants; Notice of Intent to Cancel; Denial of Applications for Registration; Partial Conclusion of Special Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of partial conclusion of the special review; notice of intent to cancel; notice of intent to deny applications for registration.

SUMMARY: On October 7, 1987 (52 FR 37510), EPA proposed to cancel the registrations of certain tributyltin (TBT) products and deny the applications of others unless the registrants modified certain terms and conditions of registration. This Notice partly concludes the Special Review and announces EPA's final decision to cancel registrations and deny applications of all pesticide products containing tributyltin (TBT) compounds as active ingredients (a.i.) for use as antifoulants unless the registrations/applications comply with the specific terms and conditions of registration as provided herein. This action is based on the Agency's determination that the use of TBT products without such modified terms and conditions of registration will result in unreasonable adverse effects on the environment.

The Agency is keeping the Special Review open on the issue of release rate. The Organotin Antifouling Paint Control Act (OAPCA) which was signed into law on June 16, 1988, established an interim release rate restriction and certification program for TBT antifoulant paints. These interim provisions will expire when the Agency's final determination regarding the release of organotin into the aquatic environment by antifouling paints becomes effective. As noted herein, such action has not been taken in this Notice, and thus the interim provisions of OAPCA remain in effect.

DATE: A request for a hearing by a registrant or applicant must be received by November 3, 1988, or 30 days from receipt by mail of this Notice, whichever is the later applicable deadline. A request for a hearing from any other adversely affected person must be received by November 3, 1988.

ADDRESS: Requests for a hearing must be submitted to: Hearing Clerk (A-110), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT:

By mail:

Rebecca S. Cool, Special Review and Reregistration Division (TS-767C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

Office location and telephone number: Rm. 1006, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703-557-7453).

SUPPLEMENTARY INFORMATION: This Notice is organized into 11 units. Unit I is an introduction providing background information concerning this cancellation action and the provisions and implications of the Organotin Antifouling Paint Control Act of 1988 (OAPCA). Unit II summarizes the risks associated with the use of tributyltin (TBT) antifouling paints. Unit III provides a discussion of TBT release rate testing and results. Unit IV summarizes the benefits associated with the use of TBT antifouling paints. Comments received from interested parties on specific risk, release rate, or benefits issues are also discussed in these units. Unit V discusses the comments of the Scientific Advisory Panel, the Secretary of Agriculture, and other public comments on the regulatory actions previously proposed by EPA in its Notice of Preliminary Determination of October 7, 1987. Unit VI describes the Agency's risk and benefit conclusions. Unit VII describes future Agency activities regarding tributyltin antifouling paints. Unit VIII describes the Agency's regulatory decision as well as existing stocks and disposal provisions. Unit IX describes the procedures which will be followed in implementing the regulatory actions EPA is announcing in this Notice, including the procedures for amending registrations of applications, for requesting a hearing, and the consequences of requesting or failing to request a hearing. Unit X describes the public docket established for the Tributyltin Antifouling Paint Special Review. Unit XI lists references used in this Notice.

I. Introduction

A. The Notice of Special Review and the Preliminary Notice of Intent To Cancel

There are nine TBT compounds registered for use as antifoulants. These are: bis(tributyltin) adipate, bis(tributyltin) dodecenyl succinate, bis(tributyltin) oxide, bis(tributyltin) sulfide, tributyltin acetate, tributyltin acrylate, tributyltin fluoride, tributyltin methacrylate, and tributyltin resinate.

TBT compounds are registered for use in paint formulations as antifoulants on vessel hulls and other marine structures to inhibit the growth of certain aquatic organisms such as barnacles and algae which cause fouling. The major use of TBT paints is on ship and boat hulls with less than four percent of the use on docks, buoys, crab pots, fish nets, etc. Approximately 624,000 gallons of TBT antifouling paint, using approximately 1 million pounds of TBT compounds, are sold annually. When the TBT Special Review was initiated in 1986, there were a total of 61 registrants with 364 registered TBT antifouling paints and 20 formulating intermediate or manufacturing use products.

On January 8, 1986, EPA issued a Notice of Special Review on certain pesticide products containing any of the nine tributyltin (TBT) compounds which were registered as antifoulants (51 FR 778), following a finding that TBT met or exceeded the risk criteria in 40 CFR 162.11(a)(3)(i)(B) and (ii)(C), which were in effect at that time. Subsequently, the risk criteria in 40 CFR 162.11 were superseded by new criteria set forth in 40 CFR 154.7(a)(3). EPA has determined that TBT compounds used in antifouling paints exceed both the old and the new risk criteria for exposure of nontarget aquatic organisms to concentrations which are acutely or chronically toxic to such organisms.

The TBT Special Review was initiated on the basis of bioassay and laboratory toxicity studies which indicated that TBT compounds are highly toxic, frequently at the parts per trillion (ppt) level, to nontarget marine and fresh water aquatic organisms. The Agency noted that TBT residue concentrations reported at sites in U.S. coastal waters exceeded the levels reported to have caused adverse effects in the laboratory studies.

At the initiation of the TBT Special Review, the Agency determined that it needed certain additional data for use in characterizing the toxicity, exposure, and benefits of TBT antifouling paints. EPA, using its authority under section 3(c)(2)(B) of FIFRA, issued a Data Call-In Notice (DCI) on July 29, 1986, to all registrants of TBT antifouling paints and the producers of the TBT active ingredients. The DCI required product chemistry data, ecological effects data, environmental fate data, TBT paint release rate data, worker exposure data, quantitative usage and application data, and efficacy data. Additional ecological effects and worker exposure data are due into the Agency in 1 to 4 years and environmental fate data are due in 1 to 2 years. The other data have already been submitted to the Agency. Registrants failing to submit required data have had their registrations suspended.

Based on public comments received in response to the Federal Register Notice, the data submitted to the Agency in response to the DCI, and on additional analyses performed since the initiation of the TBT Special Review, the Agency on October 7, 1987, made a preliminary determination to propose (1) cancellation of TBT antifouling paint products with short term cumulative release (first 14 days of release rate test) exceeding 168 micrograms (μg) of organotin (calculated as TBT cation) per square centimeter (cm^2) or average daily release rates (averaged over weeks 3 to 5 of release rate test) exceeding 4 μg of organotin (calculated as TBT cation)/ cm^2/day; (2) prohibition of use of TBT antifouling paints on non-aluminum hulled vessels less than 65 feet in length; (3) classification of TBT antifouling paints as restricted use pesticides and restriction of their sale to certified commercial applicators and their use by persons under the direct supervision of an on-site certified commercial applicator, and (4) compliance with certain requirements pertaining to removal and disposal of old paint prior to application of new paints, and/or application of new TBT paints. Also, at this time, the Agency issued the Tributyltin Technical Support Document, dated September 30, 1987, which, along with accompanying scientific reviews, comprise the technical documents in support of the Agency's preliminary determination.

Subsequently, the Congress passed the Organotin Antifouling Paint Control Act of 1988 ("OAPCA") which was signed into law on June 16, 1988, by the President. It contains both interim and permanent TBT use restrictions which are further described in Unit I.C. of this document. The Act established an interim release rate restriction and certification program for TBT antifoulant paints which will expire when the Agency's final determination regarding the release of organotin into the aquatic environment becomes effective. Among other things, the Act also establishes a permanent provision prohibiting application of TBT antifoulant paints to non-aluminum vessels under 25 meters (82 feet) in length.

EPA has evaluated the issues raised in the preliminary documents listed in Unit I.A. of this document in light of the newly enacted legislation and comments and additional data received during the Special Review process. In summary, EPA is announcing that it will cancel all TBT antifouling paint registrations which (a) do not comply with OAPCA's average daily release rate of 4.0 ug organotin/cm^2/day; (b) do not comply with OAPCA's prohibition of the use of TBT antifouling paints on all non-aluminum vessels under 82 feet (or 25 meters) in length (on deck); (c) are not classified as restricted use pesticides, restricting their sale to certified commercial applicators and their use to persons under the direct supervision of an on-site certified commercial applicator (except for products which are packaged in 16 ounce or less spray-can containers and are labeled for use only on outboard motors, propellers, and other non-hull underwater aluminum components), (d) do not have required labeling which requires compliance with applicable OSHA regulations and with the directions for work practices for application, removal, and disposal of TBT paints to reduce the introduction of TBT paint wastes into the aquatic environment, and (e) do not limit certain uses for some types of products.

This Notice announces the Agency's intention to cancel registrations and deny application for registration of all antifouling paint products containing TBT compounds, unless the terms and conditions of registration are amended as described in Unit VIII.B of this document. This action is based on the Agency's determination that the use of TBT antifouling paints will result in unreasonable adverse effects to nontarget aquatic organisms unless the required measures are adopted. A detailed discussion of the basis of this action is contained in the Notice of Preliminary Determination and the Tributyltin Technical Support Document.

B. Legal Background

In order to obtain a registration for a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, an applicant for registration must demonstrate that the pesticide satisfies the statutory standard for registration, section 3(c)(5) of FIFRA. That standard requires, among other things, that the pesticide perform its intended function without causing "unreasonable adverse effects on the environment." The term "unreasonable adverse effects on the environment" is defined under FIFRA section 2(bb) as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." This standard requires a finding that the benefits of the use of the pesticide exceed the risks of use, when the pesticide is used in compliance with the terms and conditions of registration or in accordance with widespread and commonly recognized practice.

The burden of proving that a pesticide satisfies the standard for registration rests on the proponents of registration and continues as long as the registration remains in effect. Under section 6 of FIFRA, the Administrator may cancel the registration of a pesticide or require modification of the terms and conditions of registration whenever it is determined that the pesticide causes unreasonable adverse effects on the environment.

The Special Review process, formerly called the Rebuttable Presumption Against Registration (RPAR), is a mechanism by which EPA collects information on the risks and benefits associated with the uses of pesticides to determine whether any use causes unreasonable adverse effects to human health or the environment. The Special Review Process is currently governed by 40 CFR Part 154 and was further described in the Notice of Preliminary Determination.

In determining whether the use of a pesticide poses risk which are greater than the benefits of use, EPA considers both possible changes to the terms and conditions of registration which can reduce risks, as well as the impacts of such modifications on the benefits of use. If EPA determines that such changes reduce risks to the level where the benefits outweigh the risks, it may require such changes be made in the terms and conditions of registration.

Alternatively, EPA may determine that no changes in the terms and conditions of a registration will adequately ensure that use of the pesticide will not pose any unreasonable adverse effects. In that event, the Administrator may issue a Notice of Intent to Cancel the registration or may hold a hearing to determine whether it should be cancelled under FIFRA section 6(b). In determining whether to issue such a Notice, the Administrator must take into account the impact of the action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy. In the case of TBT, the impact of the action on the marine paint and shipbuilding industry and the user community was considered. At least 60 days before formally issuing such a Notice, the Administrator must inform the Secretary of Agriculture in writing of the substance of the proposed actions and supply the Secretary with an analysis of the expected impact on the agricultural economy. At the same time, under FIFRA section 25(d), the Administrator is required to submit the proposal to the Scientific Advisory Panel for comment as to the impact on

health and the environment of the action proposed in the cancellation notice. EPA is also required by law, where appropriate, to consult with the U.S. Department of the Interior to see if the proposed action may affect an endangered species.

Unless expedited procedures are employed, EPA informs the public of its proposals to issue cancellation notices so that registrants and other interested persons can also comment or provide relevant information before a final Notice of Intent to Cancel is issued. Registrants and other interested persons are invited to review the data upon which the proposal is based and to submit data and information to address whether EPA's initial determination of risk was in error. In addition to evidence relating to risks, comments may include evidence as to whether any economic, social, and environmental benefits of use of the pesticide outweigh the risks of use.

If, after reviewing the comments received, EPA decides to issue a Notice of Intent to Cancel, any adversely affected person may request a hearing to challenge the action. In the hearing, any party opposing cancellation would have an opportunity to present evidence. Other interested parties could intervene to present evidence. At the end of the hearing EPA would decide on the basis of the evidence presented whether or not to cancel or restrict the registration of pesticide products. If no hearing is requested, each registration would be cancelled by operation of law 30 days after receipt by the registrant or publication in the Federal Register of the Final Notice, whichever occurs later.

C. The Organotin Antifouling Paint Control Act of 1988

The Organotin Antifouling Paint Control Act of 1988 ("OAPCA") (Pub. L. 100-333) was signed by the President on June 16, 1988. It is free-standing legislation that is independent of FIFRA. It has interim and permanent TBT use restrictions as well as provisions regarding sale and use of existing stocks, environmental monitoring, research on alternatives, reports to Congress, and penalties for non-compliance. All of the provisions were effective upon the date of enactment. The interim provisions pertaining to the release rate restriction and certification of TBT antifoulant paints will expire when the Agency's final regulatory decision regarding the release of organotin into the aquatic environment by antifouling paints becomes effective. As noted herein, such action has not been taken in this Notice, and thus the interim provisions of OAPCA remain in effect.

OAPCA establishes a certification program under which only products which do not exceed a release rate of 4 μg of organotin/cm2/day can be sold and used. OAPCA requires EPA to review all release rate data submitted to the Agency before the new law was enacted and to determine which products meet this release rate standard by September 14, 1988. For any release rate data submitted after June 16, 1988, EPA is required to make a decision regarding product certification within 90 days of receipt of such data.

OAPCA also establishes maximum existing stocks provisions, starting from the date of enactment, of 180 days for sale, and 1 year for use, for all organotin antifouling paints and organotin additives in existence on the date of enactment. OAPCA provides that the Administrator shall, no later than 90 days from enactment, provide reasonable times for sale and use of existing stocks which do not exceed the above noted limits. Any organotin antifouling paints certified as meeting the 4 μg release rate restriction will not be subject to these sales or use limits after notice of certification.

OAPCA also contains the following *permanent provisions.*

1. *Vessel size.* Subject to the existing stocks provision, all TBT products are prohibited from use on vessels that are less than 25 meters (82 feet), unless the vessels are aluminum. Outboard motors and lower drive units are also exempt from the prohibition.

2. *Paint additive products.* Subject to the existing stocks provision, all retail sale, distribution, purchase, and receipt is prohibited for TBT additives used to create antifouling paints. No such products are currently registered.

3. *Estuarine monitoring.* EPA, in consultation with the Department of Commerce, for the next 10 years, must conduct monitoring studies of TBT concentrations in water, sediment, and aquatic organisms from representative areas in the United States. The Agency must submit annual reports of the results of the monitoring studies to Congress (House of Representatives and Senate).

4. *Navy monitoring and testing.* The Navy must conduct similar environmental monitoring studies in naval ports serving TBT-treated vessels, continue laboratory toxicity and environmental risk studies, and report annually to each state with a naval port and to EPA for inclusion in the Agency's annual report to Congress.

5. *State assistance.* EPA must assist states, to the extent practicable, in monitoring and analyzing for TBT in waters in the states.

6. *Effectiveness report.* EPA, in 5 years, must report to Congress on the effectiveness of the TBT restrictions, compliance with the organotin water quality criteria document, and recommendations for additional protective measures.

7. *Antifoulant alternatives research.* EPA and the Navy must conduct research on chemical and nonchemical alternatives to organotin paints and, in 4 years, must report to Congress the results of such research.

8. *Water quality criteria.* EPA must issue a final water quality criteria document for organotin, pursuant to section 304(a) of the Clean Water Act, by March 30, 1989.

9. *Penalties.* Civil (not to exceed $5,000) and criminal (not to exceed $25,000) penalties will be imposed for violating the above use, sale, distribution, purchase and receipt provisions.

TBT registrants were notified of OAPCA and its provisions by an Agency letter dated August 12, 1988. Data necessary to make the OAPCA certification of release rates were required to be submitted by a July 29, 1988, Data Call-in Notice for Tributyltins Used in Paint Antifoulants and a follow-up Notice of August 13, 1987, both of which were issued under the authority of section 3(c)(2)(B) of FIFRA. All submissions of data required by these notices were determined to be inadequate because of the use of inappropriate testing procedures or the absence of critical data. The letter dated August 12, 1988, specified additional raw data and/or information that were necessary for the Agency to validate the release rate studies and required submission of such data/information within 30 days of the registrant's receipt of the letter. Registrants were informed that failure to submit adequate data might result in their receipt of a Notice of Intent to Suspend and would prevent the Agency from reaching a decision on their product's release rate and certification under OAPCA.

In a letter dated September 14, 1988, the Agency notified registrants by letter that none of their release rate data were certified under OAPCA and that the following existing stocks provisions were in effect until they were able to satisfy OAPCA's certification requirements:

1. December 16, 1988, for sale, delivery, purchase, and receipt;

2. June 16, 1989 for use.

II. Determinations on Risk

Laboratory testing and field trials have established that TBT is toxic to fish (at 0.2 parts per billion (ppb)), bivalves (at 0.02 to 0.05 ppb), gastropods (at 0.05 ppb), crustaceans (at 0.14 to 0.19 ppb), and algae (at 0.1 to 0.35 ppb). TBT concentrations at or above 0.02 ppb have been reported for at least 30 sites in the United States, predominantly in areas with heavy boating and shipping activity.

Harbors and boating activity are usually concentrated in relatively shallow (<30 ft) coastal waters. These areas also coincide with many estuaries or ecologically dynamic environments that support large fisheries and are important nursery areas. Although TBT distribution in the environment is not completely understood, a biologically significant amount has been observed to be accumulated by aquatic organisms at all taxonomic levels. Documented effects of TBT have been found in shell deformities of the commercially important oyster, *Crassostrea gigas* (in France, England, and the United States), and in sexual deformities and possible population declines of the marine snail, *Nucella lapillus* (in the United States and England).

A. Toxicity to Nontarget Aquatic Organisms

The full extent of the risks of TBT to nontarget aquatic organisms is unknown at this time. While observable effects under field conditions have not been determined for many aquatic species, TBT toxicity studies have been conducted on algae, fish, crustaceans, and molluscs (both bivalves and gastropods). Although short-term studies have demonstrated that TBT is highly toxic to certain aquatic organisms (LC_{50} = 0.1 to 24 ppb), long-term studies have revealed toxic effects from TBT concentrations that are one to two orders of magnitude lower (> 0.02 ppb). Most aquatic organisms appear to be extremely sensitive to TBT toxicity during the time of development from fertilized eggs through various larval stages. In addition to developmental effects, the sublethal toxic effects of TBT may be sufficient to gradually alter aquatic populations by changing their size or composition (individual year class strength), metabolism (TBT is a membrane effector), behavior (competition abilities, defense mechanisms, feeding strategies), and/or by deteriorating the environmental conditions through physical, chemical, or biotic factors.

The Agency's Office of Water is required to issue its Ambient Water Quality Criteria for Tributyltin by March 30, 1989 under OAPCA. The document will be a guideline to EPA Regional Offices suggesting the maximum TBT residue concentrations which the Agency believes will protect fresh and salt water organisms. The values in the Criteria Document may be changed subsequently depending upon new scientific data made available to the Agency. Additional aquatic toxicity data have been required of TBT registrants; these data are due to be submitted to the Agency over the next few years. However, there are sufficient laboratory and field data to indicate that certain harbor and estuarine areas have TBT residues above levels which may be safe to certain aquatic organisms.

1. *Fish.* Acute toxicity to both fresh and marine fish species have been reported with values ranging from 1.5 ppb to 24 ppb. TBT compounds have been widely used in the salmon aquaculture industry to retard fouling of net pens. However, researchers at the Alaskan National Marine Fisheries Service have observed, on several occasions, high mortalities in groups of Chinook salmon (*Oncorhynchus tshawytscha*) after transfer to marine net pens newly treated with TBT.

Chronic exposure of fish to TBT has resulted in physiological alterations in growth rate and in histological damage to rainbow trout (*Salmo gairdneri*) at concentrations as low as 0.2 ppb TBT. Chronic TBT exposure may affect fish fecundity or progeny survival. Exposure of parental sheepshead minnows (*Cyprinodon variegatus*) to TBT has been found to result in significant mortality of progeny that were not directly exposed to the toxicant.

Bioaccumulation (accumulation in the body of an organism at concentrations higher than in surrounding water) of TBT has been reported for sheepshead minnow where an equilibrium was not reached during a [illegible]day test period. With exposures [illegible]3 to 2.07 ppb, residues were as high as 4.19 ppb in the whole body. When transferred to clean water, depuration (loss of the toxicant from the organism) was rapid for the first 7 days, but slowed over the next 21 days. Chinook salmon were also reported to bioaccumulate TBT by a factor 200 to 4300 times greater than the TBT concentration in the water column.

2. *Bivalves.* Larval stages are more sensitive to TBT than adults. Acute toxicity to bivalve larvae (48-hour LC_{50}) has been reported to be 0.9 ppb for Pacific oyster larvae (*Crassostrea gigas*) and 2.3 ppb for mussel larvae (*Mytilus edulis*).

Chronic effects of TBT exposure are reported to cause growth retardation at 0.02 to 0.05 ppb in European oysters (*Ostrea edulis*) and clams (*Venerupis decussata*), shell deformities at 0.02 ppb in the Pacific oyster (*C. gigas*), and reproductive aberrations (predominance of males in the hermaphroditic European oyster) at 0.24 ppb.

Bivalves rapidly accumulate TBT in lipid-rich tissue, especially gonadal tissue. Bioaccumulation factors of two thousand to twenty thousandfold for Pacific oyster and a thousandfold to fifteen hundredfold for European oyster have been recorded. Unlike fish, bivalves do not readily metabolize this toxicant and the resulting effect is slow depuration of TBT.

3. *Gastropods.* Marine snails (specifically *Nassarius obsoletus* and *Nucella lapillus*) are reported to develop a condition termed "imposex" as a result of TBT exposure. Imposex is the superimposition of male characteristics (penis and vas deferens) on female organisms. In the extreme, imposex impacts gastropod reproduction. A direct relationship between TBT exposure and the development of imposex has been demonstrated in the laboratory at exposure levels of 0.05 ppb TBT for 120 days and corroborated in the field. A high frequency of imposex has been observed in areas with heavy boating and shipping activities and high levels of TBT in the water column. Imposex is infrequent in more pristine areas.

4. *Crustaceans.* Acute toxicity of TBT to tested crustacean species ranges from 0.42 ppb for a 96-hour LC_{50} for juvenile mysid shrimp (*Acanthomysis sculpta*) to 41 ppb for a 96-hour LC_{50} for adult shrimp (*Crangon crangon*).

The sublethal chronic effects of TBT to crustaceans have involved growth retardation in mysid shrimp (0.25 ppb), delayed metamorphosis in mysid shrimp (10 to 20 ppb), delayed limb regeneration in fiddler crabs (*Uca pugilator*) (0.5 ppb), reproductive effects in adult female mysid shrimp (0.14 to 0.19 ppb), and behavioral changes in daphnids (*Daphnia magna*) (0.5 ppb).

5. *Algae.* A limited number of marine diatoms and fresh water algae have been examined for toxic effects from TBT compounds. In laboratory studies, an EC_{50} (the environmental concentration at which 50 percent of the population is effected) for growth inhibition of the marine diatoms *Skeletonema costatum* and *Thalassiosira pseudonana* was observed after 75 hours exposure at 0.33 ppb and 1.33 ppb, respectively. Growth reduction was reported for *S. costatum*,

Pavlova lutheri, and *Dunaliella tertiolecta* at 0.1 ppb and death at 5 ppb after 2 days.

6. *Registrants' comments on aquatic toxicity issues.* In response to the Agency's Preliminary Determination and the TBT Technical Support Document, registrants and other parties submitted specific comments concerning the Agency's interpretation of data it used in assessing the toxicity of TBT to non-target aquatic organisms. These comments and EPA's detailed evaluations are included in the public docket (OPP-30000/49A), and are available for inspection as noted at the beginning of this Notice under "ADDRESS". Below is a summary of the principal issue regarding aquatic toxicity from TBT raised by the commenters.

The Agency based a portion of its hazard assessment on chronic effects of TBT to non-target aquatic organisms. One registrant argued that the shell thickening effect noted in the Pacific oyster (*C. gigas*) may be caused by other environmental factors, including other chemical contaminants and high turbidity, rather than TBT. The Agency has reviewed the published literature regarding this issue and maintains its conclusion that data from both field and laboratory studies appear to support a finding that TBT is the causative factor. Other environmental pollutants have been determined to be unlikely causes. Over 200 xenobiotics, including diesel fuel, aromatic hydrocarbons, copper, and zinc, were not found to cause the shell thickening effect (Refs. 1, 2, 3, and 4). Likewise, particulate matter, once believed to be associated with the effect, was subsequently discounted as a likely cause because further studies demonstrated that the particulate matter was contaminated with TBT (Ref. 1). TBT levels of 0.15 and 1.6 µg/L, which were similar to those measured in areas of England where affected species were observed, had a propensity to cause shell deformities in *C. gigas* with or without particulate matter present while particulate matter alone did not cause the shell thickening effect (Ref. 2). These findings have been further confirmed in field studies (Ref. 5).

B. Comparative Toxicities of Tributyltin, Triphenyltin, and Copper

Copper based antifouling paints are the major alternative to TBT paints. Although copper can be highly toxic to aquatic organisms, it appears to be less toxic than TBT by one to three orders of magnitude. Copper toxicity and bioavailability are reduced in the marine environment because the toxic unit, the free cupric ion, is adsorbed by and forms complexes with organic and inorganic ligands.

Also, triphenyltin (TPT) could be used as a substitute antifouling compound in paints. The Agency has a limited set of data on TPT (based on nominal concentrations) which indicates that TPT causes chronic effects in fish at 2.0 ppb and effects in crustaceans at >0.27 ppb. TBT effect levels for these organisms are >0.2 ppb and 0.09 ppb, respectively. The Agency issued a DCI on TPT antifoulant uses on August 28, 1987 which required ecological effects data along with other data. Protocols for some of the required studies have been submitted and are being reviewed by the Agency. The information obtained from this DCI will be useful to the Agency in assessing the risks of TPT to nontarget aquatic organisms.

C. International Reports of TBT Contamination and Population Effects

1. *France.* In France, a correlation has been found between TBT residue levels in certain estuaries and gross malformations in Pacific oysters (*C. gigas*) grown in commercial oyster beds in and adjacent to areas of heavy boating activity. These deformities are characterized by the perturbation of the calcification mechanism. Abnormal shells are thickened and have numerous chambers filled with a jelly-like substance consisting of high levels of the amino acid threonine, and a smaller amount of the amino acids serine, glycine, and aspartic acid as compared to normal oysters.

Environmental concentrations of organotin in the water column were measured (as Sn) at 0.2 to 0.3 ppb in Arcachon Bay during 1982 and appeared to have caused shell deformities in 70 to 100 percent of the 2-year old oysters. Following a ban on TBT antifouling paints on vessels less than 25 meters (82 feet) in length, the degree of shell deformities has decreased and the regeneration rate of juvenile oysters (spat) has improved.

2. *England.* A recent study found that environmental concentrations of 0.02 ppb TBT in the Crouch estuary resulted in oyster shell deformities similar to those found in France. This finding was corroborated in the laboratory. A reproductive abnormality (imposex) has been observed in the dogwelk snail (*Nucella lapillus*) and may be responsible for the possible decline of this once abundant population. Researchers established that this reproductive anomaly can occur in certain species of marine snails when TBT tissue concentrations exceed 0.1 ppb. Laboratory testing demonstrated that tissue levels of 1.65 ppb have been found to induce imposex after snails were exposed to 0.05 ppb TBT for four months.

3. *Canada.* In Canada, organotin residues have been found in several freshwater locations including lakes, rivers, and harbors. Several sample stations had TBT levels (0.22 to 5.0 ppb) that were comparable to the chronic level (>0.2 ppb) associated with growth retardation in rainbow trout larvae. High levels of TBT residues at these sample stations were associated with heavy boating or shipping activity.

4. *United States.* Reports on the effects of TBT on aquatic populations in the United States have been limited because the environmental impact of tin-based antifoulant paints has only been studied for a few years. However, from the information that is available, it appears that adverse effects to nontarget aquatic organisms may have occurred. Insufficient data are available to define the full extent of the problem.

The Department of Fish and Wildlife of Oregon recently found shell deformities in oysters from Coos Bay, and have attributed these abnormalities to TBT residues from paint chips coming from a nearby shipyard. Researchers at California Department of Fish and Game demonstrated that oysters (*C. gigas*) and mussels (*M. edulis* and *M. californianus*) transplanted along a known gradient of TBT concentrations in San Diego Bay exhibited shell thickening and growth effects similar to laboratory and field findings documented in France and England. A recent monitoring program indicates that TBT levels are sufficiently elevated and persistent in several major bays and harbors in California to cause the shell deformities observed in *C. gigas* (Ref. 6). Imposex in female mud snails has been reported in the United States along the East Coast and in California in close proximity to yacht harbors and marinas. In marinas and areas of high boating activity of the southern Chesapeake Bay, TBT concentrations are reported to be at 0.014 to 0.1 ppb, levels that laboratory tests indicate cause reproductive effects in mollusca.

D. Endangered Species

There are approximately 80 endangered species in fresh water lakes and streams and in marine estuaries of the United States There are no available organotin toxicity data for these species; however, EPA has asked the Fish and Wildlife Service, Department of Interior and the Marine and Estuaries Fisheries Service in the Department of Commerce to determine if organotin compounds

would jeopardize any endangered species.

B. Exposure

1. *Environmental fate.* The environmental fate of tributyltin in estuaries is complex and not completely understood. Studies indicate that photolysis and microbial action are potential mechanisms of degradation from tri- to di- to monobutyltin and finally to inorganic tin. Studies indicate the half-life of TBT may be 116 days in aerobic soils, 615 days in anaerobic soils, 6 to 12 days in seawater, and up to 238 days in fresh water. TBT is readily sorbed to soils and sediments. Sediment/water partition coefficients of 3000 and 700 ug/kg/ug/L have been reported for suspended particulate loadings of 10 and 100,000 mg/L, respectively. Thus, newly deposited sediments might be expected to have TBT residue concentrations 3000 times greater than the ambient water column concentration when the suspended particulate concentration was 10 mg/L in the water column. As the concentration of suspended particulates in the water column increased, the difference between the ambient water column TBT concentration and the sediment TBT concentration would decrease. Data from monitoring studies have consistently indicated that TBT and its di- and monobutyltin degradates concentrate in bottom sediments. Sediment-bound residues contain a higher ratio of the degradates than that found in the water column. The means of TBT deposition in sediments and the relative strength of TBT adsorption versus desorption of the degradates are not known. The overall partitioning of TBT among water, biota, sediment, surface microlayer, and atmosphere has not been fully investigated.

2. *Bioavailability.* TBT residues accumulate in sediment at levels that are one to four orders of magnitude greater than the total concentration of TBT residues measured in the water column. This amassing of toxicant may have serious consequences for organisms living and feeding in the benthos (bottom of the body of water). For example, it has been found in laboratory experiments and field trials that TBT contaminated sediment can affect growth in Pacific oyster (*C. gigas*) at 0.15 ppb. In addition, the results of a laboratory study suggest that mud crabs (*Rhithro-panopeus harrissi*) accumulate TBT from food as well as water exposure.

In estuarine environments, 95 percent of the particulate-bound TBT may be associated with bacterial cell walls (dead and alive cells). The adsorption of TBT to bacteria is a significant exposure component that may affect aquatic organisms that feed on detritus (organic matter) and suspended particulate. These organisms include species of polychaetes, snails, amphipods, sponges, bivalve molluscs, and arthropods.

3. *Environmental monitoring.* Monitoring studies have been carried out to determine the extent of TBT contamination in the water column of marine and fresh waters. Sampling was designed to compare levels of contamination in areas of varying boating activity (recreational and commercial). The seasonal, tidal, and spatial flux of TBT and its degradates were examined in some cases. Limited analyses of sediment and aquatic biota also have been performed.

TBT levels in tested areas of the Chesapeake Bay and San Diego Bay ranged from ND (nondetectable, meaning below the level of detection for the analytical method used) to 0.8 ppb and ND to 1 ppb, respectively. Other reported water column concentrations were: San Francisco Bay ND to 0.16 ppb, Honolulu Harbor 0.045 to 0.27 ppb, Los Angeles/Long Beach Harbor ND to 0.12 ppb, Narragansett Bay, Rhode Island, ND to 0.13 ppb, Thames River, Connecticut, ND to 0.009 ppb, and Mayport, Florida ND to 0.016 ppb. Fresh water samples from 285 locations across Canada were analyzed for TBT. In 10 percent of the water samples, TBT was found at levels >0.2 ppb. Consistently, TBT concentrations were highest in areas of heavy boating activity. A monitoring study in the Chesapeake Bay during the summer of 1986 showed a strong correlation between boat density and observed TBT concentrations in four harbors.

TBT concentrations have been shown to vary seasonally. In areas of moderate to high TBT loading, the water column levels of TBT appear to correlate to seasonal boating activity and boat maintenance activities. Seasonal variation in temperature may also influence the leaching of TBT from paints and/or the mobility and persistence of TBT in the marine environment.

Tidal exchange, dispersion, and convection are the most important factors affecting short-term changes in TBT concentration. Sites with fresh water influx areas or recirculating currents generally have very low concentrations of TBT. In areas where water residence times are relatively long, TBT levels increase in proportion to the loading. Accumulation of TBT degradates has been observed in locations where water movement is very slow (e.g., southern end of San Diego Bay).

4. *Environmental modeling.* The Agency is engaged in an effort to model Norfolk Harbor in Virginia. Norfolk Harbor is a major fishery with large populations of hard clams and Eastern oyster and is a nursery for spot, Atlantic croaker, Atlantic menhaden, striped bass, black sea bass, and summer flounder. The area is also an active boating and shipping area with recreational, commercial, and military use and contains large and small boat/shipyards. The Agency model will examine environmental concentrations under several loading levels and attempt to estimate the impact of possible regulatory approaches on TBT concentrations. The information may be useful to the Agency in making future regulatory decisions.

5. *Registrants' comments on exposure issues.* Registrants and other interested parties submitted many specific comments concerning the Agency's interpretation of data used in evaluating the exposure of non-target aquatic organisms to TBT. These comments and EPA's detailed evaluation are available for inspection in the public docket. There were five major exposure issues raised by the registrants. They were degradation, bioavailability, bioaccumulation, environmental concentrations, and environmental loading. The Agency's responses are summarized below.

a. *Degradation.* A registrant commented that factors such as hydrolysis, photolysis, dissipation, and other degradation pathways were not factored into the Agency's calculations regarding exposure. The registrant stated that calculation of exposure should be based on recently generated data such as that reported by Dr. Richard Lee (Ref. 7) which indicated that half-life of TBT in water may be less than one week, depending on the concentration of algae.

Response: The Agency has evaluated and considered all of the available information regarding physical and biological degradation of TBT, including the study by Dr. Lee which was not available to the Agency at the time of the Preliminary Determination.

TBT can be degraded through photolysis. However, because of the limited penetration of sunlight into an aquatic environment, this pathway is not expected to significantly affect TBT concentrations.

Hydrolysis is not a viable degradation consideration since TBT is relatively

stable in water with a degradation half-life of 1 to 3 years (Ref. 8).

The overall partitioning of TBT among water, biota, sediment, surface microlayer, and atmosphere has not been experimentally investigated although inferences may be drawn about relative partitioning from analysis of available monitoring data discussed in Unit II.E.4. of this document.

Biodegradation of TBT by algae was first suggested by the work done by Maguire *et al.* (Ref. 9). They concluded that the freshwater green algae *Ankistrodemus falcatus* could degrade TBT to dibutyltin resulting in a half-life of 25 days. However, the authors note that these estimates should be viewed with caution, since the reaction was not followed to completion.

Lee *et al.* (Ref. 7) found that at a TBT concentration of 1.5 ppb under laboratory conditions with a very high phytoplankton population (*Skeletonema costatum*), TBT was degraded with a half-life of 4 to 9 days. This information was interesting; however, insufficient data were given in the study to confirm the results. The results of this study appear to be contradicted by Walsh *et al.* (Ref. 10) who used the same species of algae and calculated an EC_{50} for growth inhibition of 0.33 ppb TBT. Lee *et al.* (Ref. 7), as well as Walsh *et al.* (Ref. 10), found low or no degradation of TBT by cultures of dinoflagellates, green algae and chrysophytes. Although the diatom used by Lee *et al.* (Ref. 7) may degrade TBT under certain optimal conditions, their presence in the water column is cyclic and appears to be dominant in temperate water during the Spring.

The effectiveness of algae degradation of TBT is a function of temperature, species, population density, and the nutritional state of TBT tolerant algae. Therefore, it is difficult to assess whether algal degradation of TBT would be a significant pathway in the environment. However, bacterial biodegradation is a strong possibility. Several researchers have concluded that certain bacteria have this capability (Refs. 6, 7, 11, 12, and 13).

b. *Bioavailability.* A registrant commented that EPA incorrectly assumes that particulate and sediment-bound TBT is potentially 100 percent bioavailable. The registrant contends that the bioavailability of sediment-bound TBT is limited.

Response: The Agency has never assumed that particulate and sediment-bound TBT were potentially 100 percent bioavailable. The Agency has concluded that the available data indicate that the level of TBT bioavailability is affected by suspended particulate, bottom sediments, and dissolved organics. However, the Agency believes that the available data are insufficient to completely assess the impact of sediment-bound TBT to aquatic organisms. Organotin bioassays required by the Agency's Data Call-In Notice of July 29, 1988 are designed to address this.

The registrant cites data published by Salazar and Salazar (Ref. 14) to support their contention that no adverse effects occur in bottom organisms exposed to TBT bound sediments. The Agency evaluated this study and found it to be limited and incomplete. The 10- to 20-day solid phase (sediment) test used mysid shrimp, clams, and polychaete worms. Supplemental feeding of the mysid shrimp and polychaete worms limited the usefulness of the test which was to determine whether organisms that ingest TBT-laden sediment are affected. The authors do acknowledge that the clams (filter feeders) did accumulate significantly more tin (2.82 ppm) than controls (0.28 ppb). In fact, they conclude that "these values . . . demonstrate that the organotins associated with sediment are bio-available." The static test of the suspended particulate phase showed no significant mortality because: (1) The test organisms (shrimp and sandcrabs) are not filter-feeding organisms that would normally ingest the particulate-bound TBT, and (2) the test organisms (except fish) were given a supplemental uncontaminated diet.

c. *Bioaccumulation.* A registrant commented that he does not believe that lethal levels of TBT will bioaccumulate in an organism exposed to low environmental concentrations because all organisms will depurate their TBT body burden, and environmental levels of TBT are not maintained for long periods.

Response: The Agency is not only concerned with lethal concentrations from bioaccumulation; sublethal levels of bioaccumulation which may lead to effects short of death also are of concern to the Agency. The risk from TBT bioaccumulation cannot be dismissed. Body burdens in various aquatic organisms (i.e. fish, bivalves, algae, and bacteria) are not totally depurated. The Agency has relied upon the work of several researchers in establishing that TBT accumulation occurs in fish, bivalves, gastropods, algae, bacteria, and crustaceans (Refs. 4, 15, 16). An interpretation of the toxicity data suggests that two poisoning mechanisms may be occurring. At high TBT concentrations, gill-breathing organisms may be affected by rapid suffocation resulting from destruction of gill epithelium. However, at low concentrations, organisms that do not efficiently depurate or metabolize TBT may accumulate levels that will inhibit main metabolic pathways. Either one of these mechanisms could result in lethal or sublethal effects. In regard to environmental levels, several researchers have found that, while peaks in TBT environmental concentrations occur in some areas (e.g., areas where there is a Spring launching of recreational boats), a relatively significant level of TBT is maintained for 6 to 7 months in temperate areas and may be even more extensive in warmer climates where boating activity is less affected by seasonal changes. Waldock and Miller (Ref. 4) found that TBT residues were still found in *C. gigas* tissue during the winter months when boating activity had ceased and most pleasure craft had been removed from the Crouch estuary. This suggests that *C. gigas* was either still being exposed to environmental residues of TBT or depuration was very slow.

d. *Environmental concentrations.* A registrant stated that he does not believe that residues of TBT in the environment will equal or exceed levels which produce adverse effects in nontarget organisms.

Response: The Agency has cited incidents from Europe where TBT has been implicated in causing adverse effects to aquatic organisms. In fact, it is because of these occurrences that regulatory actions have been initiated in France and England. Concern was first expressed in France where severe deformities were found in the commercially cultivated Pacific oyster (*C. gigas*) in areas where there was intense boating activity and relatively poor water exchange. The affected oysters were found to contain high concentrations of tin although scientists at the time could not distinguish between the inorganic and organic forms. These high levels of tin coincided with the increasing use of organotin compounds (especially TBT) as biocidal agents in antifouling paint. The French government responded by banning the use of organotin paints on boats under 25 meters in 1982. Similar problems were subsequently noted in the United Kingdom and resulted in legislation to control the total concentration of tin in antifouling paints. U.S. researchers noted several incidents of shell deformities in oysters transplanted to various California harbors and bays, that were known to contain elevated levels of TBT. These findings in California were consistent with those observed in the UK and France.

e. *Environmental loading.* A registrant maintained that TBT environmental concentrations are correlated with marina maintenance activities and not with leaching from boat hulls.

Response: Although some data on TBT environmental levels can be attributed to paint chip contamination from improper disposal, there are examples of high levels that can be attributed exclusively to boat paint leaching. Seligman *et al.* (Ref. 17), sampling at Shelter Island Yacht Basin, San Diego, found near surface concentrations of TBT (0.027 to 0.235 ug/l) that were significantly higher than near bottom concentrations. The large difference in vertical distribution was accredited to the TBT leaching from hulls in the upper 1 to 2 meters of the water column with relatively little mixing below that level. According to Stephenson (Ref. 18), marina maintenance activities are not occurring at the Shelter Island Yacht Basin. However, if paint chip contamination was occurring, it is expected that high levels of TBT would be found much further down the water column, due to the density of the paint chips.

The Agency has developed a model for examining environmental concentrations of TBT in the Norfolk, Virginia, area with regard to various TBT loading levels. One set of studies simulated the continuous long-term release of TBT paints by boat hulls. At a release rate of 1 ug/cm²/day, it was projected that TBT leaching from boat hulls would be comparable to levels found in the Norfolk area. These results lend support to the Agency's position that TBT leaching from boat hulls is a primary source of TBT contamination.

F. Risk Assessment Summary

The risk assessment contained herein is a summary of the risk assessment contained in the the Technical Support Document of the Preliminary Determination. Laboratory and field studies have demonstrated that low concentrations of TBT can cause irreversible chronic effects to a broad spectrum of nontarget aquatic organisms. At laboratory and field concentrations of approximately 0.02 to 0.05 ppb, TBT has caused shell deformities and a reduction in growth in commercially important bivalves and imposex in ecologically significant gastropods. Monitoring studies which are further discussed in the Technical Support Document have demonstrated that TBT is persistent in the marine environment and that the observed levels of TBT in the water column in and adjacent to marinas, dry dock areas, and poorly flushed harbors exceed concentrations that have been demonstrated to cause adverse effects in molluscs, gastropods, and other nontarget aquatic organisms. Also, it is believed that biologically significant levels of TBT may be transported to nearby sensitive ecologically productive areas because of movement of TBT residues via currents and tides. The Agency also is concerned about the potential accumulation of TBT in aquatic sediments and in the tissue of aquatic organisms; however, insufficient data are available to determine the extent and significance of these events.

III. Release Rates Assessment

In the Preliminary Determination of October 7, 1987, the Agency proposed restricting the release rate of TBT antifoulant paints as a means of reducing one source of environmental loading: leaching of TBT from painted hull surfaces and other surfaces such as docks and crab pots. The proposed release rate restrictions were based on EPA's preliminary analysis of release rate studies conducted according to the ASTM/EPA TBT release rate method. This method was intended to give a relative ranking of the potential for TBT release from product to product under a set of specified conditions. It was not intended to produce comparable results to any other method or to quantitate environmental loading. The Agency received numerous comments in response to the Preliminary Determination pertaining to the Agency's analysis of the release rate data, the variability of the data, and possible improvements to the method. The Agency's response to these comments and decision regarding the use of these data are set forth in this unit. A detailed analysis of specific comments is available in the public docket.

A. Background

Release rate data were originally submitted to the Agency in response to the Tributyltin Data Call-In issued July 29, 1986. This notice required all registrants of TBT antifouling paints to measure TBT release from registered paints following a test method developed in cooperation with the American Society for Testing and Materials (ASTM). In addition, each laboratory conducting the TBT release rate test was required to test a standard copolymer test paint as a means of assuring that the test method was consistent among testing facilities. The Notice did not specifically require submission of raw data or any detailed information regarding how the study was conducted. As a result, registrants submitted summaries of their release rate data.

Release rate data for the standard test paint varied substantially between testing facilities. It was assumed that this variation was due to systematic error. All data were reviewed by the Agency and a value of 90 $\mu g/cm^2$ was assigned to the short term cumulative release rate (cumulative for the first 14 days of the test) and a value of 5 $\mu g/cm^2$/day was assigned to the average daily release rate (average of weeks 3 to 5 of the test) for the standard test paint. Each laboratory's standard test paint data were normalized to these assigned values. The normalization factor obtained for each laboratory was utilized to adjust the release rate data for all paints tested at that laboratory. This adjustment was deemed necessary to fairly compare release rate results from all laboratories. Release rate data were reviewed for the 96 TBT antifouling paint products for which data were submitted prior to the PD-2/3. It was determined that at least 57 of the tests were tentatively acceptable. The other 39 tests were determined to be unacceptable because of scientifically invalid testing procedures.

Prior to the issuance of the Preliminary Determination, the Agency issued a follow-up notice on August 13, 1987, informing the registrants who submitted the 57 tests that their previous data submissions were only tentatively accepted and a complete submission of release rate data was required within 30 days. This information was needed in order to: (1) Verify that the studies were conducted in compliance with the ASTM/EPA standard test, (2) evaluate the scientific validity of the studies, and (3) determine whether the registrants correctly calculated TBT release rates and cumulative release values from the raw data. Additional letters were sent to specific registrants, when appropriate, to inform them of TBT release rate studies that were unacceptable due t scientifically invalid testing.

Subsequent to these notices, most registrants of antifoulant paints submitted additional information on their earlier release rate submissions in an attempt to comply with the August 13, 1987 Notice. New TBT release rate data have been submitted for some of the products on which the initial testing was unsatisfactory or that were not previously tested.

The Agency has completed its review of all submitted release rate data including a review of the TBT release from the EPA standard test paints. Attempts to comply with the August 13, 1987 Notice varied substantially and all

submissions are currently deficient. Many submissions did not include raw data (instrument readings), adequate information on instrument calibration, or sufficient data on blanks and controls. The descriptions of leaching and analytical methodologies were incomplete. Information needed to demonstrate that proper environmental controls (pH, temperature, and salinity) were maintained were not included in most submissions. In some cases, samples were stored beyond the period specified by the ASTM/EPA method; however, storage stability data were not submitted.

At this time no release rate studies have been validated. Registrants were informed in an Agency letter dated August 12, 1988, that additional data/information were required to be submitted before any decisions regarding specific release rates can be made.

In addition to the above deficiencies, many of the submitted studies did not adhere to the ASTM/EPA method specification that the TBT concentration in the measuring tank not exceed 50 ppb. This restriction was imposed to eliminate the possibility of autoinhibition of TBT release from the paint film. EPA and the ASTM committee suspect that the 50 ppb restriction may be too conservative. Testing is being initiated at EPA's Environmental Chemistry Laboratory (ECL) in Bay St. Louis, Mississippi, to determine the true autoinhibitory threshold.

After the ECL test results are available and the registrants respond to the above Notice, the Agency will reevaluate each study. If it is determined that the measuring tank concentration did not exceed the true autoinhibitory threshold and if the Agency finds that the registrant has supplied the additional data/information necessary to validate his submission, the Agency will use the study for regulatory purposes.

B. Release Rate Restriction

The proposed restrictions in the Preliminary Determination specified that no TBT antifouling paint could be sold or distributed which exceeds the short-term cumulative release (cumulative release over the first 14 days of the ASTM/EPA test) of 168 μg TBT (includes tributyltin and triphenyltin)/cm² or an average daily release rate (average over weeks 3 through 5) of 4.0 μg TBT/cm²/day. The proposed short-term cumulative release restriction was indexed to the average release rate restriction (3 × the average release rate over 14 days).

The short-term cumulative release was intended to reflect the initial surge of TBT release when a freshly painted vessel is first placed in the water. It was calculated by summing the time weighted release for each sampling over the first 14 days of the test. The time weighted release was calculated by multiplying the rate of TBT release for a given sampling time by the preceding length of time between sampling times. The average release rate reflects the long-term TBT release pattern that is established after the initial surge. It is defined as a simple average of the release rates measured over a certain number of weeks.

In the Preliminary Determination, release rate values were normalized to adjust for variation between testing facilities and the average daily release rate was defined as the mean of individual release rates over weeks 3 through 5. The Agency received numerous comments from TBT registrants and the FIFRA Scientific Advisory Panel regarding this analysis of the release rate data. Most commenters felt that the proposed release rate restrictions should be adjusted to account for the variability of the test method but that normalization was not an appropriate means of accounting for variability.

The standard test paint data were the only data common to all registrants and as such were used to evaluate the variability of the ASTM/EPA release rate method. Additional standard test paint data and information on testing procedures from individual testing facilities submitted after the Preliminary Determination was issued, were included in the Agency's analysis of the method's variability. It was not possible to establish that variation among testing facilities was attributable to systematic error, as was previously assumed. Variation associated with testing facilities is now assumed to represent a component of method variance. Normalization is not appropriate under these circumstances, and the Agency agrees that release rate data should not be normalized. The available data could not be analyzed by standard statistical procedures because sampling was unbalanced (a wide variation in the number of samples per laboratory). The Agency could only perform a qualitative analysis of the method's variability. It was determined that most of the variability was associated with testing among different laboratories and sampling over time within a given test. Variation between replicate cylinders and between replicate runs was low by comparison.

The Agency has determined that, due to the incomplete nature of the release rate data submissions and the uncertainty over autoinhibition, it would be inappropriate at this time to try to quantify the variability associated with the EPA/ASTM method. The Agency is unable to determine whether the high variance of the results is attributable solely to the inherent variability of the method or to possible improper conduct of the release rate studies. It would also be inappropriate to determine a release rate restriction which attempts to account for this variability based solely on the current data base.

For the present the Agency is keeping the Special Review open on the issue of release rates and is deferring to the interim release rate restriction (4 μg/cm²/day) and certification program established by OAPCA. Products will be certified on the basis of the average daily release rate calculated from validated release rate studies conducted according to the current draft ASTM/EPA method. Any new release rate data submission or resubmission (such as those required by the Agency's August 12, 1988 letter) will be reviewed and a determination regarding certification reached within 90 days of the Agency's receipt of such data.

The average daily release rate will now be calculated as the non-normalized mean of all release rate measurements during weeks 3 through 10. In the Preliminary Determination the average daily release rate was defined as the average of release rates measured over weeks 3 through 5. However, examination of the standard paint release rate data indicated that individual release rate measurements made during week 6 and beyond were equivalent to those made during weeks 3 through 5. Release rate measurements beyond 10 weeks may be required for paints with atypical patterns of TBT release over time. The additional measurements included in the calculation of the average release rate are expected to increase accuracy.

The Agency will consider release rate levels again when additional environmental monitoring data are available and the release rate method is improved. The Agency has already identified certain procedures within the method as potential sources of variability and has initiated experimentation to determine how the release rate method can be improved. This testing is further discussed in Unit VII. When the research is completed, the Agency may decide to replace the current OAPCA release rate restriction

with a restriction derived from the improved method.

C. Results

Release rate data for 109 currently registered TBT antifoulant paint products have been submitted to the Agency. Additional data have been required for 94 of these products. Data submissions covering 15 paints have been invalidated because the testing facility used inappropriate testing procedures. One specification in the protocol is temporarily deferred pending the results of EPA laboratory testing. This exception is the acceptance of data where the concentration of TBT in the measuring tank sea water exceeds 50 ppb. This concentration was exceeded for 42 of the 94 paint products.

Of the 94 paints for which release rate data were submitted, 58 have estimated release rates which tentatively meet OAPCA's average daily release rate restriction of 4.0 $\mu g/cm^2$/day. These products may be certified under OAPCA provided the registrants of these products submit adequate data as required by the Agency's letter of August 12, 1988, which will allow the Agency to validate the registrant's study. Table I characterizes the number of paints that would meet OAPCA's release rate restriction.

TABLE I—NUMBER OF PAINTS THAT TENTATIVELY MEET OAPCA'S RELEASE RATE RESTRICTION OF 4.0 $\mu G/CM^2$/DAY

Types of paints	With copper	Without copper
Free association paints	32	7
Copolymer paints with freely associated TBT	12	3
Copolymer paints	2	2

IV. Determination of Benefits

The following discussion of benefits includes consideration of the impacts of both OAPCA's requirements and the additional requirements imposed by this Notice. The OAPCA requirements, for which benefits impacts have been reviewed, include the vessel length and release rate restrictions. This Notice adds the restricted use classification requirement and requires labeling relating to OAPCA's requirements and those of this Notice. Under FIFRA the Agency must weigh the impacts on benefits of the risk-related requirements imposed pursuant to FIFRA. The Agency is not required to consider, other than as part of the already existing benefits situation, the impacts of requirements imposed pursuant to other legislative authority, such as OAPCA or OSHA, in a FIFRA-mandated risk/benefit weighing.

The benefits of TBT antifouling paints were analyzed for the boat and shipyard industry and three user groups: recreational, commercial, and military. As explained in the Technical Support *Document of the Preliminary* Determination, analysis was performed for three possible regulatory options: (1) Total ban of TBT antifouling paints, (2) restriction of TBT paints by release rate, and (3) restriction by release rate, size of vessel, and classification as a restricted use pesticide. The benefits of other regulatory options discussed in the Technical Support Document were not analyzed because it was determined that they were not feasible options to reduce the risks from TBT exposure to nontarget aquatic organisms.

Comparisons were made for TBT copolymer/ablative, TBT free association, copper conventional, and copper ablative paint systems. For each user group and each paint system, the impact of regulation was determined by subtracting the cost of hull maintenance using a particular paint system from the operational benefits gained from that system (i.e., fuel efficiency, increased time between dry dockings). The different paint systems were then compared for each user group. Hull preparation costs are lower when ablative paints are used because vessel operators can achieve extended dry docking intervals. The longer a vessel can stay in service between dry dockings or hull cleanings, the less expensive a vessel is to operate. On-ship trials conducted by the U.S. Navy indicate that organotin co-polymer/ablative paints would enable vessels to operate on a 5- to 7- year dry docking schedule.

The major, currently available alternatives to TBT antifouling paints are copper compounds, chiefly cuprous oxide. There are copper ablatives which, like TBT copolymer/ablatives, do not require hull cleaning or frequent dry docking. There are currently only three registered copper ablative paints. More testing is needed to determine if they can give the 5 to 7 years of service noted for certain TBT copolymer/ablative paints. Testing now being conducted indicates copper ablatives give acceptable control of fouling for 3 to 4 years. The conventional copper paints require frequent hull cleanings (every 9 to 18 months) to remove fouling organisms and the layer of insoluble copper compounds that precipitate near the paint surface and block the release of the toxicant. However, there is published research indicating that conventional copper paints may last over 3 years with several hull cleanings. The major disadvantage of copper is that it may cause galvanic corrosion to aluminum vessel hulls. Even with high quality anticorrosive primers, there may be small flaws in the primer coat that could allow copper corrosion to an aluminum hull, especially on vessels with long dry docking intervals.

Commercial vessels use approximately 60 percent of the TBT antifouling paints. For ocean going vessels, long periods between dry dockings and reduced fuel consumption are important considerations. Although many commercial vessels are dry docked and inspected every 2 years, TBT copolymer/ablative paints provide an estimated $318 million per year savings to U.S. commercial vessels over copper conventional paints and an estimated $143 million savings over copper ablative paints.

There are approximately 5 million recreational vessels in the U.S. Most recreational vessels are removed from the water after every use and do not use antifouling paint. However, 14 percent of recreational vessels (700,000 vessels) use some type of antifouling paint containing either copper compounds, tributyltin compounds, or a combination of the two biocides. It is estimated that approximately 60,000 recreational vessels are painted with TBT copolymer/ablative paints, but of these only some 21 percent take advantage of the extended dry docking intervals that can be achieved through use of these paints; the other users tend to paint more frequently than may be necessary. The loss of TBT paints would cost recreational boaters currently using TBT copolymer/ablative paints $0.85 million per year. Recreational vessel owners who currently use free association TBT paints would incur an estimated additional cost of $0.28 million per year over using less expensive copper based paints which will give one to two seasons of protection. Therefore, in terms of antifouling use, there appears to be an economic benefit only to those recreational boat owners who use TBT copolymer/ablative paints and take full advantage of the extended dry docking intervals by not repainting too frequently. Another consideration is that TBT compounds are colorless and offer recreational boat owners more choice of paint colors than copper based paints.

The impact of a total ban of TBT antifouling paints was calculated for the U.S. Coast Guard, Navy Sealift Command, and U.S. Navy, assuming implementation of the proposed Navy fleetwide conversion to organotin

antifouling paints. The estimated average annual net benefit of using TBT copolymer/ablative paints versus copper ablative paints is $35.3 million and $142 million over using conventional copper paints. Estimates for loss of fleet readiness (e.g. time spent in drydock) were not quantified.

The total annual benefits (including commercial and recreational vessels and assuming fleetwide conversion by the Navy) of an estimated $179 million would be lost if all users of TBT paints switched to copper based paints (copper ablatives substituted for TBT copolymer/ablatives and conventional coppers substituted for TBT free association paints). If all users substituted conventional copper paints for all TBT paint use, due to the proven product performance of conventional copper paints over the recently developed copper ablative paints, the loss would be an estimated $460.8 million annually.

The foregone benefit (i.e., additional expense) of using copper ablatives may be reduced if copper ablatives can be shown to have service lives comparable to TBT copolymer/ablative paints. Since it has been shown that existing copper ablative paint formulations have in-service lives of at least 3 years, dry docking on a 3-year schedule was used as an assumption for all copper ablative paint calculations.

There are approximately 6000 boat and shipyards in the United States, 44 percent of which use antifouling paint. Approximately 48 percent of the antifouling paints used by these firms are TBT products; this accounts for about 70 percent of the TBT antifouling paints used in boat/shipyards. U.S. shipyards compete with foreign countries as well as domestically for business. Many U.S. flag (ocean going) vessels are currently docked and painted abroad because foreign labor and materials in this sector are generally less expensive despite a substantial *ad valorem* tax (imposed by the U.S. government) on these services. The regulatory restrictions are likely to have little impact on this practice. The expected cost of the TBT regulation is small in comparison to the *ad valorem* tax currently paid and does not appear to be so excessive that it would cause shipping companies to have more work done abroad. Boat and shipyard serving vessels too small to go abroad may have more business if conventional copper paint systems are used that require frequent hull cleaning and more frequent painting than TBT copolymer/ablative paints.

Under the Agency option to restrict release rates, which is now mandated by OAPCA, there would be TBT paints (both copolymer/ablatives and free association) available for all user groups and for aluminum hulled vessels as well. An initial short supply of acceptable paints is likely and prices may be elevated in the short term until new additional paints with acceptable release rates are registered.

The last option included the following elements: (1) Release rate restrictions, (2) limiting the size of vessel treated; and (3) classifying TBT antifouling paints as restricted use pesticides. The effects on benefits from release rate restrictions and the impact on TBT paint availability was discussed above. In the Preliminary Determination, the Agency argued that restricting the size of vessel to be treated with TBT should have a minor economic impact on users because most non-aluminum hulled vessels under 65 feet in length do not gain an economic benefit from the use of TBT antifouling paints because vessels are painted frequently and there are effective alternatives. The Agency believes this conclusion is still accurate now that the OAPCA 82-foot restriction is in effect. The benefits for vessels between 65 and 82 feet in length are similar because generally they are hauled and repainted every year or two and therefore do not receive the economic benefits from extended drydocking intervals available with TBT copolymer/ablative paints.

Classifying TBT antifouling paints as restricted use pesticides builds upon OAPCA's release rate and vessel length restrictions and provides even further protection. This requirement is expected to cost users an estimated $600,000 the first year and $150,000 in subsequent years in lost revenues while they are undergoing certified applicator training. In addition, there would be an estimated cost of $25,000 to $30,000 incurred by affected states each year to establish and maintain the required training programs. The state of California has already classified TBT antifouling paints as restricted use pesticides, which lessens the cost of design and implementation of a certification and training program incurred by that State as a result of the classification in this Notice. The same would be true for any other states that may on their own classify TBT as a restricted use pesticide. Furthermore, the existence of one or more state certification and training programs may aid the design of additional programs.

The estimated cost of required compliance with the application, removal, and/or disposal directions would vary depending upon vessel size and shipyard capabilities. Qualitatively, based on information submitted by the U.S. Navy (Ref. 19), it appears that a 90 to 95 percent clean-up of drydock surfaces can be attained at minimal cost while an increase to 99% clean-up would add substantially higher costs.

Under section 4(b)(1) of the Occupational Safety and Health Act (OSHA), OSHA may be determined to be preempted if another agency exercises statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health pertaining to working conditions of employees. EPA does not intend, by making TBT antifoulant paints restricted use pesticides or by specifying certain required work practices through this Notice, to preempt or interfere in any way with OSHA requirements pertaining to any activities or facilities where TBT use, removal, or disposal is occurring. This Notice requires label language referring to OSHA requirements, which is designed to avoid any confusion on the matter of preemption. Facilities subject to OSHA requirements, including, but not limited to, regulations on the safety and health of shipyard employees engaged in surface preparation and preservation, must already comply with such standards. The cost impact of label requirements in this Notice requiring general reference to the applicability of OSHA standards, relates only to the cost of including such reference on the label. The cost impact of this Notice does not include the actual costs of compliance with requirements imposed by OSHA.

New technologies for controlling antifouling may be implemented that could reduce the impact of TBT restrictions. For example, the U.S. Navy is testing fluorocarbon coatings that contain no toxicant. The coating surface must be cleaned regularly (once a month in the summer and once every 3 months in the winter). A tug boat painted with the fluorocarbon coating has performed well since 1977 without repainting. Also, the antibiotic terramycin has recently been registered as an additive to antifouling paints; it must be incorporated with paints containing other toxicants and cannot be considered a direct substitute. Control of fouling organisms is an active area of research, especially in the U.S. Navy which conducts testing of promising new compounds for their overall performance. The U.S. Navy along with the Agency will continue to conduct research on chemical and non-chemical alternatives to organotin antifouling paints as required by OAPCA.

In conclusion, it appears that the major benefits from the use of TBT antifouling paints are gained by those vessel owners, mainly commercial, that take advantage of the extended dry docking intervals. Because of the higher costs of TBT paints versus copper paints, most recreational boaters appear to lose money by using TBT paints because they do not take advantage of the extended dry docking intervals. The U.S. Navy claims that the use of TBT paints will provide improved fleet readiness in addition to economic benefits. Copper based paints are the major alternatives to TBT paints and, for some users, the copper ablative paints may prove to be equally effective. Further research is being conducted on other alternatives.

Comments: Registrants, environmental groups, and government agencies made the following comments on the Agency's benefit assessment in the Preliminary Determination and Technical Support Document.

1. A respondent commented that the Agency should have utilized the same dry docking maintenance schedule for the TBT copolymer and copper ablative antifouling paints (5 years) and the respondent questioned whether there was sufficient data on currently marketed TBT copolymers to predict a 5-year service life.

Response: The Agency utilized dry docking maintenance cycles that are representative of the reported longevity of currently available paint products. The Agency recognizes that the data on copper-ablative paints are conservative and that data developed over the next few years may indicate that the dry docking cycles are longer than 3 years; however, currently available efficacy data indicate that a service life of three is reasonable. For TBT copolymer paints, the Agency used data supplied by users and paint companies which suggest a service life of at least 5 years for certain currently marketed TBT copolymer paints.

2. A second respondent stated that conventional copper paint lasting over 3 years with underwater hull cleaning is not a viable alternative because the coating is removed with the cleaning operation.

Response: Cologer and Preiser (Ref. 20) have stated that conventional copper paints combined with periodic underwater hull cleaning may provide up to 5 years of service. According to their data, which used in-service U.S. Navy vessels, conventional copper paints could be cleaned without destroying the paint surface although hull cleaning was needed sooner once the vessel had been cleaned for the first time.

3. A respondent questioned the validity of the assumptions regarding the marginal fuel cost avoidance derived through the use of TBT versus copper ablatives.

Response: The assumptions used were based upon empirical information gathered directly from the user groups. The Agency appreciates that numerous externalities may be involved in fuel consumption; however, it has tried to estimate the fuel cost avoidance directly attributable to the use of TBT antifouling paints.

4. A respondent stated that few facilities actually have adequate TBT controls to prevent contamination of the surrounding environment.

Response: Data available to the Agency, as discussed earlier, indicate that broom sweeping or vacuum sweeping of flat open dry dock surfaces achieves a 90 to 95 percent cleanup of TBT at minimal cost. The Agency is confident that most facilities will be able to secure equipment that will provide 90 to 95 percent cleanup.

V. Comments of the Scientific Advisory Panel, Secretary of Agriculture and Other Parties

As required under sections 6 and 25 of FIFRA, the Agency provided its Preliminary Notice of Determination and Technical Support Document to the Scientific Advisory Panel and the Secretary of Agriculture, respectively, for their comments, which are presented below. This section also includes general comments from other parties which relate to the regulatory measures proposed in the Preliminary Notice of Determination, as opposed to comments on specific risk or benefit issues.

A. Comments of the Scientific Advisory Panel

EPA presented its proposed decision on tributyltin antifoulant paints at a public meeting of the Scientific Advisory Panel held in Arlington, Virginia, on December 15, 1987. The panel issued its response in a written report of December 23, 1987. The Panel's report is reproduced below in its entirety.

Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Scientific Advisory Panel

A Set of Scientific Issues Being Considered by the Agency in Connection With the Special Review of Tributyltin

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) has completed review of the data base supporting the Environmental Protection Agency's (EPA) determination that adverse acute and chronic effects to nontarget aquatic organisms may result from the use of Tributyltin (TBT) compounds as antifoulants unless certain modifications to the terms and conditions of registration are made by the registrant(s). The review was conducted in an open meeting held in Arlington, Virginia, on December 15, 1987. All Panel members, except Drs. Edward Bresnick and Thomas W. Clarkson, were present for the review. In addition, Dr. Robert Huggett, Virginia Institute of Marine Science and Dr. Roy Laughlin, Oceanographic Institution, Incorporated served as *ad hoc* members of the Panel. Public notice of the meeting was published in the Federal Register on Monday, November 30, 1987. Oral statements were received from staff of the Environmental Protection Agency and from Dr. David B. Russell, M & T Chemicals; Dr. Alexis I. Kaznoff, Naval Sea Systems Command, U.S. Navy; Mr. Arthur Tracton, Hempel Coatings, Inc. and Mr. David S. Bailey, Environmental Defense Fund. In consideration of all matters brought out during the meeting and careful review of all documents presented by the Agency, the Panel unanimously submits the following report.

Report of Panel Recommendations

Tributyltin (TBT)

The Agency requested the Panel to focus its attention upon a scientific issue relating to the Special Review of Tributyltin.

There follows some comments to the issue and the Panel's response to the issue.

General Comments

The Panel commends the Agency on its conclusion and recommendations relative to the use of tributyltin (TBT) in antifouling paints for hulled vessels. The substance is clearly toxic which is, of course, why it is used as a biocide. Concentrations of TBT in waters which have high boating activity are sometimes high enough to adversely affect non-target organisms.

For instance, laboratory bioassays have demonstrated acute and chronic effects at levels less than 0.2 ppb TBT. Monitoring of whole water, both fresh and salt, from numerous locations around this country has shown that TBT concentrations often exceed LC_{50} values.

Field investigations in Europe and North America have detected several morphological and physiological effects on aquatic organisms which can be induced in the laboratory using TBT as the toxicant. The locations at which the field observations were made demonstrate that organisms living in closer proximity to vessels painted with TBT have a higher probability of being affected.

Tributyltin concentrates in organisms and sediments, and bioaccumulation factors of 200 to 30,000 have been reported depending on the species investigated.

The concentrations of TBT found in sediments may be 10^2 to 10^4 times higher than in the overlying water. TBT may degrade in water and sediments, but relatively high concentrations of TBT in water, sediment and the biota can be expected for some time to come even if the

input of the biocide from vessels were eliminated.

The above information leads the Panel to endorse the Agency's conclusions relative to the potential biological impact of TBT on aquatic organisms.

Issue: The Agency requests the Panel's comments on the Agency's assessment of the environmental effects of TBT based on the integration of available monitoring data with laboratory toxicity data and the use of field effects data from Europe and the United States.

Panel Response: 1. The Panel agrees that available data support the EPA's assessment of hazard to non-target organisms from TBT use.

2. The Panel is concerned that the normalization of data on leaching rates from various registrants may have introduced a degree of uncertainty to the Agency's acceptable release rate.

It is not clear to the panel how the analytical variability has been considered in the establishment of the acceptable leaching rate. The Panel suggests that the Agency carefully reevaluate test methodology for leaching rates.

3. Finally, in view of the potential hazard TBT, its projected use on commercial and military vessels, and its subsequent release from sediments; the Panel suggests that monitoring of TBT in the environment and basic toxicological effects on organisms be continued. In addition, improved information on fate and partitioning of TBTs, especially from sediments and biofilms, should be compiled.

For the Chairman. Certified as an accurate report of Findings: Stephen L. Johnson, Executive Secretary, FIFRA Scientific Advisory Panel. Date: December 23, 1987.

The Agency's response to the release rate issues raised by the SAP's comments is noted in Units III and VII of this Notice. In brief, the Agency is no longer normalizing release rate data and is considering the usefulness of other ways of dealing with variability in its continuing analysis of the release rate methodology. The Agency has initiated experimentation at EPA's Environmental Chemistry Laboratory at Bay St. Louis, Mississippi, to identify sources of error in the current methodology, to design modifications to reduce this error, and to test these modifications. It is anticipated that a final method will be jointly approved by ASTM and EPA by late 1990. In the interim, OPP and ASTM are making minor changes to the draft method which are expected to increase the precision without altering the magnitude of the measured release rates.

In regard to the SAP's last comment, the Agency will require TBT registrants to monitor water quality and environmental health to determine existing TBT levels and the impact of OAPCA's restrictions and the requirements contained herein. Additional environmental fate and aquatic toxicity data required by the July 29, 1988 DCI will be submitted to the Agency within 2 to 4 years. If these or any other data suggest that the risks to aquatic non-target organisms have not been adequately reduced, the Agency may take further regulatory action.

B. Comments of the Secretary of Agriculture

The comments of the U.S. Department of Agriculture in response to the Notice of Preliminary Determination, Draft Notice of Intent to Cancel and the Technical Support Document, dated October 7, 1987, are printed in full below:

Mr. Douglas Campt, Director,
Office of Pesticide Programs (TS-767C), U.S. Environmental Protection Agency, Washington, DC 20460.

Dear Mr. Campt: This is in response to your letter of October 15 concerning the preliminary decision to cancel registration for TBT antifouling paints. The Department interposes no objection to the consummation of this proposal.

Sincerely,

Charles L. Smith,
Coordinator, Pesticides and Pesticide Assessment.

C. Other Comments on the Proposed Regulatory Actions

1. Several respondents commented that aluminum outdrive and engine components should have the same exemption as aluminum hulled vessels and that TBT antifoulant products for such use, commonly 16-ounce pressurized containers, should not be classified as restricted use.

Response: The restriction on vessel length for the use of TBT antifouling paints on non-aluminum hulled vessels was not intended to exclude the use of TBT antifouling paints on aluminum outdrive and engine components as long as these paints meet the release rate requirements. OAPCA, which mandated the vessel length restriction, allows for use of such paints. The Agency believes that TBT antifouling paints which meet the release rate restriction can be used on aluminum outdrive and engine components without resulting in an adverse effect to non-target aquatic organisms.

The Agency agrees that use of small spray cans of 16 ounces or less of TBT antifouling paint registered for use to prevent fouling of outdrives and engine components should not be included in the restricted use classification. In the Agency's view, the amount of TBT from this use is insignificant when compared to the amount that may be introduced into the environment from the use on vessel hulls. These are products of convenience to be used by owners of non-aluminum vessels for the treatment of the underwater components of their boats. The possibility of misusing these products for treatment of hulls is believed to be very slight because of their spray-on nature. Classifying these products as restricted use would be tantamount to cancellation. However, in order for these products to be exempt from the restricted use classification, they must be labeled for use *only* on aluminum outdrive and engine components. Any other use would be unlawful.

2. A few respondents felt that the proposed restrictions would adversely affect the U.S. ship repair industry by forcing shipping companies to have work done abroad.

Response: The Agency does not anticipate that the restrictions contained in this Notice will significantly alter the current situation. The substantial *ad valorem* tax currently paid by the ship operators/owners who have their vessels maintained abroad significantly exceeds the expected cost of the TBT regulation. The expected cost of the TBT regulation does not appear to be so excessive that it should cause shipping companies to have more work done abroad. Furthermore, effective antifouling paints will continue to be available for those vessels maintained domestically including government vessels and vessels traveling only in U.S. waters.

3. One respondent stated that the Navy should be allowed to use any antifouling paint which they believe will effectively prevent fouling for the maximum period of time.

Response: Prior to the initiation of the Special Review, the Navy planned to use low release rate paints in its fleetwide conversion to TBT antifoulant paints. The Navy has expressed concern over the availability of copper-free paints for use on aluminum hulls. There are currently 12 copper-free paints with estimated release rates that tentatively meet OAPCA's release rate restriction of 4.0 $\mu g/cm^2/day$.

4. Several respondents expressed concern that if commercial paints are restricted from use on hulls of vessels under 82 feet in length, boat owners might manufacture do-it-yourself paints from widely available TBT-boosters yielding free association paints with uncontrolled release rates. Congressman Walter B. Jones, Chairman of the Merchant Marine and Fisheries Committee, asked the Agency to take action against such products which

appear to be unaffected by the Special Review.

Response: The sale and use of tributyltin additives to make antifouling paints is illegal under OAPCA. OAPCA specifically prohibits the retail sale, delivery, purchase, or receipt of any substance containing organotin for the purpose of adding the substance to paint to create an antifouling paint. The only tributyltin additive products currently registered under FIFRA by EPA are registered for application to paint to be used as mildewcides. This Notice requires these labels to be amended to specifically prohibit the application of the product to paint to create antifouling paint for use on certain listed objects. (See Section VIII.B.6.)

5. If EPA's proposed restrictions go into effect, then release rates will be about one-fifth what they were prior to regulation. However, if more large vessels are treated than in the past (mainly due to the Navy's conversion of its entire fleet), TBT concentrations in harbors may equal or exceed current levels.

Response: As of 1985, use of TBT antifoulant paints for military vessels accounted for 3.2 percent of the market. The Agency estimates that if the U.S. Navy converts its entire fleet, the military's market share will increase to 15 percent. The Agency feels that the resultant increase in environmental loading, especially in ecologically sensitive shallow water sites including estuaries, would be more than offset by OAPCA's release rate restriction and elimination of use on non-aluminum vessels less than 82 feet, and the requirements of this Notice pertaining to the classification of TBT antifoulant paints as restricted use pesticides, and the proper use and disposal of TBT paints. Further, as stated above, if results of future monitoring suggest that current restrictions have not reduced concentrations to reasonable levels, the Agency may take fur[illegible]egulatory action to achieve lo[illegible]vironmental concentrations.

6. Several respondents stated that the release rate restrictions were not developed with regard to achieving any specific water quality objectives.

Response: OAPCA's release rate restriction cannot be correlated to any specific water quality standard. OAPCA's release rate restriction was designed to reduce one source of environmental loading: TBT leaching from painted surfaces. Congress chose this as an interim way of regulating TBT release. It did not choose other means such as restricting the number of boats treated or the number of paints used.

7. The Agency's predictions of the reductions in environmental loading of TBT that will result from the proposed regulatory decision are flawed.

Response: The Agency's estimate that an approximately five fold reduction in release rate from 20 to 4 $\mu g/cm^2$/day (the level now mandated by OAPCA) was based on estimated release rates for all TBT antifouling paint products registered when the Special Review was initiated and not on weighted averages of the volume of paint sold. On a weighted average, it is estimated that the pre-Special Review release rate was approximately 10 $\mu g/cm^2$/day. Under OAPCA's release rate restriction and assuming the same percentage of distribution as when the Special Review was initiated, the new weighted average release rate would be approximately 2 $\mu g/cm^2$/day (also a five fold reduction).

The Agency also believes that the market will change due to OAPCA's vessel length restriction of 82 feet. Because paint registrants may switch from marketing their products from small vessel owners to large vessel owners, the Agency did not attempt to estimate the weighted average release rate in the Technical Support Document. However, the Agency does have data to indicate that approximately 40 percent of the TBT antifouling paint has been used on non-aluminum hulled commercial and recreational vessels that are shorter than OAPCA's size restriction. Therefore, based on those data, once the effect of OAPCA's restrictions is felt, TBT loading into the aquatic environment should be reduced by at least 40 percent. In addition to the elimination of use on vessels under 82 feet in length, the remaining use will be with paints that have a lower release rate (that is certified under OAPCA as having a release rate of 4.0 $\mu g/cm^2$/day or less).

8. Several respondents expressed concern that there would not be a sufficient number of copper-free tributyltin antifouling paints with acceptable release rates available for use on aluminum hulled vessels. One respondent recommended that a maximum release rate of 10 $\mu g/cm^2$/day for aluminum hulls should be established for an 18 month period following enactment of the regulations to allow for the reformulation of copper-free antifouling paints. Final release rates for aluminum hulled vessels should be 5 $\mu g/cm^2$/day. Another respondent recommended that a separate release rate restriction for aluminum hulled vessels should be established at 6.0 $\mu g/cm^2$/day to ensure that efficacious copper-free paints are available to protect Navy ships with aluminum hulls.

Response: The release rate data currently available to the Agency indicates that 12 copper-free TBT antifouling paints, suitable for use on aluminum hulls, have estimated release rates which tentatively meet OAPCA's release restriction. At least 5 of these 12 paints are intended for use on commercial or military vessels. Establishing a separate release rate restriction for copper-free TBT paints is not necessary, because it appears that in the short-term a sufficient number of copper-free TBT paints will be available under OAPCA's release rate restriction and existing stocks provisions. This partly assumes that the registrants for these paints will provide the Agency with the additional release rate data, enabling the Agency to certify these paints under OAPCA. In the long-term, new copper-free TBT paints may be registered which should provide additional market options.

9. A respondent stated that the maximum permitted release rate of tributyltin should be the lowest release rate shown to be effective as an antifoulant. He has information indicating that manufacturers can reformulate antifoulants to be effective at a release rate of 3.0 to 3.5 $\mu g/cm^2$. Another respondent states that 5 $\mu g/cm^2$/day was the lowest effective rate.

Response: Neither respondent included supporting efficacy data with their comment. The Agency does not have data to suggest the lowest effective release rate; however, it plans to require registrants to submit such data. Until these data are available, the Agency believes that it, in conjunction with OAPCA's requirements, is taking regulatory action that should significantly reduce environmental loading of TBT and thereby lessen the possibility of effects occurring to non-target aquatic organisms.

VI. Risk/Benefit Analysis

FIFRA requires EPA to weigh the risks against the benefits of the use of pesticides to determine whether continued registration would cause unreasonable adverse effects on man and the environment. The Agency has determined that with current label restrictions and formulation of products, the risks posed to nontarget organisms from the use of TBT antifouling paints outweigh the benefits. Detailed discussion of the risk and benefit components of this action (including consideration of possible alternative regulatory options) appears in the

previous Units of this Notice and in the Technical Support Document.

TBT has been shown to be highly toxic to aquatic organisms at or near 0.02 ppb. In particular, TBT has been shown to be persistent in the environment and to bioaccumulate in animal and plant tissue. potential TBT exposure to nontarget organisms is high in areas of boating and shipping activity and also may be high in sensitive ecologically productive areas because of movement of TBT residues via currents and tides. TBT binding to sediments and particulate suggests the potential for TBT bioavailability among filter and deposit feeding organisms. TBT residues have been found in U.S. waters at levels comparable to the values that have caused population effects in Europe and and to the values that have been shown to cause effects to nontarget organisms during laboratory experiments. Recent reports in the United States link TBT exposure to adversely affected oyster beds in Coos Bay, Oregon. The Agency believes that there is adequate information available to support the set of regulatory actions required herein, which are designed to reduce environmental loading of TBT and thereby lessen the possibility of effects occurring to populations of non-target aquatic organisms.

The total annual benefits of TBT antifoulant use are estimated to be $179 million compared with using the next best alternative, either copper ablative or copper conventional paints depending upon what the user is currently applying. However, the benefits are highest for those users taking advantage of the extended dry docking schedule offered by TBT copolymer/ablative paints. In most cases, recreational boat owners using TBT copolymer/ablative paints incur an additional cost from which they appear not to benefit compared to using less expensive copper based paints, because they generally do not take advantage of the extended dry docking schedule.

The Agency believes the risks resulting from the use of TBT antifouling paints can be reduced without losing benefits for most commercial and military users through the use of TBT antifouling paints which release less TBT into the aquatic environment, while complying with the requirements provided herein. It is believed that many recreational vessel owners will save money by use of non-TBT alternatives. While there may be costs to states for training certified applicators and costs to user groups who must become certified under restricted use and comply with certain application, disposal, and removal requirements, the Agency believes that the benefits of reducing the environmental loading of TBT outweigh the costs.

In order to reduce the concentrations of TBT in the aquatic environment, the Agency announces by this Notice that it will cancel all TBT antifouling paint registrations which:

(1) Do not comply with OAPCA's average daily release rate limit of 4.0 ug organotin/cm^2/day.

(2) Do not comply with OAPCA's prohibition on the use of TBT antifouling paints on all non-aluminum vessels under 82 feet (or 25 meters) in length (on deck).

(3) Are not classified as restricted use pesticides, restricting their sale to certified commercial applicators and their use to persons under the direct supervision of an on-site certified commercial applicator (except for products packaged in 16 ounce or less spray-can containers which are labeled for use only on outboard motors, propellers, and other non-hull underwater aluminum components).

(4) Do not have labeling which requires compliance with applicable OSHA regulations and with the following directions for use:

(a) During and after paint removal and/or application of new TBT paint, employ methods designed to prevent introduction of TBT paints into aquatic environments.

(b) Following removal of TBT paint and/or application of new TBT paint, all paint chips and spent abrasives, paint containers, unused paint, and any other waste products from paint removal or application must be disposed of in a sanitary landfill.

(5) Do not limit certain uses for some types of products, as specified herein.

In addition to the other measures which should reduce risk, risk reduction should result from the restricted use classification while still maintaining the benefits of TBT use. The Agency's restricted use classification for TBT antifouling paints requires that applicators or their supervisors are trained in matters such as proper TBT antifouling paint application, disposal, and removal, and the consequences of misuse of TBT antifouling paint. This training will help ensure that applicators follow appropriate requirements for application, clean-up, and disposal. If the appropriate procedures are followed, the risk from inadvertent aquatic contamination should be reduced. The restricted use classification further ensures that applicators adhere to the recordkeeping requirements regarding TBT paint application and disposal of TBT paint wastes. It also helps to ensure that applicators will adhere to OAPCA's size restriction as stated on the label.

The Agency has determined that it would take approximately nine months to develop a prototype training program for the use/disposal/and removal of TBT paints and paint wastes. Therefore, the Agency is requiring that the registrants develop and submit a prototype program within 180 days from the date of their application for conditional registration. The Agency has allowed an additional three months for Agency review of the program and an additional 6 months for the states to train and certify. After considering these time periods, the Agency is designating March 1, 1990 as the effective date for the restricted use classification.

The Agency has determined that the costs of meeting its requirements (that is, those pertaining to the incorporation of label language to: Reflect classification as restricted use and associated requirements for development of training specifications and materials; require adherence to certain work practices; and refer to pre-existing OSHA and OAPCA requirements) do not exceed the benefits of use of products which comply. Compliance with these requirements will serve to reduce environmental loading of TBT and the exposure of non-target aquatic organisms.

VII. Future Activities Regarding Tributyltin Antifoulant Paints

The Agency believes that the regulatory steps taken at this time under this Special Review and OAPCA should have a significant impact on reducing the environmental loading of TBT and the adverse effects on non-target aquatic species. However, the Agency also recognizes that there is a need to pursue further study of this environmental issue for at least two reasons. First, it is not clear that these regulatory actions will go far enough in protecting non-target aquatic species and, second OAPCA clearly establishes research requirements on environmental monitoring and alternatives to TBT antifoulant paints. As a result of future studies, the Agency may determine that additional regulatory actions are necessary in order to further reduce environmental loading and effects on non-target aquatic species. Therefore, the following areas of research are being pursued.

Over the next 2 to 4 years, TBT and TPT registrants will be conducting additional ecological effects studies in response to DCIs already issued by the

Agency. These studies include additional research on acute and chronic toxicity to freshwater, marine, and estuarine organisms and effects of TBT on aquatic food chains. These registrants will also be conducting environmental fate studies including degradation and metabolism studies, accumulation in fish, and bioconcentration in oysters. Registrants will also be generating data to characterize potential toxicity and exposure to humans. These studies include residue studies of TBT and TPT in edible fish and shellfish, and exposure studies of TBT to paint applicators, as well as acute, subchronic, and chronic mammalian toxicity studies. All of these studies have been required by Data Call-In Notices issued January 31, 1985, July 29, 1986, and August 28, 1987.

The Agency will issue an additional Data Call-In Notice by late 1988, which will require TBT registrants to conduct multiyear and multisite monitoring studies which will provide additional information on the extent, concentration, and fate of organotin residues in the aquatic environment and the impact of these organotin residues on indicator organisms *in situ*. These studies will develop data for representative dry docks, marinas, and other sensitive areas in order to provide information needed to evaluate the impact of the regulatory action contained in this Notice and of OAPCA's requirements on environmental concentrations of TBT. Also, the Agency is continuing its efforts to model Norfolk Harbor, Virginia as discussed in Unit II of this Notice. This model will examine environmental concentrations under several loading levels and attempt to estimate the impact of various regulatory approaches on TBT concentrations. This modeling information may be useful to the Agency if it needs to take additional regulatory action on TBT.

The Agency also plans to require from TBT and TPT registrants data that will enable the Agency to determine the lowest efficacious TBT and TPT release rate levels. This information may allow the Agency to better assess the impact on benefits of any future regulatory action and provide a guide for a further reduction of release rates if the Agency finds that this is necessary. Also, the Agency will be consulting with the U.S. Navy in regard to initiating joint research on chemical and nonchemical alternatives to organotin antifouling paints as required by OAPCA.

A more precise release rate methodology is desirable and may be a requirement for future action. The current ASTM/EPA method yields results with a relatively high variance. If monitoring studies indicate that additional reduction of TBT loading in the environment is necessary, then the release rate restriction may be lowered. If the present ASTM/EPA method cannot be modified to give more consistency, then a more precise method might have to be developed that could be relied on to distinguish between paints that have very similar release rates.

EPA is actively working to improve the precision of the current method. However, the laboratory research needed to investigate the sources of error in the current method will require 12 to 18 months to complete. To provide the best available methodology in the interim, the Agency in a joint effort with ASTM is making minor modifications to the method. These modifications are primarily aimed at tightening specifications and simplifying certain procedures. The purpose of such changes is to improve the precision of the release rate measurements. A revised draft ASTM/EPA release rate method is expected to be published in the Fall of 1988.

A research program to improve the release rate methodology has been initiated at EPA's Environmental Chemistry Laboratories. The objectives of this program are to: (1) Identify aspects of the methodology that significantly contribute to the variability, (2) design method modifications that increase the precision of the release rate measurements, (3) compare the relative precision obtained from individual modifications, and (4) select those modifications which will maximize the overall precision of the method.

Laboratory testing by the Agency will continue until appropriate modifications have been designed and tested. The Agency, in conjunction with ASTM, will use the results of these tests to finalize a method. Testing of the method by other laboratories (so called "round robin" testing) is anticipated before adoption as an official ASTM method. The extent to which the final method differs from the current method cannot be estimated at this time.

The Agency may issue a final determination regarding the release of organotin into the aquatic environment which would supersede the OAPCA release rate restriction if data submitted to the Agency indicates any of the following: (1) That release rates measured by the final method are substantially different from those estimated by the current method, (2) that additional restriction of TBT loading in the environment is necessary, or (3) that the current release rate restriction is not the lowest efficacious rate.

VIII. Compliance With This Notice

A. Definitions

The following terms are defined for the purposes of this Unit.

1. "Manufacturer" refers to any registrant who, as defined, sells, or distributes an antifouling paint (pesticide) product containing tributyltin.

2. "Distribute and sell" and grammatical variants refer to the distribution, sale, offering for sale, holding for sale, shipping, delivering for shipment, or receiving and (having so received) delivering or offering to deliver a pesticide product.

B. Requirements for Complying With This Notice

A manufacturer of any antifouling paint product containing tributyltin must submit an application to amend the registration of their product within 30 days of publication in the Federal Register or receipt of this Notice, whichever is later, to be allowed to continue to sell and distribute the product. Similarly, applicants for a registration subject to this final notice must file an amended application for registration within the applicable 30-day period to avoid denial of their application. The application must propose to amend the registration of the product to include the following terms and conditions and modifications:

→ 1. A manufacturer must include a declarative statement that he has submitted appropriate release rate data for this product and the results demonstrate that the product has a release rate of organotin which does not exceed OAPCA's average daily release rate limit of 4.0 ug organotin/cm^2/day.

This release rate must be supported by a validated release rate study using the ASTM/EPA release rate method. Within 90 days of the Agency's receipt of data, the Agency will determine if the study is valid and, if so, whether the Agency can certify that the product meets OAPCA's release rate restriction.

→ 2. A manufacturer must commit in writing to submit prototype specifications and materials for a certification and training program for the use/disposal/and removal of TBT antifouling paints and paint wastes. The actual prototype specifications and materials for the program will be required to be submitted within 180 days

from the date of application for conditional registration. Once submitted, the program will be reviewed by a committee comprised of the Agency's Office of Pesticide Programs Staff, including the Certification and Training Staff. Additionally, the Agency will ask for comments from representatives of the State FIFRA Issues Research and Evaluation Group (SFIREG). After final acceptance by EPA it will be passed on to the States for oversight and certification responsibilities. This program will facilitate the applicator's achievement of "commercial certified applicator's status" as prescribed by the certifying State Lead Agency (SLA). The certified applicator must meet, as a minimum, the certification requirements of FIFRA and all pertinent Federal regulations under 40 CFR Part 171. Applicators trained by this program will be considered eligible only for the status of certified commercial applicator of TBT products in the Federal aquatic pest control category or the state equivalent category or subcategory. The effective date of the restricted use classification is March 1, 1990. Training for this limited certification of competency shall include, as a minimum, sections on the following topics.

a. *Overview.* A general, practical overview of the principles and practices of using antifouling materials.

b. *Labels.* 1. Pesticide label and labeling comprehension.

2. The general format and terminology of pesticide labels.

3. The understanding of instructions, warning terms, symbols, and other information commonly appearing on pesticide labels.

4. The meaning of the terms "restricted use" and "general use".

5. Necessity for "use consistent with the label".

c. *Safety.* 1. Pesticide toxicity in general and potential tributyltin hazards to humans via common exposure routes.

2. Using antifouling paints as an example, common types and causes of pesticide exposures/accidents.

3. Precautions necessary to avoid application exposures to antifouling chemicals such as tributyltin.

4. Need for, and use of, protective clothing and equipment in the application and removal of TBT containing products.

5. Symptoms of pesticide poisoning in general.

6. Emergency procedures to be followed in case of excessive exposure to TBT antifoulant paint.

d. *Storage, handling, and disposal.* 1. Proper identification, storage, transportation, handling, mixing procedures and disposal methods for tributyltin containing compounds.

2. Proper disposal methods for paint chips and dusts suspected of containing tributyltin compounds.

3. Proper disposal methods for unused antifouling compounds containing TBT, associated wastes, spent sand-blasting grit, and containers.

e. *Environment.* The potential environmental consequences of the use/misuse or improper disposal of pesticides containing TBT as may be influenced by factors such as:

1. Precipitation, wind, and other climatic factors that may influence site run-off, drift, drying times, and the release of TBT-containing compounds.

2. Types of terrain/drainage, soil, and other work site conditions that contribute to application/removal/disposal site runoff or leaching.

3. Presence of fish, shellfish, invertebrate and other beneficial non-target organisms.

4. Desorption, solubility, absorbency, and/or persistence as related to the exposure of TBT to non-target species.

f. *Pests and pesticidal properties.* 1. The inhibition of specified pests and method of action must be demonstrated.

2. Common features of aquatic/marine pests and relevant life cycles.

g. *Antifouling product properties.* 1. Dilution procedures if any.

2. General understanding of pesticidal properties such as "What is a herbicide, biocide, mildewcide, (aquatic and otherwise).

3. Types of formulations.

4. Factors that influence effectiveness.

h. *Application techniques.* Methods/procedures/equipment used in applying tributyltin-containing compounds including the advantages and disadvantages of each.

1. Maintenance, cleaning, and calibration of equipment.

2. Relationship of discharge and placement of pesticide to proper use, unnecessary use, and misuse.

3. Prevention of drift, overspray, and other exposures to humans and endangered species.

i. *Laws and regulations.* 1. Applicable State, Federal, and local pesticide disposal laws and regulations.

2. Levels and requirements of supervision associated with the application of tributyltin restricted use products.

j. *Recordkeeping.* Certified commercial applicators or users of tributyltin will be required to maintain, at a minimum, for 2 years, records of kinds of the products, uses, dates, and application sites of restricted use products containing tributyltin. For purposes of this regulatory action "uses" will include the disposal site of tributyltin-containing dust, chips, or other waste. Therefore the location and dates of disposal will be a recordkeeping requirement. For purposes of this regulatory action, "application site" is determined to be not only the geographic location of the application site, but also the identification of the vessel receiving the application.

→ 3. The following required statement added to the label:

It is unlawful to use this product on nonaluminum hulled vessels less than 82 feet (25 meters) in length (on deck) except for the outboard motor or lower drive unit of such vessel.

→ 4. The following required statement added to the label:

Restricted Use Pesticide due to toxicity to Aquatic Organisms including shellfish: For sale only to certified commercial applicators and for use only by persons under the direct supervision of an on-site (at the work site) certified commercial applicator. These restrictions become effective on March 1, 1990.

→ 5. The following required statements added to the label:

During and after paint removal and/or application of new TBT paint, methods must be employed which are designed to prevent release of TBT paints into the aquatic environment. Following removal of old TBT paint and/or application of new TBT paint, all paint chips and spent abrasives, paint containers, unused paint, and any other waste products from paint removal or application must be disposed of in a sanitary landfill.

→ 6. The following required statement added to the label:

Users must comply with all applicable OSHA requirements.

→ 7. Products that are formulated in pressurized containers of 16 ounces or less and are registered solely for use on outboard motor and/or lower drive units of vessels must meet the following terms and conditions:

a. Release rate requirements specified in Unit VIII.B.1. of this Notice.

b. The following required label statement:

For use only on outboard motor and/or lower drive units of vessels. Any other use is unlawful.

c. The label statement in Unit VIII.B.5. of this Notice.

d. The label statement in Unit VIII.B.6. of this Notice.

→ 8. Products containing an organotin compound as an active ingredient and which are to be used as a paint additive to prevent or control mildew must have the following label prohibition:

It is unlawful to add this product to paints to create an antifoulant paint for use on hulls of vessels, outboard motors, lower drive units, crab pots, buoys, docks, fish nets or any other object or structure that contacts or may contact marine or fresh water.

Applications which conform to the terms and conditions included in this Notice of Intent to Cancel which are found by the Agency to be acceptable will be granted conditional registrations. Among other things, a condition of such registrations will be that acceptable specifications and materials for a prototype certification and training program must be submitted to the Agency within 180 days from the date of application for conditional registration.

C. Existing Stocks and Disposal Provisions

Pursuant to FIFRA section 6(a)(1), "the Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration [is cancelled pursuant to this Notice] to such extent, under such conditions, and for such uses as he may specify, if he determines that such sale or use is not inconsistent with FIFRA and will not have unreasonable adverse effects on the environment." The Agency has determined that limited sale and use of certain existing stocks of tributyltin antifoulant paints is not inconsistent with FIFRA and will not cause unreasonable adverse effects on the environment.

OAPCA established an existing stocks provision for all TBT antifoulant paint products that were in existence on the date of enactment. These existing stocks provisions continued in effect for any product which did not comply with OAPCA's release rate certification requirement or vessel length restriction. The maximum deadlines established by OAPCA were December 16, 1988, for sale, delivery, purchase, and receipt and June 16, 1989, for use. EPA was given authority to provide shorter time frames. In taking its action, the Agency has built upon the requirements of OAPCA, in that OAPCA's release rate restriction and existing stocks provisions remain in effect. The Agency has deferred a final decision on the release rate issue, as discussed earlier. In a letter dated September 11, 1988, TBT registrants were notified that none of the existing TBT antifoulant paint products passed the initial OAPCA certification review and thus they remained subject to OAPCA's existing stocks provisions. In that letter the Agency concurred in the maximum OAPCA provision for sale and use of existing stocks. Only after satisfying the requirements for certification, would these products no longer be subject to OAPCA's existing stocks deadlines. The Agency has determined that these same existing stocks dates should apply to any product which does not meet the additional requirements of this Notice. Aside from allowing for a smoother transition and less confusion in the channels of trade by not establishing a different set of existing stocks dates, this would be consistent with the risk reduction scheme under OAPCA as well as that required by this Notice. Use of existing stocks for the maximum time allowed by OAPCA rather than for a shorter period allows users and registrants a smoother transition to products which comply with OAPCA and this Notice while not increasing the risk to non-target organisms beyond levels considered acceptable by Congress.

Accordingly, under the authority of OAPCA and FIFRA section 6(a)(1), EPA will permit the continued sale and use of existing stocks of tributyltin antifoulant paint whose registrations are cancelled pursuant to this Notice, subject to the following conditions and limitations. For purposes of this Notice, EPA defines the term "existing stocks" to mean any quantity of tributyltin antifoulant paint product in the United States on the date of cancellation pursuant to this Notice of Intent to Cancel or through voluntary cancellation that has been formulated, packaged, and labeled for use and is being held for shipment or release, or has been shipped or released into commerce.

EPA will allow the sale and distribution of existing stocks of TBT antifouling paint products until December 16, 1988. EPA will also allow use of those existing stocks until June 16, 1989. EPA requires registrants to relabel with stickers, existing stocks in their possession or control, to indicate the time limitations on distribution, sale and use. These stickers must state the following:

Any sale, delivery, purchase, or receipt after December 16, 1988 is unlawful. Any use after June 16, 1989 is unlawful.

In addition, EPA is also requiring registrants to contact immediately commercial distributors of TBT antifouling paint products to inform them of the time limitations on distribution, sale, and use, and to provide supplemental sticker labels reflecting the time limitations for existing stocks in the possession of the commercial distributors. Upon expiration of the time limitation for sale and use of existing stocks, disposal must be arranged for by the person holding or possessing such stocks and must be in accordance with the Federal, State and local requirements. Any existing stocks provisions involved in voluntary cancellation of a TBT antifouling paint product prior to the publication of the final Notice is not affected by this provision, except that the maximum length of such existing stocks provisions cannot exceed the time allowed pursuant to OAPCA and such products must be restickered as noted above.

IX. Procedural Matters

This Notice announces EPA's intent to cancel the registrations of TBT antifouling paint products. This unit explains how current registrants may apply to amend their registrations to comply with the terms and conditions discussed in Unit VII of this Notice.

Under sections 6(b) and 3(c)(6) of FIFRA, applicants, registrants, and certain other adversely affected persons are also entitled to respond to this Notice by requesting a hearing on the actions that EPA is initiating. Unless a hearing is properly requested with regard to a particular registration or application, this action will become final by operation of law.

This unit of the Notice explains how such persons may request a hearing on EPA's final cancellation and denial Notice (and the consequences of requesting a hearing or failing to request a hearing in accordance with these procedures).

A. Procedure for Amending the Terms and Conditions of Registration to Avoid Cancellation or Denial of Application

Registrants affected by the cancellation actions set forth in this Notice may avoid cancellation by filing an application for an amended registration which contains the applicable label modifications, compliance with OAPCA release rate and size requirements, and certification and training program requirements detailed in Unit VIII.B. of this Notice. This application must be filed within 30 days of receipt of this Notice or within 30 days from the publication of this Notice, whichever occurs later. Applicants for a registration subject to this Notice must file an amended application for registration within the applicable 30-day period to avoid denial of their pending application.

Applications must be submitted to: John H. Lee, Product Manager, Registration Division (TS-767C), Office of Pesticide Programs, Environmental

Protection Agency, 401 M Street SW., Washington, DC 20460, (703-557-0485).

B. Procedures for Requesting a Hearing

To contest the cancellation action set forth in this Notice, Federal registrants or applicants may request a hearing within 30 days of receipt of this Notice, or within 30 days from publication of this Notice, whichever occurs later. Any other person adversely affected by the action described in this Notice may request a hearing within 30 days of publication of this Notice in the Federal Register.

A registrant or other adversely affected party who requests a hearing must file the request in accordance with the procedures established by FIFRA and EPA's Rules of Practice Governing Hearings under 40 CFR Part 164. These procedures require, among other things, that all requests must identify the specific pesticide product(s) for which a hearing is requested, and that all requests must be received by the Hearing Clerk within the applicable 30-day period. Failure to comply with these requirements may result in denial of the request for a hearing. Requests for a hearing should also be accompanied by objections that are specific for each use of each pesticide product(s) for which a hearing is requested.

Requests for a hearing must be submitted to: Hearing Clerk (A-110), Environmental Protection Agency, 401 M Street SW., Washington, DC 20460.

1. *Consequences of filing a timely and effective hearing request.* If a hearing on the action initiated by this Notice is requested in a timely and effective manner, the hearing will be governed by EPA's Rules of Practice for hearings under FIFRA section 6 (40 CFR Part 164), as modified below. The hearing will be limited to the specific uses and specific product registrations for which the hearing is requested.

In the event of a hearing, the specific use or uses of the specific registered product which is the subject of the hearing request will not be cancelled except pursuant to an order of the Administrator at the conclusion of the hearing.

2. *Consequences of failure of file in a timely and effective manner.* If a hearing concerning the registration of a specific pesticide product subject to this Notice is not requested by the end of the applicable 30-day period, registration of that product will be cancelled, unless the registrant files a request for an amended or conditional registration within the statutory period provided herein (see Unit VIII of this Notice).

If the registration of a product covered by this Notice is cancelled by operation of law, the sale and distribution of existing stocks will be governed by the provisions of Unit VIII of this Notice.

C. Separation of Functions

EPA's Rules of Practice forbid anyone who may take part in deciding this case, at any stage of the proceeding, from discussing the merits of the proceeding *ex parte* with any party or with any person who has been connected with the preparation or presentation of the proceeding as an advocate or in any investigative or expert capacity, or with any of their representatives (40 CFR 164.7).

Accordingly, the following EPA offices, and the staffs thereof, are designated as the judicial staff to perform the judicial function of EPA in any administrative hearing arising from this Notice of Intent to Cancel: the Office of the Administrative Law Judge, the Office of the Judicial Officer, the Administrator, and the Deputy Administrator. None of the persons designated as the judicial staff may have any *ex parte* communication on the merits of any of the issues involved in this proceeding, with the trial staff or any interested person not employed by EPA, without fully complying with the applicable regulations.

X. Public Docket

Pursuant to 40 CFR 154.15, the Agency has established a public docket (OPP-30000/49A) for the Tributyltin Special Review. This public docket includes (1) this Notice; (2) any other notices pertinent to the Tributyltin Special Review; (3) non-CBI documents and copies of written comments or other materials submitted to the Agency in response to this Notice, and any other Notice, regarding TBT antifouling paints submitted at any time during the Special Review process by any person outside government; (4) a transcript of any public meeting held by the Agency for the purpose of gathering information on tributyltin antifouling paints; (5) memoranda describing each meeting held during the Special Review process between Agency personnel and any person outside government pertaining to tributyltin antifouling paints; and (6) a current index of materials in the tributyltin public docket.

On a monthly basis, the Agency will distribute a compendium of indices for newly received comments and documents that have been placed in the public docket for this Special Review. This compendium will be distributed by mail to those members of the public who have specifically requested such material for this Special Review, pursuant to 40 CFR 154.15(f)(3).

XI. References

The following list of references includes all documents cited in this Notice. These documents are part of the public docket for this Special Review (OPP-30000/49B). The Agency will continue to supplement the public docket with additional information as it is received.

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Dated: September 23, 1988.

John A. Moore,

Acting Deputy Administrator.

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