zone is prohibited unless authorized by the Captain of the Port.

DATES: This temporary regulation is effective from 10 a.m. to 4 p.m. on May 4, 1997.

ADDRESSES: Marine Safety Office San Diego, 2716 N. Harbor Drive, San Diego, CA 92101–1064.

FOR FURTHER INFORMATION CONTACT:

LT Mike Arguelles, U.S. Coast Guard Marine Safety Office San Diego at (619) 683–6484.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 553, a notice of proposed rulemaking was not published for this regulation and good cause exists for making it effective in less than 30 days after **Federal Register** publication. Publication of a notice of proposed rulemaking and delay of its effective date would be contrary to the public interest since the details of the safety zone boundaries and WWI Oceanside Grand Prix Powerboat Race were not finalized until a date fewer than 30 days prior to the event date.

Discussion of Regulation

This regulation is necessary to protect the lives and property of the race participants and spectators by establishing an exclusionary zone around the WWI Oceanside Grand Prix Powerboat Race. During race times, vessels will be traveling at high rates of speed which will hinder their reaction time to obstacles. This safety zone will be marked by the sponsor, and enforced by U.S. Coast Guard personnel with the assistance of the Oceanside Harbor Police. Persons and vessels are prohibited from entering into, transiting through, or anchoring within the safety zone unless authorized by the Captain of the Port.

Regulatory Evaluation

This proposal is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has been exempted from review by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (44 FR 11040; February 26, 1979). Due to the short duration and limited scope of the safety zone the Coast Guard expects the economic impact of this proposal to be so minimal that a full Regulatory Evaluation under paragraph 10(e) of the regulatory policies and procedures of Department of Transportation is unnecessary.

Collection of Information

This regulation contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.).*

Federalism

The Coast Guard has analyzed this regulation under the principles and criteria contained in Executive Order 12612, and has determined that this regulation does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environmental Assessment

The Coast Guard has considered the environmental impact of this regulation and concluded that under section 2.B.2. of Commandant Instruction M16475.1B as revised in 59 FR 38654, July 29, 1994, it will have no significant environmental impact and it is categorically excluded from further environmental documentation. A Categorical Exclusion Determination and Environmental Analysis Checklist will be available for inspection and copying in the docket to be maintained at the address listed in **ADDRESSES.**

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

Regulation

In consideration of the foregoing, Subpart F of Part 165 of Title 33, Code of Federal Regulations, is amended as follows:

1. The authority citation for 33 CFR Part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; 49 CFR 1.46.

2. A new temporary section 165.T11–038 is added to read as follows:

§ 165.T11–001 Safety Zone: Oceanside, CA.

(a) *Location.* The following area constitutes a safety zone in the navigable waters in the vicinity of Oceanside, CA: beginning at a point located at latitude 33°25′00″ N, longitude 117°24′00″ W; thence southeast to a point located at latitude 33°09′04″ N, longitude 117°21′07″ W; thence southwest to a point located at latitude 33°09′02″ N, longitude 117°22′00″ W; thence northwest to a point located at latitude 33°11′54″ N, longitude 117°24′03″ W; thence northeast to the point of the beginning. All coordinates referred use Datum: NAD 83.

(b) *Effective Dates.* This temporary regulation is effective from 10 a.m. to 4 p.m. (DST) on May 4, 1997, unless cancelled earlier by the Captain of the Port.

(c) *Regulations.* In accordance with the general regulations in Section 165.23 of this part, entry into, transit through, or anchoring within this zone is prohibited unless authorized by the Captain of the Port.

Dated: April 9, 1997.

J.A. Watson,

Commander, U.S. Coast Guard, Captain of the Port, San Diego, California.

[FR Doc. 97–10733 Filed 4–24–97; 8:45 am]

BILLING CODE 4910–14–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300478; FRL–5713–1]

RIN 2070–AB78

Oxyfluorfen; Pesticide Tolerance for Emergency Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of the herbicide Oxyfluorfen in or on the food commodity strawberry in connection with EPA's granting of emergency exemptions under the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of Oxyfluorfen on strawberries in Massachusetts, New Hampshire, Connecticut, Maine, Washington and Oregon. This regulation establishes maximum permissible levels for residues of Oxyfluorfen in this food pursuant to the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and is revoked on April 15, 1998.

DATES: This regulation becomes effective April 25, 1997. Objections and requests for hearings must be received by EPA on or before June 24, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300478], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations

Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300478], must also be submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Such copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [OPP–300478]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Pat Cimino, Registration Division (7505W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Highway, Arlington, VA, (703) 308–8328, e-mail: cimino.pat@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing a tolerance for residues of the herbicide oxyfluorfen, [2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl)benzene] in or on strawberries, at 0.05 part per million (ppm). The residue requiring regulation is parent oxyfluorfen only. This tolerance will expire and be revoked by EPA on April 15, 1998. After April 15, 1998, EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 et seq., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq. The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 CFR 58135, November 13, 1996) (FRL–5572–9).

New section 408(b)(2)(A)(i) allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

Section 408(l)(6) requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Section 408(l)(6) also requires EPA to promulgate regulations by August 3, 1997, governing the establishment of tolerances and exemptions under section 408(l)(6) and requires that the regulations be consistent with section 408(b)(2) and (c)(2) and FIFRA section 18.

Section 408(l)(6) allows EPA to establish tolerances or exemptions from the requirement for a tolerance, in connection with EPA's granting of FIFRA section 18 emergency exemptions, without providing notice or a period for public comment. Thus, consistent with the need to act expeditiously on requests for emergency exemptions under FIFRA, EPA can establish such tolerances or exemptions under the authority of section 408(e) and (l)(6) without notice and comment rulemaking.

In establishing section 18-related tolerances and exemptions during this interim period before EPA issues the section 408(l)(6) procedural regulation and before EPA makes its broad policy decisions concerning the interpretation and implementation of the new section 408, EPA does not intend to set precedents for the application of section 408 and the new safety standard to other tolerances and exemptions. Rather, these early section 18 tolerance and exemption decisions will be made on a case-by-case basis and will not bind EPA as it proceeds with further rulemaking and policy development. EPA intends to act on section 18-related tolerances and exemptions that clearly qualify under the new law.

II. Emergency Exemption for Oxyfluorfen on Strawberries and FFDCA Tolerances

The Massachusetts Department of Food and Agriculture; Maine Department of Agriculture, Food and Rural Resources; Connecticut Department of Environmental Protection; and New Hampshire, Oregon and Washington Departments of Agriculture requested specific exemptions under FIFRA section 18 for the use of oxyfluorfen on strawberries to control wood sorrel (*Oxalis* sp.), and field pansy (*Viola tricolor*) in Massachusetts, Maine, Connecticut and New Hampshire and common groundsel (*Senecia vulgaris*), common lambsquarter (*Chenopodium album*), redroot pigweed (*Amaranthus retroflexus*), prostate knotweed, (*Polygonum aviculare*), smartweed (*Polygonum persicaria*), corn spurry (*Spergula arvensis*), wild buckwheat (*Polygonum convolvulus*), mayweed (*Anthemis cotula*), and pineappleweed (*Capsella bursa-pastoris*) in Oregon and Washington. The states indicated that an emergency situation is present due to lack of registered, effective alternatives to control these broadleaf weeds. The voluntary cancellations of chloroxuron (Tenoran) and dipenamid (Enide), depletion of the existing stocks of these materials, and recent label changes, varietal sensitivity and plant-back restrictions for terbacil (Sinbar) have resulted in a lack of effective materials

for control of the above weeds. The states indicate that they will suffer significant losses without an effective control for these weeds. After reviewing the applicants' submissions, the Agency concurs that emergency conditions exist for these states.

As part of its assessment of these crisis declarations, EPA assessed the potential risks presented by residues of oxyfluorfen in or on strawberries. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided to grant the section 18 exemptions only after concluding that the necessary tolerance under FFDCA section 408(l)(6) would clearly be consistent with the new safety standard and with FIFRA section 18. This tolerance for oxyfluorfen will permit the marketing of strawberries treated in accordance with the provisions of the section 18 emergency exemptions. Consistent with the need to move quickly on the emergency exemptions and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment under section 408(e) as provided for in section 408(l)(6). Although this tolerance will expire and is revoked on April 15, 1998, under FFDCA section 408(l)(5), residues of oxyfluorfen not in excess of the amount specified in the tolerance remaining in or on strawberries after that date will not be unlawful, provided the pesticide is applied during the term of, and in accordance with all the conditions of, section 18 of FIFRA. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

EPA has not made any decisions about whether oxyfluorfen meets the requirements for registration under FIFRA section 3 for use on strawberries, or whether a permanent tolerance for oxyfluorfen in or on strawberries would be appropriate. This action by EPA does not serve as a basis for registration of oxyfluorfen by a State for special local needs under FIFRA section 24(c). Nor does this action serve as the basis for any State other than Massachusetts, Maine, New Hampshire, Connecticut, Oregon and Washington to use this product on this crop under section 18 of FIFRA without following all provisions of section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemptions for oxyfluorfen, contact the Agency's Registration Division at the address provided above.

III. Risk Assessment and Statutory Findings

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. For many of these studies, a dose-response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100 percent or less of the RfD) is generally considered by EPA to pose a reasonable certainty of no harm.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight-of-the-evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure-activity relationships. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments [e.g., linear low-dose extrapolations or margin of exposure (MOE) calculation based on the appropriate NOEL] will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, and other non-occupational exposures, such as where residues leach into groundwater or surface water that is consumed as drinking water. Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100 percent of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

IV. Aggregate Risk Assessments, Cumulative Risk Discussion, and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. Oxyfluorfen is registered by EPA for outdoor residential uses.

Tolerances have been established (40 CFR 180.381) for the combined residues of oxyfluorfen, [2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl)benzene] and its metabolites containing the diphenyl ether linkage expressed in or on certain food commodities ranging from 0.05 ppm in stone fruits to 0.25 ppm in mint oil. There are no livestock feed items associated with these section 18 requests and secondary residues are not expected to occur in meat, milk, poultry or eggs as a result of these section 18 uses. Based on information submitted to the Agency, EPA has sufficient data to assess the hazards of oxyfluorfen and to

make a determination on aggregate exposure, consistent with section 408(b)(2), for the time-limited tolerance for residues of oxyfluorfen on strawberries at 0.05 ppm. EPA's assessment of the dietary exposures and risks associated with establishing this tolerance follows.

A. Toxicological Profile

1. *Acute risk.* For the acute dietary risk assessment, the Agency recommended use of the NOEL of 10 mg/kg/day, based on fused sternebrae observed in pups at the Lowest Effect Level (LEL) of 30 mg/kg/day, from the developmental toxicity study in rabbits. This NOEL is used to evaluate the Margin of Exposure (MOE) from the acute dietary risk to pregnant women 13+ years or older.

2. *Chronic risk.* The RfD of 0.003 mg/kg/day was established by the Agency on April 14, 1986, based on a 20–month feeding study in mice with a NOEL of 0.3 mg/kg/day and an uncertainty factor of 100. The effects observed at the LEL of 3.0 mg/kg/day were necrosis, hyperplastic nodules, and absolute liver weight.

3. *Cancer risk.* Oxyfluorfen has been classified as a Group C chemical by the Agency based on liver adenomas and carcinomas in the 20–month feeding study in mice. The Agency recommended using the Q_1* approach to assess cancer risk. The Q_1* is 0.128 $(mg/kg/day)^{-1}$.

4. *Developmental toxicity risk.* From the developmental toxicity study in rats, the maternal NOEL was 18 mg/kg/day and the maternal LEL was 183 mg/kg/day, based on decreased weight gain and food consumption, increased incidences of soft or scant feces, increased alkaline phosphatase and SGOT and mortality at high-dose. The developmental (pup) NOEL was 18 mg/kg/day and the developmental LEL was 183 mg/kg/day based on decreased fetal body weight, increased resorptions, and an increase in the incidences of left carotid artery arising from the innominate, bent bones of the forelimbs, and other ossification irregularities; these effects were confined to the mid-dose level, since there was 100% litter loss in the high-dose group [848 mg/kg/day] as the result of maternal mortality and resorptions. From the developmental toxicity study in rabbits, the maternal (systemic) NOEL was 10 mg/kg/day and the maternal LEL was 30 mg/kg/day based on anorexia and decreased body weight gain. The developmental (pup) NOEL was 10 mg/kg/day and the developmental LEL was 30 mg/kg/day based on fused sternebrae.

5. *Reproductive toxicity risk.* In the 2-generation reproduction study in rats, the reproductive (pup) NOEL was 400 ppm [20 mg/kg/day] and the reproductive LEL was 1,600 ppm [80 mg/kg/day] based on decreased pup body weight during lactation in both the F1a and F2a litters and also a decreased litter size at birth in F1a and F2a litters. The systemic (parents) NOEL was 400 ppm and LEL was 1,600 ppm based on pelvic mineralization of P1 males, P2 males and females, and pelvic papillary hyperplasia in P1 and P2 males and P2 females. Also at 1,600 ppm, there were additional kidney effects, consisting of dilatation of collecting ductules in both P2 sexes. Other high-dose histological findings consisted of hepatocellular hypertrophy in both sexes of P1 and P2 animals. Additional high-dose effects were alopecia in both sexes of P1 and P2 animals during growth, and decreased weight gain during growth and gestation of P1 and P2 parental animals.

B. Aggregate Exposure

In examining aggregate exposure, FQPA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures. The primary non-food sources of exposure the Agency looks at include drinking water (whether from groundwater or surface water), and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

Permanent oxyfluorfen food tolerances have been established and there are no livestock feed items associated with these section 18 requests. Oxyfluorfen is registered for outdoor residential uses.

1. *Chronic exposure*— i. *Dietary risk assessment considerations.* In conducting exposure assessments for these section 18 requests, EPA partially refined the chronic RfD and cancer risk assessments by using a combination of the TMRC (worst-case) and dietary exposure assumptions based on anticipated residues and/or percent of crop treated. Percent of crop treated estimates are derived from reliable federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. In addition, actual residues are expected to be quite low because the majority of the use patterns direct sprays onto weeds and away from the crop and there are long pre-harvest intervals for sprays which are directly applied to crops.

To determine chronic (using the RfD) and cancer (using the Q_1* approach) risks, the Agency has utilized the TMRC to estimate dietary exposure from proposed uses of oxyfluorfen on strawberries and peanuts, and from registered uses of oxyfluorfen with tolerances established for the following food items: dates, figs, guava, loquats, olives and olive oil, papaya, persimmon, pomegranate, plantains, kiwi, cocoa butter, coffee, artichokes, taro-roots and greens, garlic, shallots, cauliflower, bok-choy and other chinese variety cole crops, dry beans, crabapples, quince, blackberry, raspberry, brazil nut, cashew, chestnuts, hazelnuts, hickory nuts, macadamias, pecans, horseradish and peppermint and spearmint oils. The TMRC is obtained by multiplying the tolerance level residue for these foods by the average consumption data (estimates of the amount of the foods eaten by various population subgroups). The risk assessment using TMRC assumptions is considered to be overestimated.

Refined dietary exposure estimates using percent of crop treated were used to assess chronic dietary risk for registered uses of oxyfluorfen with established tolerances for the following foods and/or animal feed items: pistachio nuts, cottonseed meal, cherries, nectarines, plums, prunes, almonds and walnuts. Refined dietary exposure estimates using anticipated residues were used to assess chronic dietary risk for registered uses of oxyfluorfen with established tolerances on the following food items: bananas, broccoli, cabbage, apricots, meat and milk. Refined dietary exposure estimates using percent of crop treated and anticipated residues were used to assess chronic dietary risk for registered uses of oxyfluorfen with established tolerances on the following food and/or animal feed items: cottonseed oil, onions, soybeans, soybean oil, apples, pears, peaches, grapes and corn.

The Agency considers the partially refined estimates for chronic RfD and cancer risks to be conservative.

ii. *Drinking water considerations.* The Agency has reviewed environmental fate data which indicate that oxyfluorfen is persistent but non-mobile. There is no established Maximum Concentration Level (MCL) for residues of oxyfluorfen in drinking water. No health advisory levels for oxyfluorfen in drinking water have been established. As noted in ''Pesticides in Groundwater Database'' EPA 734–12–92–001, Sept 1992, 188 wells were

monitored in Texas in 1987 and 1988. No detectable residues of oxyfluorfen were found in any of the samples.

Because the Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water risk assessment for many pesticides, EPA has commenced and nearly completed a process to identify a reasonable yet conservative bounding figure for the potential contribution of water related exposure to the aggregate risk posed by a pesticide. In developing the bounding figure, EPA estimated residue levels in water for a number of specific pesticides using various data sources. The Agency then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints (RfD's or acute dietary NOEL's) and assumptions about body weight and consumption, to calculate, for each pesticide, the increment of aggregate risk contributed by consumption of contaminated water. While EPA has not yet pinpointed the appropriate bounding figure for consumption of contaminated water, the ranges the Agency is continuing to examine are all below the level that would cause oxyfluorfen to exceed the RfD if the tolerance being considered in this document were granted. In addition, chronic exposure to oxyfluorfen residues resulting from potential water exposure would not increase the total cancer risk so that it exceeds the Agency's level of concern. The Agency has therefore concluded that the potential exposures associated with oxyfluorfen in water, even at the higher levels the Agency is considering as a conservative upper bound for RfD exposure considerations, would not prevent the Agency from determining that there is a reasonable certainty of no harm if the tolerance is granted.

iii. *Non-dietary, non-occupational considerations.* Oxyfluorfen is registered for outdoor residential use. Acceptable, reliable data are not currently available with which to assess acute risk. However, based on the available residential exposure data and the best professional judgment of scientists who have worked with the available occupational exposure data, 5% of the risk for outdoor residential uses is a reasonable, protective default assumption for this pesticide. In the best scientific judgment of the Agency, chronic exposure to oxyfluorfen residues resulting from potential outdoor residential exposure would not increase the total chronic or cancer risks so that they exceed the Agency's level of concern.

2. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day or single exposure. Under FQPA, drinking water is also considered a component of the acute dietary exposure.

Theoretically, it is also possible that a residential, or other non-dietary, exposure could be combined with the acute total dietary exposure from food and water. However, the Agency does not believe that aggregating multiple exposure to large amounts of pesticide residues in the residential environment via multiple products and routes for a 1–day exposure is a reasonably probable event. It is highly unlikely that, in 1 day, an individual would have multiple high-end exposures to the same pesticide by treating their lawn and garden, treating their house via crack and crevice application, swimming in a pool, and be maximally exposed in the food and water consumed.

The acute dietary exposure endpoint of concern for oxyfluorfen is fused sternebrae in developing pups which was observed in the rabbit developmental study. The population subgroup of concern is females 13+ years old (women of childbearing age). Acute dietary exposure (food only) was calculated using the TMRC (worst case) assumptions. An MOE of 100 (food only) or greater is acceptable for these section 18 requests.

Despite the potential for acute exposure to oxyfluorfen in drinking water, EPA does not expect the aggregate acute exposure to exceed the Agency's level of concern if the tolerance being considered in this document were granted. The Agency has therefore concluded that the potential acute term exposures associated with oxyfluorfen in water, even at the higher levels the Agency is considering as a conservative upper bound, would not prevent the Agency from determining that there is a reasonable certainty of no harm if the tolerance is granted.

C. Cumulative Exposure to Substances with Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether oxyfluorfen has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, oxyfluorfen does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that oxyfluorfen has a common mechanism of toxicity with other substances.

D. Determination of Safety for U.S. Population

1. *Chronic RfD and cancer risk.* Using the partially refined dietary exposure assumptions described above and taking

into account the completeness and reliability of the toxicity data, EPA has concluded that aggregate dietary exposure (food only) to oxyfluorfen will utilize <1% of the RfD for the U.S. population. EPA generally has no concern for exposures below 100 percent of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to oxyfluorfen in drinking water and from the 5% default-level contribution from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

As noted above, oxyfluorfen has been classified as a Group C chemical by the Agency based on liver adenomas and carcinomas in the 20–month mouse feeding study. The Agency recommended using the Q_1* approach to assess cancer risk, with a value of 0.128 $(mg/kg/day)^{-1}$. The partially refined dietary assumptions for existing oxyfluorfen tolerances plus amortized section 18 strawberry use (adjusted for a 6 year duration of exposure to this section 18 use over a 70 year lifetime) result in a Anticipated Residue Contribution (ARC) that is equivalent to 1.8×10^{-6} (food only). Although this number is partially refined, it is still considered conservative by the Agency. Actual residues are expected to be quite low because the majority of the use patterns direct sprays onto weeds and away from the crop and there are long pre-harvest intervals for sprays which are directly applied to crops. Environmental fate data indicate that oxyfluorfen strongly adheres to soil, does not leach into groundwater and has not been detected in sampled groundwater. Based on this information, occurrence of oxyfluorfen in drinking water is unlikely. Outdoor residential uses of oxyfluorfen are limited and exposure is expected to be low. Oxyfluorfen is toxic to lawn grasses and certain ornamental plants, and use is generally limited to spot treatments for non-selective weed control. In the best scientific judgment of the Agency, chronic exposure to oxyfluorfen residues resulting from potential residential and/or water exposure would not increase the total cancer risk so that it exceeds the Agency's level of concern. EPA concludes that there is a reasonable certainty that no harm will result from chronic aggregate exposure to oxyfluorfen residues.

2. *Acute risk.* The acute dietary exposure endpoint of concern for oxyfluorfen is fused sternebrae in developing pups which was observed in the rabbit developmental study. The population subgroup of concern is females 13+ years old (women of childbearing age). For this subgroup, the calculated MOE at the high end exposure is 5,000. The Agency considers dietary (food) MOEs of greater than 100 to be acceptable for oxyfluorfen. Acute dietary exposure (food only) was calculated using the TMRC (worst case) assumptions.

In the absence of data for drinking water exposure, the ranges of exposure being considered by the Agency for consumption of contaminated water will be reserved for drinking water. The aggregate MOE level of concern for dietary plus the addition of upperbound estimates for drinking water is not likely to raise the MOE level of concern above 150. Despite the potential for acute exposure to oxyfluorfen in drinking water, EPA does not expect the aggregate exposure to exceed the Agency's level of concern if the tolerance being considered in this document were granted. The Agency has therefore concluded that the potential acute exposure associated with oxyfluorfen in water, even at the higher levels the Agency is considering as a conservative upper bound, would not prevent the Agency from determining that there is a reasonable certainty of no harm if the tolerance is granted.

E. Determination of Safety for Infants and Children

In assessing the potential for additional sensitivity of infants and children to residues of oxyfluorfen, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In either case, EPA generally defines the level of appreciable risk as exposure that is greater than 1/100 of the no observed effect level in the animal study appropriate to the particular risk assessment. This hundredfold uncertainty (safety) factor/margin of exposure (safety) is designed to account for combined inter- and intra-species variability. EPA believes that reliable data support using the standard hundredfold margin/actor not the additional tenfold margin/factor when EPA has a complete database under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard margin/factor.

The toxicology data base is complete for oxyfluorfen relative to pre- and post-natal toxicity. In the developmental toxicity study in rabbits, at the maternally toxic dose of 30 mg/kg/day, there were developmental anomalies (fused sternebrae) in the fetuses which demonstrated that pre-natal toxicity should be evaluated by an acute dietary risk estimate. As described above, the acute dietary MOE for pregnant women 13+ years old was 5,000 based on the developmental NOEL of 10 mg/kg/day. This MOE is much higher than the minimal acceptable MOE (100 for dietary-food only) and suggests that pre-natal developmental risks to infants and children from exposure to oxyfluorfen dietary residues is not a concern. Additionally, the rabbit developmental NOEL of 10 mg/kg/day is 33 times greater than the NOEL of 0.3 mg/kg/day used to calculate the RfD. In the developmental toxicity study in rats, both the developmental and maternal NOEL and LOEL of 18 and 183 mg/kg/day, respectively, occurred at the same dose levels and demonstrates that there is no special sensitivity in infants and children exposed to oxyfluorfen. Although the developmental findings in the rat were severe effects, the developmental NOEL of 18 mg/kg/day is greater than the rabbit developmental NOEL of 10 mg/kg/day used to calculate acute dietary MOEs. Therefore, the acute dietary risk estimates calculated from the rabbit developmental NOEL are lower than acute dietary MOEs which could be calculated for the more severe effects occurring in rats above the NOEL of 18 mg/kg/day. By basing the acute dietary MOEs on the NOEL in the most sensitive species (rabbit), pregnant women are protected against both types of pre-natal toxicity effects as seen in the rat and rabbit developmental toxicity studies. Therefore, there are no

significant pre-natal toxicity concerns for infants and children due to the high MOE for pregnant women 13+ years old. In the 2-generation reproductive toxicity study in rats used to assess the post-natal toxicity potential of infants and children, the NOEL and LOEL of 20 mg/kg/day and 80 mg/kg/day, respectively, for developmental/reproductive and systemic toxicity demonstrated that there are no pup toxicity effects in the absence of parental toxicity (NOEL and LOEL are the same for pups and parental animals). Therefore, there are no special post-natal sensitivities in infants and children which can be attributed to the findings of the 2-generation reproductive toxicity study in rats. Additionally, the developmental/reproductive NOEL of 20 mg/kg/day [which is the NOEL for decreased litter size at birth as well as decreased pup body weight] and the parental systemic NOEL of 20 mg/kg/day is 66 times greater than the NOEL of 0.3 mg/kg/day used to calculate the RfD.

Based on the above, EPA concludes that reliable data support use of the standard hundredfold margin of exposure/uncertainty factor and that an additional margin/factor is not needed to protect the safety of infants and children.

1. *Chronic risk.* Using the partially refined, conservative exposure assumptions described above and taking into account the completeness and reliability of the toxicity data, EPA has concluded that aggregate dietary exposure to oxyfluorfen will utilize 1% of the RfD for infants and 1.4% of the RfD for children. EPA generally has no concern for exposures below 100 percent of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to oxyfluorfen in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the chronic aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from chronic aggregate exposure to oxyfluorfen residues.

2. *Acute risk.* As mentioned above, the acute dietary exposure endpoint of concern for oxyfluorfen is fused sternebrae in developing pups which was observed in the rabbit developmental study. The population subgroup of concern is females 13+ years old (women of childbearing age). For this subgroup, the calculated MOE at the high end exposure is 5,000. The Agency considers dietary (food) MOEs of greater than 100 to be acceptable for oxyfluorfen. Acute dietary exposure (food only) was calculated using the TMRC (worst case) assumptions.

In the absence of data for drinking water exposure, the ranges of exposure being considered by the Agency for consumption of contaminated water will be reserved for drinking water. Based on the ranges under consideration, the aggregate MOE level of concern for dietary plus the addition of drinking water is not likely to raise the MOE above the Agency's level of concern. The large MOE calculated for this use of oxyfluorfen provides assurance that there is a reasonable certainty of no harm for infants and children.

V. Other Considerations

There is a practical analytical method for detecting and measuring levels of oxyfluorfen in or on food with a limit of detection that allows monitoring of food with residues at or above the levels set in these tolerances. EPA has provided information on this method to FDA. The method is available to anyone who is interested in pesticide residue enforcement from: By mail, Calvin Furlow, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Crystal Mall #2, Rm. 1128, 1921 Jefferson Davis Highway, Arlington, VA, 703–305–5805.

VI. Conclusion

Therefore, a tolerance in connection with the FIFRA section 18 emergency exemptions is established for residues of oxyfluorfen in/on strawberries at 0.05 ppm.

VII. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by June 24, 1997, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VIII. Public Docket

A record has been established for this rulemaking under docket number [OPP–300478]. A public version of this record, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above, is kept in paper form. Accordingly, in the event there are objections and hearing requests, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record. The official rulemaking record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

IX. Regulatory Assessment Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and, since this action does not impose any information collection requirements as defined by the Paperwork Reduction Act, 44 U.S.C. 3501 et seq., it is not subject to review by the Office of Management and Budget. This action does not impose any enforceable duty, or contain any ''unfunded mandates'' as described in Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), entitled Enhancing the Intergovernmental Partnership, or special consideration as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Because FFDCA section 408(l)(6) permits establishment of this regulation without a notice of proposed rulemaking, the regulatory flexibility analysis requirements of the Regulatory Flexibility Act, 5 U.S.C. 604(a), do not apply. Nonetheless, the Agency has previously assessed whether establishing tolerances or exemptions from tolerance, raising tolerance levels, or expanding exemptions adversely impact small entities and concluded, as a generic matter, that there is no adverse impact. (46 FR 24950, May 4, 1981).

Under 5 U.S.C. 801(a)(1)(A) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Title II of Pub. L. 104–121, 110 Stat. 847), EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2) of the APA as amended.

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 16, 1997.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR Chapter I is amended as follows:

PART 180— [AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. Section 180.381 is amended as follows:

i. In paragraph (a) by adding the heading *''General.''*

ii. By redesignating paragraph (b) as paragraph (c), and adding a new paragraph (b).

iii. In newly designated paragraph (c) by adding a paragraph heading *''Tolerances with regional registrations.''*

iv. By adding and reserving new paragraph (d) with the heading *''Indirect or inadvertent residues.''*

v. By revising the phrase ''raw agricultural'', to read ''food'' throughout the section.

§ 180.381 Oxyfluorfen; tolerances for residues.

(a) *General.* * * *

(b) *Section 18 emergency exemptions.* Tolerances are established for residues of the herbicide oxyfluorfen [2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl)benzene] in or on the following food commodities:

Commodity	Parts per million	Expiration/ Revocation Date
Strawberries	0.05	April 15, 1998

(c) *Tolerances with regional registrations.* * * *

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 97–10724 Filed 4–24–97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300476; FRL–5712–7]

RIN 2070–AB78

Fenoxycarb; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for combined residues of the insecticide fenoxycarb in or on the commodity pear in connection with EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of fenoxycarb on pears in Oregon and Washington. This regulation establishes maximum permissible levels for residues of fenoxycarb in this food pursuant to section 408(l)(6) of the Federal Food, Drug and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and is revoked on April 30, 1998.

DATES: This regulation becomes effective April 25, 1997. Objections and requests for hearings must be received by EPA on or before June 24, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300476], must be submitted to Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300476], must also be submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Such copies of objections and hearing requests must be