88.502 be removed from the approved program. In the December 23, 2003, letter, Pennsylvania revised the 1998 amendment as submitted to retain, as part of its approved program, the above referenced regulations which provide effluent limits and the definitions of ''dry weather flow'' and ''best professional judgment.'' Therefore, we consider those portions of the 1998 amendment submission as withdrawn and they will not be considered further in this rulemaking. No comments will be accepted with regard to these areas.

Also in the December 23, 2003, letter Pennsylvania indicated that the 1998 program amendment had included Sections 4(g.1), 4(g.2), and 4(g.3) of PASMCRA relating to minimal impact postmining discharges and the release of bonds on mine sites with discharges. Pennsylvania noted in that letter that since the definition of minimal impact postmining discharges and the regulations for postmining discharges were not included in the program amendment, it was requesting that these sections of PASMCRA be removed from the proposed amendment. Pennsylvania noted in the letter that it was intending to submit these sections along with the associated regulations as a separate program amendment. Therefore, these sections are also withdrawn and will not be considered further in this rulemaking. No comments will be accepted with regard to these areas.

In the April 13, 2004, letter, Pennsylvania notified us that it wished to withdraw Section 18(a.4) of PASMCRA from consideration under the 1998 program amendment because the areas suitable for reclamation by remining program has not yet been developed. Therefore, this section will not be considered further in this rulemaking. No comments will be accepted with regard to these areas.

Also in its April 13, 2004, letter Pennsylvania requested that we consider for approval Sections 4.10 and 4.11 of PASMCRA and the corresponding regulations at 25 Pa. Code Sections 86.251 through 86.270. These sections of the statute and regulations provide for Pennsylvania's Remining Operators Assistance Program. This program provides incentives to operators to undertake reclamation and remining of abandoned mine lands and bond forfeiture sites. These provisions are now included in this rulemaking action and we are seeking comment with regard to these sections of PASMCRA and 25 Pa. Code Chapter 86.

In the April 13, 2004, letter, and its attachment, Pennsylvania also notified us that it intends to address outstanding issues in this amendment relating to: *De minimis* cost increases for a replacement water supply; temporary replacement of water supply; waivers for water supply replacement; adequate versus equivalent water supply; operation and maintenance costs for replaced water supplies; financial guarantees to operators to reclaim abandoned mine lands through remining; and, operator cost recovery, through additional regulation changes. While Pennsylvania has indicated that it intends to further revise those portions of the pending package, it has not withdrawn those portions and has asked that we proceed with a decision. Since we received no changes or clarifications from the original amendment with regard to these areas, we are not reopening the comment period for them.

III. Public Comment Procedures

Under the provisions of 30 CFR 732.17(h), we are seeking your comments on whether the information described above satisfies the applicable program approval criteria of 30 CFR 732.15. If we approve the amendment, it will become part of the State program.

Written Comments

Send your written or electronic comments to OSM at the address given above. Your written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of your recommendations. We will not necessarily consider or respond to your comments when developing the final rule if they are received after the close of the comment period (*see* **DATES**). We will make every attempt to log all comments into the administrative record, but comments delivered to an address other than the Harrisburg Office may not be logged in.

Electronic Comments

Please submit Internet comments as an ASCII or Word file avoiding the use of special characters and any form of encryption. Please also include ''Attn: SATS No. PA–124–FOR'' and your name and return address in your Internet message. If you do not receive a confirmation that we have received your Internet message, contact the Harrisburg Office at (717) 782–4036.

Availability of Comments

We will make comments, including names and addresses of respondents, available for public review during normal business hours. We will not consider anonymous comments. If individual respondents request confidentiality, we will honor their request to the extent allowable by law. Individual respondents who wish to withhold their name or address from public review, except for the city or town, must state this prominently at the beginning of their comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public review in their entirety.

List of Subjects in 30 CFR Part 938

Intergovernmental relations, Surface mining, Underground mining.

Dated: September 9, 2004.

Brent Wahlquist,

Regional Director, Appalachian Regional Coordinating Center.

[FR Doc. 04–25971 Filed 11–23–04; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0142; FRL–7686–4]

Trifluralin; Proposed Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes to establish a tolerance for residues of trifluralin in mint oil under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). The amendment substantially rewrote section 408 of FFDCA. As a result, the revisions made it necessary, once again, to establish tolerances on certain commodities, such as mint oils, that had previously been deemed unnecessary.

DATES: Comments must be received on or before January 24, 2005.

ADDRESSES: Submit your comments, identified by docket identification (ID) number OPP–2004–0142, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov/*. Follow the on-line instructions for submitting comments.
- *Agency Website*: *http://www.epa.gov/edocket/*. EDOCKET, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Follow the on-line instructions for submitting comments.
- *E-mail*: Comments may be sent by e-mail to *opp-docket@epa.gov*,

Attention: Docket ID Number OPP–2004–0142.

- *Mail*: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID Number OPP–2004–0142.
- *Hand Delivery*: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID Number OPP–2004–0142. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number OPP–2004–0142. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.epa.gov/edocket/*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through EDOCKET, regulations.gov, or e-mail. The EPA EDOCKET and the regulations.gov websites are ''anonymous access'' systems, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through EDOCKET or regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit EDOCKET on-line or see the **Federal Register** of May 31, 2002 (67 FR 38102) (FRL–7181–7).

Docket: All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket/*. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: John W. Pates, Jr., Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8195; e-mail address: *pates.john@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are a professional applicator, commercial applicator, residential applicator, agricultural worker, and/or a non-residential user. Potentially affected entities may include, but are not limited to:

- Crop Production (NAICS 111)
- Animal Production (NAICS 112)
- Food Manufacturing (NAICS 311)
- Pesticide Manufacturing (NAICS 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Unit II. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (*http://www.epa.gov/edocket/*), you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available on E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

C. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through EDOCKET, regulations.gov, or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the rulemaking by docket ID number and other identifying information (subject heading, **Federal Register** date, and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns, and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Background and Statutory Findings

EPA on its own initiative, under section 408(e) of FFDCA, 21 U.S.C. 346a(e), is proposing to establish a permanent tolerance for residues of the herbicide trifluralin in mint oil at 2.0 parts per million (ppm).

Tolerances under section 408 of FFDCA for trifluralin in or on peppermint tops and spearmint tops are established in 40 CFR 180.207 at 0.05 ppm. Previously, under section 409 of FFDCA, tolerances were established for trifluralin in peppermint oil and spearmint oil at 2.0 ppm. In 1996, these section 409 of FFDCA tolerance regulations were revoked as unnecessary. Shortly thereafter, the FFDCA was amended by FQPA. This amendment substantially rewrote section 408 of FFDCA and consolidated, for the most part, the authority addressing pesticide residues in food under section 408 of FFDCA. The revisions to section 408 of FFDCA also made it necessary, once again, to establish tolerances on certain commodities, such as mint oils, that had previously been deemed unnecessary.

The Agency has completed the human health risk assessment for trifluralin and is now proposing to establish a permanent tolerance at 2.0 ppm for mint oil. Also, all existing tolerances are being maintained at current levels and are considered to be reassessed by the Trifluralin Tolerance Reassessment Eligibility Decision (TRED) signed on August 31, 2004.

Section 408(b)(2)(A)(i) of FFDCA 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) of FFDCA 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 and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA 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....''.

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a tolerance for residues of trifluralin in mint oil at 2.0 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows:

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by trifluralin are discussed in Table 1 of this unit as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY TABLES

Guideline No./Study Type	MRID No. (year)/Classification/ Doses	Results/Comments
870.3100 2-Week R-F Feeding—Rats (male)	00157154 (1983) 0; 6,500 ppm range-finding study for 00157156 (1985), 41038301 (1986) Acceptable/Nonguideline	NOAEL = Not achieved LOAEL = 6,500 ppm based on renal epithelial damage, urine triple phosphates crystals and urinary sediment
870.3100 90-Day Oral toxicity—Rat	00151906 (1980) 0; 800; 2,000; or 5,000 ppm M: 0, 59, 154, and 392 milligram/kilogram/day (mg/kg/day) F: 0, 69, 168, and 421 mg/kg/day Acceptable/Guideline	NOAEL = 2,000 ppm (154/168 mg/kg/day, Male/Female (M/F)) LOAEL = 5,000 (392/421(mg/kg/day), M/F) Based on minor decreases in overall body weight gains and food consumption in males and females, decreased hemoglobin, alkaline phosphatase, and alanine aminotransferase in the males, and increased absolute and relative (to body) liver weights in males and females
870.3200 21/28-Day dermal toxicity—Rabbit	41993810 (1991) 0, 100, 500, or 1,000 mg/kg/day (formulation containing 35.8% trifluralin and 2.6% XRD-498) Acceptable/Guideline	Systemic NOAEL =1,000 mg/kg/day Systemic LOAEL = Not achieved Dermal NOAEL = Not achieved Dermal LOAEL = 100 mg/kg/day, edema, and/or scaling and fissuring 100 mg/kg/day based skin irritation
870.3200 31-Day dermal toxicity—Rat	00153171 (1982) 0; 40; 200; or 1,000 mg/kg/day Acceptable/Guideline	Systemic NOAEL = 1,000 mg/kg/day (limit dose) Systemic LOAEL = Not achieved Dermal NOAEL = 40 mg/kg/day Dermal LOAEL = 200 mg/kg/day based on sub-epidermal inflamation and ulcerations inmales and females

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY TABLES—Continued

Guideline No./Study Type	MRID No. (year)/Classification/ Doses	Results/Comments
870.3200 21/28-Day dermal toxicity—Rat	00152888 (1985) 0; 1,000 mg/kg/day (limit dose) Acceptable/Guideline	Systemic NOAEL = 1,000 mg/kg/day Systemic LOAEL = Not achieved Dermal NOAEL= Not achieved Dermal LOAEL = 1,000 mg/kg/day (limit dose) based on erythema, edema, and desquamination of the treated skin
870.3465 30-Day inhalation toxicity	40392312 (1987) reformat of 00151904 (1982) 0; 100; 301; 1,006 mg/m^3(6 hours/day 5 days/week for up to 30 days) Acceptable/Nonguideline	NOAEL = 301 mg/m^3 LOAEL = 1,006 mg/m^3 based on increased bilirubin in females and incidences of dyspnea and ruffled fur in males and females
870.3700 Developmental Toxicity Study—Rat	00151899 (1983), 159620 (1986), 40392310 (1987) 0, 20, 100, 500 mg/kg/day	Systemic Maternal NOAEL = 100 mg/kg/day Systemic Maternal LOAEL = 500 mg/kg/day based on mortality, clinical signs, decreased body weight gains, decreased food consumption, and increased liver and spleen weights Developmental NOAEL =100 mg/kg/day Developmental LOAEL = 500 mg/kg/day based on reduced ossification of the vertebrae and ribs and thickened, wavy or bent ribs and increased incidences of resorptions
870.3700 Developmental Toxicity Study—Rat	00152419 (1984) 0; 100; 225; 470; or 1,000 mg/kg/day Acceptable/Guideline	Maternal NOAEL = 475 mg/kg/day Maternal LOAEL = 1,000 mg/kg/day based on decreased body weights and decreased food consumption Offspring NOAEL = 475 mg/kg/day Offspring LOAEL = 1,000 mg/kg/day based on decreased fetal body weights Developmental NOAEL = 1,000 mg/kg/day Developmental LOAEL was not established
870.3700 Developmental Toxicity—Rabbit	00152421 (1984) 0, 100, 225, 500 mg/kg/day Acceptable/Guideline	Maternal NOAEL = 100 mg/kg/day Maternal LOAEL = 225 mg/kg/day based on abortions, macroscopic changes in the liver and lungs, and decreased food consumption Developmental NOAEL = 100 mg/kg/day Developmental LOAEL = 225 mg/kg based on abortions
870.3800 2-Generation reproduction—Rat	00151901 (1984) 00151902 (1984) Feed analysis 00151903 (1984) Path 0; 200; 650; 2,000 ppm 0, 20, 32.5, 200 mg/kg/day (1 ppm = 0.5 mg/kg/day) Acceptable/Guideline	Parental NOAEL = 200 ppm (10 mg/kg/day) Parental LOAEL = 650 ppm (32.5 mg/kg/day) based on mortality due to acute renal failure and increased lesions of the renal proximal tubules in the F1 females; increased relative (to body) weights of the liver, kidney (males), and testes in both generations Offspring NOAEL = 200 ppm (10 mg/kg/day) Offspring LOAEL = 650 ppm (32.5 mg/kg/day) based on decreased pup weights in both generations and increased relative to body liver weights in the F2b females Repro NOAEL = 2,000 ppm (100 mg/kg/day) Repro LOAEL = Not established
870.3800 2-Generation reproduction—Rat	00162543 (1986), 44135107 (1996) 0; 200; 630; 2,000 ppm 0, 15, 47, 148 mg/kg/day Acceptable/Guideline	Parental NOAEL = 200 ppn (15 mg/kg/day) Parental LOAEL = 630 ppm (47 mg/kg/day) based on decreased body weight gains (BWG) and food consumption Offspring NOAEL = 200 ppm (15 mg/kg/day) Offspring LOAEL = 630 ppm (47 mg/kg/day) based on small pup size in 3 litters Reproductive NOAEL = 2,000 ppm (148 mg/kg/day) Reproductive LOAEL = Not established
870.3800 2-Generation reproduction—Rat	40405007 (1987) 0; 50; 450; 4,000 ppm M: 0, 3.9, 35, 295 mg/kg/day F: 0, 4.7, 42, 337 mg/kg/day Acceptable/Guideline	Parental NOAEL = 450 ppm (35/42 mg/kg/day M/F) Parental LOAEL = 4,000 ppm (295/337 mg/kg/day M/F) based on decreased body weights, body weight gains, food consumption, and food efficiency in males and females of both generations; decreased ovary weights in both generations; colon distension in the F1 males; and uterine atrophy in the females of both generations Offspring NOAEL = 450 ppm (35/42 mg/kg/day M/F) Offspring LOAEL = 4,000 ppm (295/337mg/kg/day, M/F) based on decreased pup weight in F1a litters Reproductive NOAEL = 450 ppm (35/42 mg/kg/day) Reproductive LOAEL = 4,000 ppm(295/337 mg/kg/day M/F) based on decreased fetal, neonatal, and litter viability and decreased lactation index in the F1a pups; and decreased number of implantation sites, newborn pups, litter size, and pup weights in both generations

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY TABLES—Continued

Guideline No./Study Type	MRID No. (year)/Classification/ Doses	Results/Comments
870.4100 1-Year Oral (capsule) Study—Dog	00151908 (1984), 00159618 (1985) 0, 30, 150, or 750 ppm 0.0, 0.8, 3.8, 18.8 mg/kg /day Acceptable/Guideline	NOAEL = 30 ppm (0.8 mg/kg/day) LOAEL = 150 ppm (3.8 mg/kg/day) based on increased absolute liver weights in males
870.4100 1-Year Oral (capsule) Study—Dog	42447001 (1992) 0, 0.75, 2.4, 40 mg/kg/day Acceptable/Guideline	Systemic NOAEL = 2.4 mg/kg/day Systemic LOAEL = 40 mg/kg/day, based on increased frequency of abnormal stool and pigment deposition in the kidney and liver in males and females, decreased body weights and body weight gains, and on decreased erythrocytes and hemoglobin and increased thrombocytes in males
870.4300 24-Month Chronic Toxicity/Carcinogenicity Study—Rat	00162457 (1985), 00162458 (1985) 0; 200; 800; or 3,200 ppm M: 0, 10, 40, and 169 mg/kg/day F: 0, 13, 53, and 219 mg/kg/day Acceptable/Guideline	NOAEL = 800 ppm (40/53 mg/kg/day M/F) LOAEL = 3,200 ppm (169/219 mg/kg/day M/F) based on decreases in body weight and body weight gains At the doses tested, the carcinogenic potential of trifluralin was negative. Dosing was considered adequate based on differences in body weight and body weight gains.
870.4300 24- Month Carcinogenicity Study—Mouse	00158935 (1986), 40392313 (1987) 0, 50, 200, or 800 ppm M: 0, 7.5, 29, and 118 mg/kg/day F: 0, 10.5, 41, and 165 mg/kg/day Unacceptable/Guideline	Sys NOAEL = 800 ppm (118/165 mg/kg/day in males/females); highest dose tested System LOAEL = Not achieved NOAEL for the range finder was 2500 ppm (375 mg/kg/day), the highest dose tested
870.5100 Bacterial Reverse Gene Mutation Assay	MRID 00148345 (1984) Acceptable/Guideline	There was no evidence of induced mutant colonies over background.
870.5100 Bacterial Reverse Gene Mutation Assay	MRID 40334707 (1987) Acceptable/Guideline	There was no evidence of induced mutant colonies over background.
870.5100 Bacterial Reverse Gene Mutation Assay	MRID 00153173 (1979) Acceptable/Guideline	There was no evidence of induced mutant colonies over background.
870.5250 Gene Mutation Assay—Yeast	MRID 00151898 (1982) Acceptable/Guideline	There was no concentration-related positive response of induced mutant colonies over background.
870.5300 *In vitro* Mammalian Cell Gene Mutation Assay	MRID 00126661 Acceptable/Guideline	There was no concentration-related positive response of induced mutant colonies over background.
870.5450 Dominant Lethal—Rat	MRID 00148319 (1984) Acceptable/Guideline	There was no time-related positive response of increased pre- or post-implantation loss compared to controls.
870.5300 Forward Gene Mutation Assay	MRID 40765601 (1988) Acceptable/Guideline	There was no evidence of induced mutant colonies over background in the presence or absence of S9-activation.
870.5300 Forward Gene Mutation Assay	MRID 00148318 (1984) Acceptable/Guideline	There was no evidence of induced mutant colonies over background in the presence or absence of S9-activation.
870.5385 *In Vivo* Mammalian Cytogenetics (Bone Marrow/Spermatogonial Aberration Test)	MRID 40765603 (1988) Acceptable/Guideline	There was no evidence of chromosome aberration induced over background.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY TABLES—Continued

Guideline No./Study Type	MRID No. (year)/Classification/ Doses	Results/Comments
870.5385 *In Vivo* Mammalian Cytogenetics (Bone Marrow Chromosome Aberration Test)	MRID 00148320 Acceptable/Guideline	There was no evidence of chromosome aberration induced over background.
870.5395 *In Vivo* Mouse Erythrocyte Micronucleus Assay	MRID 00151895 (1981) Acceptable/Guideline	There was no significant increase in the frequency of micronucleated polychromatic erythrocytes in bone marrow compared to controls.
870.5450 Dominant Lethal—Mouse	MRID 00151896 (1984) Acceptable/Guideline	There was no time-related positive response of increased pre- or post-implantation loss compared to controls.
870.5550 Unscheduled DNA synthesis in mammalian cell culture	MRID 40765602 (1988) Acceptable/Guideline	There was no evidence that unscheduled DNA synthesis, as determined by radioactive tracer procedures (nuclear silver grain counts), was induced.
870.5550 Unscheduled DNA synthesis in mammalian cell culture	MRID 00151894 (1982) Acceptable/Guideline	There was no evidence that unscheduled DNA synthesis, as determined by liquid scintillation counting procedures, was induced.
870.5900 *In Vivo* Sister Chromatid Exchange Assay	MRID 00133426 (1983) Acceptable/Guideline	There was no evidence of SCE induced over background.
870.7845 Metabolism—Rat Urinary metabolites	41218901 (1989) Acceptable/Guideline	The objective of this study was to identify the urinary metabolites of trifluralin. There was no sex-dependent effect on metabolic profiles. A minimum of 20–30 non-conjugated metabolites and an additional 10–20 conjugated metabolites were present in the urine, but no parent compound was detected. Information on the percentage of the administered dose excreted in the urine was not provided. However, no single metabolite accounted for more than 8–10% of the total urinary radioactivity, and the majority of the metabolites were present at 1–2% of the total urinary radioactivity. Thus, almost all of the metabolites were minor (<5% of the total radioactive dose). Metabolite F1B was found at 8.2–8.9% of the total urinary radioactivity in both sexes, and Metabolite F2, N-[(3-(acetylamino)-2-amino-5-(trifluoromethyl)phenyl] acetamide, was found at 4.0–5.2%. Metabolite F1B was partially characterized as retaining the trifluoromethyl groups, the two equivalent aromatic protons, and the two nitro groups, but the propyl groups were lost. Ten other metabolites were identified (<0.1–3.7% of total urinary radioactivity, each compound in each sex). Two additional metabolites were partially characterized (0.–2.6% of total urinary radioactivity, each compound in each sex). Four metabolic pathways were identified as follows: i. Oxidative N-dealkylation of one or both propyl groups and metabolites which were hydroxylated on the propyl side chain. ii. Reduction of one or both nitro groups to the corresponding amine. iii. Cyclization reactions to give a variety of substituted and unsubstituted benzimidazole metabolites. iv. Conjugation reactions, including acetylation of the reduced nitro groups, sulfate, and glucuronic acid conjugates.
Special study 3-Month Feeding—Rat with Urinalysis Study	00157156 (1985), 40138301(1986), 41086101 (1989) 0; 50; 200; 800; 3,200; and 6,400 ppm 0, 2.6, 10.7, 42.2, 170.2, and 342.1 mg/kg/day Acceptable/Nonguideline.	NOAEL = 200 ppm (10.7 mg/kg/day) LOAEL for nephrotoxicity = 800 ppm (42.2mg/kg/day), based on the presence of cortical tubular cytoplasmic hyaline droplets; increased total protein, aspartate aminotransferase (AST), and lactate dehydrogenase (LDH) in the urine; and increased urinary volume upon protein electrophoresis and urinalysis. This study was to provide additional information to establish a NOAEL for nephrotoxicity, which was observed in a chronic feeding study in rats at the lowest dose tested.

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory

animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. A UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such an additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor (SF).

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach is a conservative method which assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Even though the Agency does not have a mouse study, the database is considered to be complete with the rat data. A summary of the toxicological endpoints for trifluralin used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.—TOXICOLOGICAL DOSE AND ENDPOINTS FOR TRIFLURALIN

Exposure scenario	Dose used in risk assessment, UF	Special FQPA SF* target MOE	Study and toxicological effects
Acute Dietary (Females 13–50 years of age)	NOAEL = 100 mg/kg/day UF = 100 Acute RfD = 1.0 mg/kg/day	Special FQPA SF = 1 aPAD = 1.0 mg/kg/day	Developmental Toxicity Study—Rat LOAEL = 500 mg/kg/day based on increased total litter resorptions
Acute Dietary (General population, including infants and children)	No appropriate single dose endpoint was selected.		
Chronic Dietary All population	NOAEL = 2.4 mg/kg/day UF = 100 Chronic RfD = 0.024 mg/kg/day	Special FQPA SF = 1 cPAD = 0.024 mg/kg/day	Chronic Toxicity (capsule)—Dog LOAEL = 40 mg/kg/day based on based on increased frequency of abnormal stool, decreased body weights and body weight gains, and on decreased erythrocytes and hemoglobin and increased thrombocytes in males
Short-Term Incidental Oral (1–30 days)	NOAEL = 10 mg/kg/day	MOE = 100	2-Generation Reproduction Study—Rat LOAEL = 32.5 mg/kg/day based on decreased pup weights in both generations
Intermediate-Term Incidental Oral (1–6 months)	NOAEL = 10 mg/kg/day	MOE = 100	Special Urinalysis Study—Rat LOAEL = 40 mg/kg/day based on based on the presence of tubular cytoplasmic hyaline droplets; increased total protein, AST, and LDH in the urine; albumin α1-globulin and α2-globulin observed by urine electrophoresis; and increased urinary volume
Short-Term Dermal (1 to 30 days)	No quantification required since there was no systemic toxicity at the limit dose in the dermal toxicity study. There are no developmental toxicity concerns. The HIARC also recommends that the products containing trifluralin should be labeled as SENSITIZER.		
Intermediate-Term Dermal (1 to 6 months)	Oral study NOAEL = 10 mg/kg/day (dermal absorption rate = 3%)	Residential MOE = 100 Occupational MOE = 100	Special Urinalysis Study—Rat LOAEL = 40mg/kg/day based on based on the presence of tubular cytoplasmic hyaline droplets; increased total protein, AST, and LDH in the urine; albumin α1-globulin and α2-globulin observed by urine electrophoresis; and increased urinary volume
Long-Term Dermal (>6 months)	Oral study NOAEL = 2.4 mg/kg/day (dermal absorption rate = 3% when appropriate)	Residential MOE = 100 Occupational MOE = 100	Chronic Toxicity (capsule)—Dog LOAEL = 40mg/kg/day based on based on increased frequency of abnormal stool, decreased body weights and body weight gains, and on decreased erythrocytes and hemoglobin and increased thrombocytes in males

TABLE 2.—TOXICOLOGICAL DOSE AND ENDPOINTS FOR TRIFLURALIN—Continued

Exposure scenario	Dose used in risk assessment, UF	Special FQPA SF* target MOE	Study and toxicological effects
Short-Term Inhalation (1 to 30 days)	Inhalation study NOAEL= 81 mg/kg/day	Residential MOE = 100 Occupational MOE = 100	30-Day Inhalation Study—Rat LOAEL = 270 mg/kg/day based on increased methemoglobin and bilirubin in females and incidences of dyspnea and ruffled fur in males and females
Intermediate-Term Inhalation (1 to 6 months)	Oral study NOAEL = 10 mg/kg/day (inhalation absorption rate = 100%)	Residential MOE = 100 Occupational MOE = 100	Special Urinalysis Study—Rat LOAEL = 40 mg/kg/day based on based on the presence of tubular cytoplasmic hyaline droplets; increased total protein, AST, and LDH in the urine; albumin α1-globulin and α2-globulin observed by urine electrophoresis; and increased urinary volume
Long-Term Inhalation (>6 months)	Oral studyNOAEL= 2.4 mg/kg/day (inhalation absorption rate = 100%)	Residential MOE = 100 Occupational MOE = 100	Chronic Toxicity (capsule)—Dog LOAEL = 40 mg/kg/day based on based on increased frequency of abnormal stool, decreased body weights and body weight gains, and on decreased erythrocytes and hemoglobin and increased thrombocytes in males
Cancer (Oral, dermal, inhalation)	Q_1* = 5.8 X 10^{-3} $(mg/kg/day)^{-1}$. The Agency concluded that trifluralin is a ''Group C'' (limited evidence of carcinogenicity) carcinogen with a Q_1* of 0.0077 $(mg/kg/day)^{-1}$; (Based on male rat thyroid follicular cell tumors combined). Recalculation of the Q_1* with ¾s interspecies scaling factor resulted in a Q_1* of 0.00579 $(mg/kg/day)^{-1}$. (No additional data needed).		

UF = uncertainty factor, Special FQPA SF = Special FQPA safety factor - a FQPA safety factor based on concerns unique to the FQPA, NOAL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, NA = Not Applicable

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.207) for the residues of trifluralin, in or on a variety of raw agricultural commodities. Dietary exposure estimates are also factored by the estimated weighted average usage, or percent crop treated (PCT) data. Risk assessments were conducted by EPA to assess dietary exposures from trifluralin in food as follows:

i. *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 one day or single exposure. The Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. Additionally, acute risks were also estimated using the Lifeline model (version 2.0). Lifeline converts the raw agricultural commodity (RAC) residues into food residues by randomly selecting a RAC residue value from the user defined residue distribution (created from the residue, PCT, and processing factors data), and calculating a net residue for that food based on the ingredient's mass contribution to that food item. The Lifeline model estimated acute exposure based on the acute 1-day dietary dose drawn randomly from an age-specific seasonal exposure profile of 1,000 individuals.

In the course of conducting a Tier 3 dietary exposure analysis, decisions are made regarding the following: The residue data used in the analysis (field trials, monitoring data, etc.) refinements incorporated in such as PCT and processing factors. Monitoring data were used for the majority of crops whereby field trial data was used for the remainder of the commodities. Monitoring data were translated to similar crops when possible, generally according to the Agency's Standard Operating Procedure (SOP) 99.3 ''Translation of Monitoring Data.'' The following commodities used USDA Pesticide Data Program (PDP) monitoring data: Carrots, celery, orange, peach, squash, sweet pepper, and wheat. For PCT, the following commodities noted 100 PCT: Apricot, apricot juice, apricots-dried, brussel sprouts, cherries, cherries-dried, cherries-juice, chicory, eggplant, endive (escarole), flax seed, horseradish, kohlrabi, mustard seeds, mung beans, oats, oats-bran, parsnip, rapeseed (canola oil), and salsify. However, the majority of PCT for all other commodities is well below 100% (e.g, mint = 3%). For a more comprehensive listing of all commodities regarding PCT see the Residue Chemistry Chapter for Trifluralin, which is provided as background in EPA's public docket at *http://www.epa.gov/edocket/* under docket ID number OPP–2004–0142.

An acute dietary assessment was not conducted for the general U.S. population or infants and children because there was no appropriate single dose endpoint for this population subgroup. Trifluralin is not acutely toxic and there is no expectation that single, or single-day high-end exposure, including aggregate exposure, will have an adverse effect.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 and 1998 CSFII and accumulated exposure to the chemical for each commodity. The following summarizes the Agency's current method for determining exposure due to use on food commodities. Chronic dietary exposure is estimated for the general U.S. population and population subgroups defined by sex, age, region, and ethnicity. Durations of chronic

exposure vary from 1-year as represented by ''all infants,'' to lifetime exposure as represented by the general U.S. population, which combines all population subgroups to form a mean exposure value. It should be noted that all parameters of chronic dietary exposure estimates are averaged values (i.e., average food consumption, average residue, etc.). The assessment is based on PDP, field trial (provides an upper bound estimate of dietary exposure) and processing data. Dietary exposure estimates are also factored by the estimated weighted average usage, or ''percent crop treated'' data.

iii. *Cancer*. The estimated exposure of the general U.S. population (only) to trifluralin is 0.000028 mg/kg/day. Carcinogenic dietary risk is based on the chronic exposure estimate for the general U.S. population derived from the same residue, percent use, and averaged consumption data. Note that the consumption data for the general U.S. population represents all age groups, all geographic areas, all ethnic groups, and incorporates reports of no consumption (non-user). The final risk estimate is calculated by multiplying the average U.S. exposure estimate by the trifluralin upper-bound potency factor, or Q_1*.

iv. *Anticipated residue and percent crop treated (PCT) information*. The dietary assessment relies on field trial, monitoring (PDP), and usage data (PCT). Trifluralin residues were LOQ in/on all commodities except alfalfa, collards, flax seeds, and mint field trials.

Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E) of FFDCA, EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual PCT for assessing chronic dietary risk only if the Agency can make the following findings:

Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue.

Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group.

Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

Crops with less than 2.5 PCT: Alfalfa, almonds, apples, corn, grapes, lettuce, mint, onions, oranges, peaches, pears, pecans, prunes and plums, sorghum, and walnuts.

Crops with 5–20 PCT: Barley (5), broccoli (10), cantaloupes (15), cauliflower (10), celery (10), cucumbers (5), dry peas (15), honeydew (5), hops (5), lemons (5), okra (20), spring wheat (5), peanuts (10), potatoes (5), pumpkins (5), radishes (10), soybeans (15), spinach (10), squash (5), sugar beets (5), sugarcane (10), and watermelons (15).

Crops with 25 or more PCT: Asparagus (25), beans, green (35), cabbage (45), carrots (55), collards (35), cotton (45), dry beans (30), durum wheat (35), kale (25), greens, mustard (25), peas, green (30), peppers (25), safflower (60), sunflowers (30), tomatoes (50), and turnip (30).

Modeling was performed by using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) and Lifeline. Using the DEEM-FCID method, an estimate of the residue level in each food or food-form on the food commodity residue list is multiplied by the average daily consumption estimate for that food/food form. The resulting residue consumption estimate for each food/food form is summed with the residue consumption estimates for all other food/food forms on the commodity residue list to arrive at the total average estimated exposure. Exposure is expressed in mg/kg body weight/day and as a percent of the cPAD. This procedure is performed for each population subgroup. Using the same consumption data, Lifeline converts the Raw Agricultural Commodity an average daily exposure from a profile of 1,000 individuals over a 1-year period. In conjunction, a Screening Level Estimates of Agricultural Uses (SLUA) for trifluralin was used to estimate PCT. The SLUA provides a quick snap shot of pesticide use, by crop. For mint, the PCT of 3% was based on the SLUA report, which averages the total pounds applied to trifluralin and PCT from 1997–2001.

The Agency believes that the three conditions listed in this unit have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which trifluralin may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient data to accurately determine dietary exposure from drinking water. Therefore, contamination estimates for drinking water are refined by PRZM-EXAMS modeling, incorporating percent cropped area (PCA) data.

Since trifluralin is registered on several crops, Tier II modeling crop scenarios were selected to reflect crops with the highest uses of trifluralin (soybeans and cotton), the maximum application rate (sugarcane), and availability of scenarios. The maximum daily peak concentration of trifluralin from PRZM/EXAMS simulation (38.1 parts per billion (ppb)) is greater than the highest concentration in the United States Geological Survey (USGS) National Water Quality Assessment (NAWQA) monitoring database (1.74 ppb) for surface water. However, the maximum annual average trifluralin concentration in surface water (1.9 ppb) is comparable to time weighted annual means (TWAM) concentrations in USGS monitoring studies (0.618 ppb). The minimum criteria for calculating TWAM concentration at a sampling station in a given year was a single detection of trifluralin. As to groundwater, the maximum trifluralin concentration predicted by SCI-GROW is 0.035 ppb and the maximum single value from NAWQA monitoring of ground water is 0.150 ppb. The 99.8 percentile NAWQA value is 0.012 ppb. Because these values are well below predicted and actual surface water values, no further analysis of the reliability of the maximum NAWQA groundwater value was conducted. Modeling was conducted using the maximum application rate for specific crops. Modeling estimates from typical application rates on specific crops will predict lower concentrations. For further information on trifluralin modeling and monitoring, see docket ID number OPP–2004–0142 at *http://www.epa.gov/edocket/* for the following documents: Trifluralin—Drinking Water Assessment for Tolerance Reassessment Eligibility Decision and a memorandum entitled Clarification of the Trifluralin Drinking Water Assessment for the Health Effects Division (HED) Tolerance Reassessment (PC Code: 036101) and characterization on relative differences of USGS NAWQA ground water monitoring data and its comparison to SCI-GROW model predictions as presented in the NRDC objection (see Imidacloprid in the **Federal Register** of May 26, 2004 (69 FR 30042) (FRL–7355–7)) and the trifluralin TRED.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

3. *Non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Trifluralin is currently registered for use on the following residential non-dietary sites: Home lawns, vegetable gardens, ornamental gardens (including planting beds, flowers, shrubs, and trees), including other residential sites such as golf courses, recreational parks, bike/golf cart paths, and cemeteries. The risk assessment was conducted using the following residential exposure assumptions:

- For residential scenarios, homeowner handlers are expected to complete all tasks associated with the use of a pesticide product, including mixing/loading as well as application.
- Residential handler exposure scenarios are only considered to be short-term in nature due to the episodic uses associated with homeowner products.
- Label use rates and use information specific to residential products serve as the basis for the risk calculations.
- Area/volumes of spray or chemical used in the risk assessment are based on Agency guidance specific to residential use patterns.

The Agency has determined that there are potential exposures to residential handlers (i.e., mixer, loader, applicators) during the usual use-patterns associated with trifluralin. Likewise, the Agency has determined that there are potential post-application exposures to adults and children in residential settings during the usual use-patterns associated with trifluralin. For non-cancer post-application risks, since there is no short-term dermal toxicological endpoint of concern for trifluralin and no intermediate-term dermal exposure is anticipated, the only assessment is for incidental ingestion by toddlers.

The Agency has also determined that there are potential post-application cancer risks for adults in residential areas treated with trifluralin. The following scenarios were assessed:

- Dermal exposure to residue on lawns.
- Dermal exposure to golf course turfgrass.
- Dermal exposure to residue on home gardens.

For the residential turfgrass scenario, the cancer risks were combined for residential handlers applying granular formulation to lawns with post-application cancer risks to adults from exercising on just-treated lawns. This combined two screening-level calculations.

4. *Cumulative exposure to substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA 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.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to trifluralin and any other substances and 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 has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure 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 MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity*. There are no residual uncertainties for pre- and/or postnatal toxicity.

3. *Conclusion*. There is a complete toxicity database for trifluralin and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Based on this information and the lack of any residual concerns for pre- and/or postnatal toxicity, EPA concludes it has

reliable data to remove the additional 10X FQPA safety factor.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water [e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)]. This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and groundwater are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

Aggregate exposure assessment is based, in part, on the assumption that there is a predictable level of chronic pesticide exposure, attributable to food and drinking water, and this level is estimated on a per day basis (mg/kg/day) by using averaged estimates of residue, use, and consumption. This average, or ''background'' level of exposure is assumed to be constant, not seasonal, and residential or other exposures are additive to this background.

For trifluralin, homeowner use is highly seasonal (mostly early Spring) and this exposure will likely be acute (one day of golf) or short-term (multiple residential applications). The route of exposure may be oral (children on turf), dermal (at application or post-application), or by inhalation (at application).

1. *Acute risk*. A quantitative acute dietary assessment was not conducted for the general U.S. population or population subgroups other than females 13–49 because there was no appropriate single dose endpoint. Exposure to trifluralin is not expected to pose an acute risk to these population groups. The upper-bound acute risk estimate for females 13–49 years of age is less than 1% of the aPAD at the 99.9th exposure percentile. Results of the Lifeline analysis (see Table 3 of this unit) are fully consistent with DEEM-FCID results (<1% aPAD).

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO TRIFLURALIN (FOOD/ WATER COMBINED)

Acute Dietary Estimates (99.9th Percentile of Exposure)					
Population subgroup	PAD, mg/kg/day	DEEM-FCID		Lifeline	
		Exposure, mg/kg/day	% PAD	Exposure, mg/kg/day	%PAD
Females 13–49 years	1	0.000262	0.03	0.000311	<1

2. *Chronic risk*. Dietary risk for trifluralin is assessed by comparing chronic dietary exposure estimates (in mg/kg/day) to the trifluralin cPAD, with dietary risk expressed as a percent of the cPAD. The cPAD is the chronic population adjusted dose; the chronic reference dose (0.024 mg/kg/day) modified by the FQPA safety factor. The trifluralin cPAD is 0.024 mg/kg/day based on a RfD of 0.024 mg/kg/day (see section 3.3.1, Endpoint Selection Discussion in the Trifluralin: Human Risk Assessment document), and incorporating the FQPA safety factor of 1X (no additional factor) for the overall U.S. population or any population subgroups.

The cPAD method of risk assessment is applicable to the oral exposure route and is used to assess both food and drinking water exposure. Exposure estimates that are less than 100% of the cPAD indicate a determination of safety can be concluded (see Table 4 of this unit).

TABLE 4.—CHRONIC DIETARY EXPOSURE AND RISK ESTIMATES

Chronic PAD Dietary Estimates					
Population subgroup	PAD, mg/kg/day	DEEM-FCID		Lifeline	
		Exposure, mg/kg/day	%PAD	Exposure, mg/kg/day	%PAD
U.S. Population	0.024	0.000030	<1	0.000019	<1
All infants (< 1 year)	0.024	0.000062	<1	0.000033	<1

TABLE 4.—CHRONIC DIETARY EXPOSURE AND RISK ESTIMATES—Continued

Chronic PAD Dietary Estimates					
Population subgroup	PAD, mg/kg/day	DEEM-FCID		Lifeline	
		Exposure, mg/kg/day	%PAD	Exposure, mg/kg/day	%PAD
Children 1–2 years	0.024	0.000073	<1	0.000051	<1
Children 3–5 years	0.024	0.000062	<1	0.000039	<1
Children 6–12 years	0.024	0.000041	<1	0.000024	<1
Youth 13–19 years and All Adults	0.024	0.000025	<1	0.000016	<1

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Dietary exposure is assumed to be constant, not seasonal and residential or other exposures are additive to this background. Homeowner use for trifluralin is highly seasonal and this exposure will likely be acute or short-term. Thus, the route of exposure may be oral (children on turf), dermal, or inhalation where residential exposure could occur with the use of trifluralin. However, no toxicological effects have been identified for short-term toxicity. Therefore, the aggregate risk does not exceed the Agency's level of concern.

The chronic dietary exposure and risk estimates for the general United States and population subgroups, are aggregate estimates based on both food and drinking water sources. The aggregate (3 specific exposure scenarios) incidental-oral exposure estimate for children on turf is 0.00009 mg/kg/day. When combined with the estimated chronic dietary exposure (0.000051 mg/kg/day) for children 1–2 years old, the sum is 0.00014 mg/kg/day. Compared to the appropriate dose (10 mg/kg/day) for short-term incidental-oral risk assessment, this aggregate exposure estimate is much greater than the target MOE of 100, and a conclusion of safety can be made.

4. *Intermediate-term risk*. Intermediate and long-term residential exposure is not expected for trifluralin and thus no such risk is expected from the use of trifluralin.

5. *Cancer risk*. When using the Q_1* approach to assess a pesticide, the Agency considers all exposure to be additive to aggregate carcinogenic risk, regardless of exposure route or exposure duration (per season). For trifluralin, this means that the chronic exposure from foods (0.000022 mg/kg/day) is added to chronic exposure due to drinking water (0.000008 mg/kg/day) and this in turn is added to exposure estimated for residential use. Based on this assumption, carcinogenic risk estimates are made for those applying trifluralin themselves, each season, throughout adulthood (50 years).

The exposure and carcinogenic risk estimates for residential applicators vary significantly depending on the application method, even if other inputs (rate and area treated) remain the same. Since the carcinogenic risk assessment attempts to reflect long-term exposure, the most appropriate exposure estimate would be based on the most common application method; the push-type spreader (for homeowners).

The risk estimate represents the probability of ''excess'' cancers attributable to trifluralin. In general, the Agency considers carcinogenic risk estimates in the range of 10^{-6}, or less, to be negligible. Applying the Q_1* of 5.8 x 10^{-3} $(mg/kg/day)^{-1}$ to the exposure value, results in a cancer risk estimate of 1.64 x 10^{-7} (DEEM-FCID) and 1.13 x 10^{-7} (Lifeline). Therefore, estimated cancer risk is below the Agency's level of concern.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to trifluralin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (GC method; TFN0291) using an electron capture detector (ECD), Eli Lilly Method AM-AA-CA-R023-AA-755, and GRM 92.11) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

Canada, Codex, and Mexico do not have maximum residue limits (MRLs) for residues of trifluralin in mint oil or in/on spearmint and peppermint tops. Furthermore, no maximum MRLs for trifluralin have been established or proposed by Codex for any agricultural commodity. Therefore, no compatibility questions exist with respect to U.S. tolerances.

C. Conditions

Currently, there are no additional requirements. Also, all existing tolerances are being maintained at current levels and are considered to be reassessed by the Trifluralin Tolerance Reassessment Eligibility Decision signed on August 31, 2004.

V. Conclusion

A tolerance is proposed for residues of trifluralin in mint oil at 2.0 ppm.

VI. Statutory and Executive Order Reviews

This proposed rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this proposed rule has been exempted from review under Executive Order 12866 due to its lack of significance, this proposed rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This proposed rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any

enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Because this action will not have an adverse impact on small business, I certify, under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), that this action will not have a significant economic impact on a substantial number of small entities. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This proposed rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this proposed rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This proposed rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this proposed rule.

List of Subjects in 40 CFR Part 180

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

Dated: November 16, 2004.

Debra Edwards,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Section 180.207 would be amended by revising the table in paragraph (a) to read as follows:

§ 180.207 Trifluralin; tolerances for residues.

(a) * * *

Commodity	Parts per million
Alfalfa, hay	0.2
Asparagus	0.05
Barley, hay	0.05
Barley, straw	0.05
Bean, mung, sprouts	2.0
Carrot, roots	1.0
Corn, field, forage	0.05
Corn, field, grain	0.05
Corn, field, stover	0.05
Cotton, undelinted seed	0.05
Cress, upland	0.05
Flax, seed	0.05
Friut, citrus, group 10	0.05
Fruit, stone, group 12	0.05
Grain, crop, except corn, sweet and rice grain	0.05
Grape	0.05
Hop	0.05
Legume, forage	0.05
Nut, tree, group 14	0.05
Peanut	0.05
Peppermint oil	2.0
Peppermint, tops	0.05
Rapeseed, seed	0.05
Safflower, seed	0.05
Sorghum, forage	0.05
Sorghum, grain, stover	0.05
Spearmint oil	2.0
Spearmint, tops	0.05
Sugarcane, cane	0.05
Sunflower, seed	0.05
Vegetable, cucurbit, group 9	0.05
Vegetable, fruiting, group 8	0.05
Vegetables, leafy	0.05
Vegetables, root (exc. carrots)	0.05
Vegetables, seed and pod	0.05
Wheat, grain	0.05
Wheat, straw	0.05

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