programs, and this document addresses those revisions. In this document, EPA is proposing approval of Bay Area's title V operating permits program revisions which add optional permit shield provisions, clarify permit application requirements, and make other minor program changes in response to local concerns. EPA is also proposing to approve revisions to Bay Area's synthetic minor regulations which clarify permit modification requirements under the federally enforceable state operating permit program (FESOP). EPA is proposing approval of the revised synthetic minor regulations as a revision to Bay Area's portion of the California State Implementation Plan (SIP) and pursuant to section 112(l) of the Act.

In the Final Rules Section of this **Federal Register**, EPA is promulgating direct final approval of Bay Area's title V and FESOP revisions without prior proposal because EPA views these changes as noncontroversial amendments and anticipates no adverse comments. A detailed rationale for these approvals is set forth in the direct final rule. If no adverse comments are received in response to this proposed rule, no further activity is contemplated in relation to this rulemaking. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period on this document. Any parties interested in commenting on this action should do so at this time.

DATES: Comments on this proposed rule must be received in writing by July 24, 1995.

ADDRESSES: Written comments on this action should be addressed to: Celia Bloomfield, Operating Permits Section (A–5–2), Air and Toxics Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105.

Copies of the District's submittal, EPA's Technical Support Document, and other supporting information used in developing the proposed approvals are available for public inspection at EPA's Region IX office during normal business hours.

FOR FURTHER INFORMATION CONTACT: Celia Bloomfield (telephone 415/744–1249), Operating Permits Section (A–5–2), Air and Toxics Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105.

SUPPLEMENTARY INFORMATION: On November 29, 1994, EPA proposed in the **Federal Register** to grant interim approval to Bay Area's title V operating permits program (59 FR 60939) in accordance with title V of the Act (as amended in 1990) and 40 CFR part 70 (the title V implementing regulations). In the same notice, EPA proposed approval of Bay Area's synthetic minor program based on the June 28, 1989 (54 FR 27274) approval criteria for federally enforceable state operating permit programs. On February 1, 1995, Bay Area adopted revisions to Regulation 2, Rule 6 (Regulation 2–6) and the District's Manual of Procedures, Volume II, Part 3 (MOP) that implement the District's title V and synthetic minor programs. These revisions were not made in response to the deficiencies identified in the proposed rulemaking, but rather to address local issues and concerns. EPA is proposing direct final approval of the amendments to coordinate the effective date of the title V and FESOP programs with the effective date of the revisions.

Amendments to Bay Area's title V program were submitted to EPA by the California Air Resources Board (CARB) on March 23, 1995. The regulations covered by this direct final approval include: Regulation 2, Rule 6, Sections 232, 233, 234, 305, 307, 311, 403.1, 403.1.1, 403.1.2, 403.1.3, 404.6, 404.7, 405.2, 405.4.1, 405.4.2, 405.6, 405.6.1, 405.6.2, 409.12, 410.6, 411, 418.3, 420, 421.3, 421.4, 422, 422.3, 422.4, 422.6, 423, 423.2.1, 423.5; and the Manual of Procedures, Volume II, Part 3. Bay Area's synthetic minor program amendments were submitted to EPA by CARB on March 31, 1995. The regulations covered by this direct final SIP and section 112(l) approval include: Regulation 2, Rule 1, Section 129; and Regulation 2, Rule 6, Sections 232, 234, 310, 311, 403, 404, 420, 421, 422, and 423. For further information, please see the direct final action which is located in the Final Rules Section of this **Federal Register**.

Authority: 42 U.S.C. 7401–7671q.

Dated: May 25, 1995.

David P. Howekamp,

Acting Regional Administrator.

[FR Doc. 95–15036 Filed 6–22–95; 8:45 am]

BILLING CODE 6560–50–W

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40 CFR Part 180

[OPP–300390; FRL–4962–6]

RIN 2070–AC18

Dimethoate; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to establish an import tolerance for total residues of the insecticide dimethoate including its oxygen analog in or on the raw agricultural commodity blueberries. EPA is issuing this proposal on its own initiative pursuant to a project to harmonize certain tolerances with those established by the Canadian government.

DATES: Comments, identified by the document control number [OPP-300390], must be received on or before July 24, 1995.

ADDRESSES: By mail, submit written comments 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 comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Information submitted as a comment concerning this notice 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 comment 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. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: 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. Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [OPP-300390]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: Robert Forrest, Product Manager (PM) 14, Registration Division (7505C), Office of Pesticide Programs,

Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. Office location and telephone number: Rm. 219, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-6600; e-mail: forrest.robert@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: Own its own initiative and pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e), EPA is proposing to amend 40 CFR 180.204 by establishing an import tolerance for total residues of the insecticide dimethoate including its oxygen analog in or on the raw agricultural commodity blueberries at 1 part per million (ppm). As part of the Canada-U.S. Trade Agreement (CUSTA), and through the Pesticides Technical Working Group's Maximum Residue Limit (MRL) Harmonization Pilot Project, the Canadian government has requested that the U.S. establish a tolerance of 1 ppm for residues of dimethoate in or on blueberries. This insecticide is registered for use on blueberries in Canada, but not in the U.S. The Canadian tolerance is 1 ppm. The Agency has reviewed Canadian crop field trial residue data and determined that they are adequate to support an import tolerance. All relevant materials have been evaluated. The toxicological data considered in support of the proposed tolerance include:

1. A 3-month feeding study in rats fed diets containing 0, 2, 8, 32, 50, and 400 ppm with a no-observed-effect level (NOEL) for plasma, red blood cell and brain cholinesterase inhibition of 32 ppm (equivalent to 1.6 milligrams (mg)/kilogram (kg)/day) and a systemic NOEL of 50 ppm (equivalent to 2.5 mg/kg/day) based on depressed growth and food consumption, and increased kidney and liver weights ratios at the 400-ppm dose level.

2. A 3-month feeding study in dogs fed diets containing 0, 2, 10, 50, 1,500, and 3,000 ppm with a NOEL for red blood cell cholinesterase inhibition of 2 ppm (equipvalent to 0.05 mg/kg/day) and a NOEL for systemic effects of 50 ppm (equivalent to 1.25 mg/kg/day) based on tremors and decreased food consumption in females at the 1,500-ppm dose level.

3. A 1-year feeding study in dogs fed diets containing 0, 5, 20, or 125 ppm with a NOEL of less than 5 ppm (equivalent to less than 0.18 mg/kg/day) based on decreased brain and red blood cell cholinesterase in males and decreased liver weight in females at the 5-ppm dose level.

4. A two-generation reproduction study in rats fed diets containing 0, 1, 15, or 65 ppm (equivalent to 0/0, 0.8/0.9, 1.2/1.3, or 5.46/6.04 mg/kg/day for males/females) with a tentative reproductive NOEL of 15 ppm based on decreased fertility in the F1b and F2a, and F2b matings; decreased pup weight during the lactation period for both sexes and generations; and decreased live births in the F2b litters.

5. A developmental toxicity study in rats given gavage doses of 0, 3, 6, or 18 mg/kg/day with no developmental toxicity observed under the conditions of the study. The NOEL for maternal toxcity was established at 6 mg/kg/day; rats fed 18 mg/kg/day (lowest-effect level) displayed hpersensitivity, tremors, and unsteady gait.

6. A developmental toxicity study in rabbits given gavage doses of 1, 10, 20, or 40 mg/kg/day from day 7 to day 19 of gestation with a developmental NOEL of 20 mg/kg/day based on significant reduction in fetal weight at the 40 mg/kg/day dose level. The maternal NOEL/LEL were 10/20 mg/kg/day based on body weight decrement at 20 mg/kg/day.

7. A 2-year chronic feeding/carcinogenicity study in rats fed diets containing 0, 5, 25, or 100 ppm (equivalent to 0, 0.25, 1.25, or 5.0 mg/kg/day) with a systemic NOEL of 25 ppm based on increased female mortality, decreased male body weight gain, anemia in males, and increased leukocytes in male and female rats at the 100-ppm dose level. The NOEL for cholinesterase inhibition was established at 5 ppm based on cholinesterase inhibition at the 25-ppm dose level. In male rats, there were dose-related trends for (1) spleen hemangiosarcomas (malignant tumors associated with connective tissue and blood and lymph vessels); (2) combined spleen hemangioma (benign tumors) and hemangiosarcoma; and (3) combined spleen hemangioma and hemangiosarcoma, and skin hemangiosarcoma. Furthermore, there were significant pair-wise comparisons between control and the high-dose (100 ppm) for spleen (hemangioma/hemangiosarcoma) and in the combined tumors of spleen and skin hemangioma/hemangiosarcoma and lymph angioma/angiosarcoma (benign and malignant tumors made up of lymph vessels). There was also a significant difference by pair-wise comparison between the control and low dose (5 ppm) for (1) lymph angiosarcoma, (2) combined lymph angioma and angiosarcoma, and (3) combined spleen and skin hemangioma/hemangiosarcoma and lymph angioma/angiosarcoma. There were no significant tumor increases in female rats.

8. A 78-week carcinogenicity study in B6C3F1 mice fed diets containing 0, 25, 100, or 200 ppm (equivalent to 0, 3.75, 15, or 30 mg/kg/day). In male mice there were significant dose-related incrased trends for (1) combined lung adenoma and/or adenocarcinoma, (2) for lymphoma, and (3) for the combined group of lymphoma, reticularsarcoma, and leukemia. In female mice there were significant dose-related trends for (1) liver carcinoma and for (2) combined liver adenoma and/or carcinoma.

9. Dimethoate is regarded as a mutagenic compound based on the results of studies designed to determine gene mutation and structural chromosome aberrations. Dimethoate is a bacterial mutagen and shows equivocal results for gene mutations in mammalian cells. It produces clastogenic effects in several studies *in vitro* and *in vivo*, and there are suggestive results for dominant-lethal effects. The National Toxicology Program has concluded that dimethoate is a mutagenic compound based on its testing for gene mutation and chromosomal aberrations. A third category of studies to determine other genotoxic effects is a data gap for dimethoate.

Dimethoate has been classified as a possible human carcinogen (category C) by the Office of Pesticide Programs' Health Effects Division's Peer Review Committee. The Peer Review Committee supports this classification based on the appearance of equivocal hemolymphoreticular tumors in male mice, the compound-related (no dose response) weak effect of combined spleen (hemangioma and hemangiosarcoma), skin (hemangiosarcoma), and lymph (angioma and angiosarcoma) tumors in male rats, and positive mutagenic activity associated with dimethoate.

The Peer Review Committee concluded that the lung tumors seen in male mice were not biologically significant tumors related to compound administration since there were no statistically significant differences based on pair-wise comparisons with controls and each dose level. The incidence of lung tumors in the control groups was variable, and there was a high background level of these tumors. The increase in lymphoma observed in male mice in the high-dose group was of borderline statistical significance by pair-wise comparison with controls. The incidence of lymphoma in mice is also common and variable. The Committee agreed that the increased incidence for the combined hemolymphoreticular tumors in male mice is compound related, but could only classify this

incidence as equivocal. The incidence of hemolymphoporeticular tumors in male mice was relatively low and consistent with historical control, only occurred in one sex (males), and was evident only in the highdose group.

The Committee concluded that in female mice there were no significant pair-wise comparisons, there was only the trend with combined tumors, and the combined incidence was similar to historical controls. In addition, there also was no evidence of precursor lesions to carcinogenicity. Regarding the carcinogenicity study in rats, the Committee concluded that although there were significant pair-wise comparisons at the low and high doses for all tumors combined, these tumors did not indicate much more than a weak effect.

EPA has concluded that dimethoate poses no greater than a negligible cancer risk to humans; therefore, the Agency has chosen to use reference dose calculations to estimate dietary risk from dimethoate residues. The dietary risk exposure analysis used a Reference Dose (RfD) for dimethoate of 0.0005 mg/kg/body weight/day, based on a NOEL of 0.05 mg/kg/bwt/day for brain cholinesterase inhibition from a 2-year feeding study in rats, and an uncertainty factor of 100. The anticipated residue contribution (ARC) for the general population from published uses and the proposed use on blueberries utilizes 22 percent of the RfD. The ARC for the most highly exposed subgroup, nonnursing infants, from published uses and the proposed use on blueberries, utilizes 57% of the RfD.

The nature of the residue in plants is adequately understood and an adequate analytical method, gas-liquid chromatography with a thermionic detector, is available for enforcement purposes. An analytical method for enforcing this tolerance has been published in the Pesticide Analytical Manual (PAM), Vol. II. No secondary residues in meat, milk, poultry, or eggs are expected since blueberries are not considered a livestock feed commodity.

The pesticide is considered useful for the purpose for which the tolerance is sought. There are presently no actions pending against the continued registration of this chemical.

Based on the information and data considered, the Agency has determined that the tolerance established by amending 40 CFR 180.204 would protect the public health. Therefore, it is proposed that the tolerance be established as set forth below.

Any person who has registered or submitted an application for registration of a pesticide, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, which contains any of the ingredients listed herein, may request within 30 days after publication of this notice in the Federal Register that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the FFDCA.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number, [OPP–300390]. All written comments filed in response to this petition will be available in the Public Response and Program Resources Branch, at the address given above from 8 a.m. to 4:30 p.m., Monday through Friday, except legal holidays.

A record has been established for this rulemaking under docket number [OPP-300390] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 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 can 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 will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in **ADDRESSES** at the beginning of this document.

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines ''significant'' as those actions likely to lead to a rule (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also known as ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, EPA has determined that this rule is not ''significant'' and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96–354, 94 Stat. 1164, 5 U.S.C. 601–612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

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

Dated: June 15, 1995.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR part 180 be 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. In § 180.204, by amending paragraph (a) by amending the table therein to add and alphabetically insert the following commodity, to read as follows:

§ 180.204 Dimethoate including its oxygen analog; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Blueberries[1]	1
* * * * *	

[1]There are no U.S. registrations as of (date of publication of final rule) for dimethoate on blueberries.

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[FR Doc. 95–15427 Filed 6–20–95; 1:50 pm]

BILLING CODE 6560–50–F

40 CFR Parts 180 and 185

[OPP–300391; FRL–4962–7]

RIN 2070–AC18

Clethodim; Pesticide Tolerance and Food Additive Regulation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to establish an import tolerance and a food additive regulation, respectively, for residues of the herbicide clethodim ((E)-(±)-2-[1-[[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one) and its metabolites containing the 2-cyclohexen-1-one moiety in or on the raw agricultural commodity potatoes and the food additive commodities potato flakes and granules. EPA is issuing this proposal on its own initiative pursuant to a project to harmonize certain tolerances and food additive regulations with those established by the Canadian government.

DATES: Comments, identified by the document control number [OPP-300391], must be received on or before July 24, 1995.

ADDRESSES: By mail, submit written comments 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 comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Information submitted as a comment concerning this document 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 comment 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. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: 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. Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [OPP-300391]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne Miller, Product Manager (PM) 23, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. Office location and telephone number: Rm. 237, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703)-305-6224; e-mail: miller.joanne@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: On its own initiative and pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act by (FFDCA), 21 U.S.C. 346a(e), EPA is proposing to amend 40 CFR 180.458 by establishing an import tolerance for residues of the herbicide clethodim and its metabolites containing the 2-cyclohexen-1-one moiety in or on the raw agricultural commodity potatoes at 0.5 part per million (ppm); and to add new § 185.1075 (40 CFR 185.1075) by establishing a food additive regulation for residues of the herbicide clethodim and its metabolites containing the 2-cyclohexen-1-one moiety in or on the food additive commodity potato granules and potato flakes at 1 part per million (ppm). Clethodim residues on potatoes grown in Canada and imported into the United States have been identified as a Canada-United States Trade Agreement (CUSTA) irritant. The Agency has reviewed Canadian crop field trial residue data and determined that they are adequate to support an import tolerance. All relevant materials have been evaluated. The toxicological data considered in support of the proposed tolerances and food additive regulation include:

1. Several acute toxicology studies placing the technical-grade herbicide in Toxicity Category II for primary dermal irritation, Toxicity Category III for oral and inhalation toxicity and primary eye irritation, and Toxicity Category IV for dermal toxicity.

2. A 2-year rat chronic toxicity/carcinogenicity study found the compound to be noncarcinogenic to rats under the conditions of the study. The systemic no-observed-effect level (NOEL) was 500 ppm (approximately 19 mg/kg/day), and the systemic lowest-observed-effect level (LOEL) was 2,500 ppm (approximately 100 mg/kg/day) based on the observed body weight gain, the increases in liver weights, and the presence of centrilobular hepatic hypertrophy.

3. An 18-month mouse carcinogencity study which showed the compound to be noncarcinogenic to mice under the conditions of the study. The systemic NOEL was 200 ppm (approximately 30 mg/kg/day), and the systemic LOEL was 1,000 ppm (approximately 150 mg/kg/day) based on treatment-related effects on survival, red cell mass, absolute and relative liver weights, and microscopic findings in liver and lung.

4. A 1-year feeding study in dogs with a systemic NOEL of 1 mg/kg/day in both sexes and a LOEL of 75 mg/kg/day based on increased absolute and relative liver weights, and alterations in hematology and clinical chemistry.

5. A developmental toxicity study in rats with a developmental and maternal NOEL and LOEL of 100 and 350 mg/kg/day, respectively. The LOEL for developmental toxicity was based on reductions in fetal body weight and increases in skeletal anomalies.

6. A developmental toxicity study in rabbits with a maternal toxicity NOEL and LOEL of 25 and 100 mg/kg/day, respectively. Maternal toxicity was manifested as clinical signs of toxicity and reduced weight gain and food consumption during treatment. Developmental toxicity was not observed, and therefore the developmental toxicity NOEL was 300 mg/kg/day (HDT).

7. A two-generation reproduction study in the rat with a parental toxicity NOEL and LOEL of 500 and 2,500 ppm (51 and 263 mg/kg/day), respectively, based on reductions in body weight in males, and decreased food consumption in both generations. The NOEL for