

purpose of judicial rule, nor does it extend the time within which a petition for judicial review may be filed and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. See section 307(b)(2) of the CAA.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Oxides of nitrogen, Incorporation by reference, Intergovernmental relations, Ozone.

Dated: January 18, 1996.

Carol M. Browner,
Administrator.

40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart T—Louisiana

2. Section 52.992 is amended by adding paragraph (b) to read as follows:

§ 52.992 Area-wide nitrogen oxides (NO_x) exemptions.

* * * * *

(b) The LDEQ submitted to the EPA on November 17, 1994, a petition requesting that the Baton Rouge serious ozone nonattainment area be exempted from the NO_x control requirements of the CAA. In addition, supplemental information was submitted to the EPA by the LDEQ on January 26, 1995, June 6, 1995, and June 16, 1995. The Baton Rouge nonattainment area consists of East Baton Rouge, West Baton Rouge, Pointe Coupee, Livingston, Iberville, and Ascension Parishes. The exemption request was based on photochemical grid modeling which shows that reductions in NO_x would not contribute to attainment in the nonattainment area. On January 18, 1996, the EPA approved the State's request for an areawide exemption from the following requirements: NO_x new source review, NO_x reasonably available control technology, NO_x general conformity, and NO_x inspection and maintenance requirements.

[FR Doc. 96–1288 Filed 1–25–96; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 185

[OPP–300394A; FRL–4983–6]

RIN 2070–AB78

Trifluralin; Revocation of Food Additive Regulation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is revoking the food additive regulation (FAR) for residues of the herbicide trifluralin in peppermint oil and spearmint oil. EPA is taking this action because peppermint oil and spearmint oil are not ready-to-eat commodities, and residues of trifluralin are not likely to concentrate in ready-to-eat foods containing peppermint and spearmint oil. Therefore, this FAR is not required.

EFFECTIVE DATE: This final rule becomes effective January 26, 1996.

ADDRESSES: Written objections, requests for a hearing, and/or requests of stays identified by the document control number, OPP-300394A, must be submitted by February 26, 1996, and comments on all of the above must be submitted by March 11, 1996 to the OPP docket: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Hand deliver to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Information submitted as a filing 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 filings 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 (non-CBI) filings 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.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and

hearing requests will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [OPP-300394A]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: Niloufar Nazmi, Special Review Branch (7508W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Crystal Mall #2, Rm. 1113, 1921 Jefferson Davis Hwy., Arlington, VA, (703)-308-8028; e-mail: nazmi.niloufar@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

EPA is revoking the FAR for residues of the herbicide trifluralin in peppermint oil and spearmint oil (40 CFR 185.5900).

A. Statutory Background

The Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 et seq., authorizes the establishment by regulation of maximum permissible levels of pesticides in foods. Such regulations are commonly referred to as "tolerances." Without such a tolerance or an exemption from the requirement of a tolerance, a food containing a pesticide residue is "adulterated" under section 402 of the Federal Food, Drug, and Cosmetic Act (FFDCA) and may not be legally moved in interstate commerce. 21 U.S.C. 331, 342. EPA was authorized to establish pesticide tolerances under Reorganization Plan No. 3 of 1970. 5 U.S.C. App. at 1343 (1988). Monitoring and enforcement of pesticide tolerances are carried out by the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA). EPA can establish a tolerance in response to a petition (FFDCA sections 408(d)(1) and 409(b)(1)) or on its own initiative (FFDCA sections 408(e) and 409(d)).

The FFDCA has separate provisions for tolerances for pesticide residues on raw agricultural commodities (RACs) and tolerances on processed food. For pesticide residues in or on RACs, EPA establishes tolerances, or exemptions from tolerances when appropriate, under section 408 of the act (21 U.S.C. 346a.) EPA regulates pesticide residues in processed foods under section 409 of

the act, which pertains to "food additives" (21 U.S.C. 348). Maximum residue regulations established under section 409 of the act are commonly referred to as food additive regulations (hereafter referred to as "FARs"). Section 409 FARs are needed, however, only for certain pesticide residues in processed food. Under section 402(a)(2) of the FFDCA, a pesticide residue in processed food generally will not render the food adulterated if the residue results from application of the pesticide to a RAC and the residue in the processed food when ready to eat is below the RAC tolerance. This exemption in section 402(a)(2) is commonly referred to as the "flow-through" provision because it allows the section 408 raw food tolerance to flow through to the processed food forms. Thus, a section 409 food additive regulation is only necessary to prevent foods from being deemed adulterated when the level of the pesticide residue in a processed food when ready to eat is greater than the tolerance prescribed for the RAC, or if the processed food itself is treated or comes in contact with a pesticide.

B. Regulatory Background

In the Federal Register of July 14, 1993 (58 FR 37862) EPA issued a final order, hereafter referred to as "1993 Order", that was subject to objections and requests for a hearing and that revoked the trifluralin FAR for peppermint oil and spearmint oil. The 1993 Order was issued in response to the decision by the U.S. Court of Appeals, Ninth Circuit, in the case of *Les v. Reilly*, 968 F.2d 985 (9th Cir. 1992), cert. denied, 113 S.Ct. 1361 (1993). DowElanco, the manufacturer of trifluralin, filed objections to the revised Order, as well as requests for a hearing on, and a stay of, the revocation Order. In the Federal Register of June 30, 1994 (59 FR 33684), EPA issued a final order (hereafter referred to as "1994 Order") denying DowElanco's objections and requests for a hearing and a stay of the revocation. On July 14, 1994, DowElanco filed an action in the U.S. Court of Appeals, D.C. Circuit, for review of EPA's 1993 Order, and moved for summary reversal or, in the alternative, an emergency stay of the revocation. *E.I. DuPont DeNemours and Co., et al. v. EPA*, Civ. Action No. 94-1504 (D.C. Cir.). On August 24, 1994, the Court denied DowElanco's motion for summary reversal, but issued an emergency stay of the revocation. In the Federal Register of September 12, 1994 (59 FR 46768), EPA reinstated the FAR for trifluralin (as well as for benomyl), and they are currently in effect.

On September 11, 1992, the National Food Processors Association (NFPA) and other organizations filed a petition with EPA challenging, among other things, EPA's interpretation of the phrase "ready to eat" in the Delaney Clause. (Petition to the Environmental Protection Agency, Office of Pesticide Programs, Concerning EPA's Pesticide Concentration Policy (1992)) (hereinafter cited as "NFPA petition"). The petition requested that EPA apply the term "ready to eat" in the flow-through provision according to what NFPA asserts is its plain meaning. EPA sought public comment on the petition (58 FR 7470, Feb. 5, 1993). In the Federal Register of June 14, 1995 (60 FR 31300), EPA issued a partial response to the NFPA petition, addressing the "ready to eat" policy. In that response, EPA agreed that the term "ready to eat" food has a common-sense meaning of food which is consumed without further preparation, and stated its intention to apply that interpretation in future actions.

In the Federal Register of July 28, 1995 (60 FR 38781), EPA issued a proposed rule to revoke the FAR for trifluralin on peppermint and spearmint oils. In the same proposed rule, EPA proposed to withdraw its Order dated July 14, 1993 (58 FR 37862), to the extent that it revoked the FAR for trifluralin in peppermint oil and spearmint oil. Today's document contains a final rule revoking the trifluralin FAR and responds to comments on the July 28, 1995 proposal.

II. Revocation of the Food Additive Regulations for Trifluralin in Peppermint Oil and Spearmint Oil

EPA has determined that no section 409 FAR is necessary for mint oils because they are not "ready to eat" processed foods, and because "ready to eat" foods containing mint oils are unlikely to have trifluralin residues greater than the RAC tolerances for peppermint hay and spearmint hay. The proposed rule for this action was published in the Federal Register of July 28, 1995 (60 FR 38781). The Federal Register document and all the supporting documents are in the OPP docket number 300394.

As noted above, under FFDCA section 402(a)(2), processed foods containing pesticide residues are not deemed adulterated if the level of pesticide residues in the processed food "when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity." EPA believes that the common sense meaning of the term "ready to eat" food is food ready for consumption without further

preparation. Mint oils are not consumed "as is" but are used as a flavoring in other foods. As such, peppermint oil and spearmint oil are not "ready to eat."

Mint oils are used as flavoring agents in foods such as beverages, ice cream, candy, and chewing gum. Chewing gum is a ready-to-eat food with the highest concentration of peppermint and spearmint oils. The information available to EPA shows that trifluralin residues are diluted during manufacturing so that there is no concentration over the RAC tolerance in the ready-to-eat chewing gum. Thus, no section 409 FAR is needed for peppermint oil and spearmint oil, and EPA is revoking the existing FAR. (60 FR 38781)

III. Response to Comments

EPA received comments on the proposed revocation of the trifluralin FAR. All the commenters support the basis for the revocation of the referenced FAR. In addition, many of the commenters raise other issues that EPA believes are not relevant to EPA's conclusion that mint oils are not ready-to-eat commodities and that as a result, the section 409 FAR covering residues of trifluralin in mint oils are not necessary. However, the following are brief responses to these comments.

Comment

The National Food Processor's Association (NFPA), the American Crop Protection Association (ACPA), DowElanco, and Gowan Co. submitted comments in support of the revocation of the proposed FAR and the withdrawal of the July 14, 1993 Order. However, NFPA, ACPA, and DowElanco contend that there are other controlling legal reasons why the 1993 and 1994 Orders must be withdrawn.

The commenters contend that once it has been determined that trifluralin residues in mint oil are subject to the section 402 flow-through provision, the 1993 and 1994 Orders must be withdrawn because those Orders purported to revoke the FAR on the grounds that the pesticide "induces cancer" within the meaning of the Delaney clause. The commenters contend that, as a matter of law, EPA is precluded from revoking a section 409 FAR under the safety standard in section 409(c) if EPA has determined, as it has here, that the FAR is not needed to prevent the adulteration of processed food.

According to the commenters, the flow-through provision prohibits EPA from determining that an agricultural pesticide in a processed food is "unsafe," notwithstanding the

provisions of section 409, if the pesticide residue has been removed to the extent possible in good manufacturing practice and the level of the residue in the processed food when ready to eat is not greater than the applicable section 408 tolerance. Thus, the commenters reason that since EPA has decided that trifluralin residues in mint oil are likely to fall within the protection of the flow-through provision, EPA is barred from revoking the trifluralin FAR on grounds that the pesticide "induces cancer" within the meaning of the Delaney clause in section 409 of the FFDCA. On June 10, 1995, NFPA separately filed a petition with EPA raising this same issue.

EPA's Response

As will be explained in more detail in EPA's response to the June 10, 1995 NFPA petition, the commenters' argument is without any legal basis. The commenters misunderstand the relationship between a section 409 FAR and the flow-through provision. As a result of the flow-through provision, a FAR only has legal effect as to residues of the pesticide in processed food that exceed the residue levels qualifying under the flow-through provision. Thus, a finding that a pesticide does not meet the safety standard under section 409 and a revocation of a FAR based on such a finding has no effect on residues of the pesticide that are in compliance with the flow-through provision. Such a lack of safety finding under section 409(c) does not render pesticide residues in compliance with the flow-through provision unsafe. If a section 409 FAR is revoked, residues still retain the same legal safe harbor they always had under the flow-through provision. Accordingly, the flow-through provision contains no bar to the revocation of a section 409 FAR on safety grounds.

Comment

DowElanco further requests that the Agency explicitly acknowledge that DowElanco and other adversely affected parties will not be precluded from challenging any "induce cancer" finding for trifluralin in any future FFDCA tolerance revocation actions. DowElanco insists that without such an acknowledgement, today's Notice will not resolve the underlying controversy in the *Dupont and DowElanco v. Browner* litigation. In addition, DowElanco urges that the EPA should use today's Notice to clarify its position on chemicals classified as Group C carcinogens with quantification by the Reference Dose approach (or found not to be quantifiable). DowElanco further argues that by using the Reference Dose

approach for quantifying risk, EPA is recognizing that the carcinogenic risk is so uncertain that it is disregarded for evaluating risk.

EPA's Response

EPA believes that there are no additional trifluralin tolerances or FARs that are likely to be revoked on grounds that trifluralin "induces cancer." The trifluralin Reregistration Eligibility Document, which will soon be issued by EPA, indicates that there are no section 409 FARs needed for this chemical. Therefore, EPA does not foresee a situation that would result in any hearings under the FFDCA on whether trifluralin "induces cancer." However, as explained below, EPA will consider future hearing requests raising any evidence relevant and material to a finding that trifluralin "induces cancer" within the meaning of the Delaney clause when that finding serves as the basis for an order issued by EPA under the authority of sections 408 and 409 of the FFDCA.

EPA believes that precluding review of issues that could have and should have been raised in prior proceedings is an appropriate and essential policy and legal position for the Agency to take in FFDCA proceedings because it ensures that such Agency decisions are accorded finality. In the interest of administrative efficiency and economy, final determinations in such administrative proceedings deserve to be treated with the same finality as final determinations in judicial proceedings. Further, under section 409 of the FFDCA, the only way to prevent EPA from according finality to a section 409(f) order, and the legal and factual basis for that order, is to file objections within the time period specified, *Nader v. EPA*, 859 F.2d 747 (9th Cir. 1988), *cert. denied*, 490 U.S. 1931 (1989); and *CNI v. Young*, 773 F.2d 1356 (1985).

EPA found, in its 1990 and 1991 Orders, that trifluralin "induces cancer" but that because the trifluralin cancer risks were *de minimis*, EPA would retain the trifluralin FAR that was the subject of NRDC's petition. However, because EPA retained the FAR, and because this was the first proceeding of this nature under section 409 of the FFDCA, proponents of the FAR and chemicals, including DowElanco, may not have understood that their failure to raise objections to the cancer finding at that time could result in that finding being accorded finality by EPA. Given that such circumstances are not likely to be repeated, EPA believes it is appropriate to assure DowElanco that EPA will not assert in future FFDCA proceedings that the issue of whether

trifluralin "induces cancer" must or will be accorded finality based on EPA's 1990 and 1991 Orders.

Because EPA is providing the assurances requested by commenters, EPA believes there should be no objections to an EPA final order withdrawing the 1993 and 1994 Orders.

IV. Procedural Matters

A. Filing of Objections and Requests for Hearings

Any person adversely affected by this final rule may file written objections to the final rule, and may include with any such objection a written request for an evidentiary hearing on the objection. Such objections must be submitted to the Hearing Clerk on or before February 26, 1996. A copy of the objections and hearing requests filed with the Hearing Clerk shall be submitted to the Office of Pesticide Programs Docket Room. Regulations applicable to objections and requests for hearings are set out at 40 CFR parts 178 and 179. Those regulations require, among other things, that objections specify with particularity the provisions of the final rule objected to, the basis for the objections, and the relief sought. Additional requirements as to the form and manner of the submission of objections are set out at 40 CFR 178.25. The Administrator will respond as set forth in 40 CFR 178.30, 178.35, and/or 178.37 to objections that are not accompanied by a request for evidentiary hearing.

A person may include with any objection a written request for an evidentiary hearing on the objection. A hearing request must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on each such issue, and a summary of any evidence relied upon by the requestor. Additional requirements as to the form and manner of submission of requests for an evidentiary hearing are set out at 40 CFR 178.27. Under 40 CFR 178.32(c), the Administrator, where appropriate, will make rulings on any issues raised by an objection if such issues must be resolved prior to determining whether a request for an evidentiary hearing should be granted. The Administrator will respond to requests for evidentiary hearings as set forth in 40 CFR 178.30, 178.32, 178.35, 178.37, and/or 179.20. Under 40 CFR 178.32(b), a request for an evidentiary hearing on an objection will be granted if the objection and request have been properly submitted and if the Administrator determines that the material submitted show: (1) There is a genuine and substantial issue of fact for resolution at a hearing; (2) There is a

reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor; and (3) Resolution of one or more of the factual issues in the manner sought by the person requesting the hearing would be adequate to justify the action requested.

Any person wishing to comment on any objections or requests for a hearing may submit such comments to the Hearing Clerk on or before March 11, 1996.

A record has been established for this rulemaking under docket number [OPP-300394A] (including objections and hearing requests 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 Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Written objections and hearing requests, identified by the document control number [OPP-300394A], may be submitted to the Hearing Clerk (1900), Environmental Protection Agency, Rm. 3708, 401 M St., SW., Washington, DC 20460.

A copy of electronic objections and hearing requests filed with the Hearing Clerk can be sent directly to EPA at: opp-Docket@epamail.epa.gov

A copy of electronic objections and hearing requests filed with the Hearing Clerk 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 any objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all objections and hearing requests submitted directly in writing. The official rulemaking record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document.

B. Effective Date

EPA is making this final rule effective January 26, 1996 given the lack of

adverse comments on EPA's proposed action. In addition, if EPA does not receive objections to this Order, this Order and the factual and legal basis for this Order become final and are not judicially reviewable. See section 409(g)(1), 21 U.S.C. 348(g)(1), and *Nader v. EPA*: 859 F.2d 747 (9th Cir. 1988), *cert. denied*, 490 U.S. 1931 (1989).

C. Request for Stays of Effective Date

A person filing objections to this final rule may submit with the objections a petition to stay the effective date of this final rule. Such stay petitions must be submitted to the Hearing Clerk on or before February 26, 1996. A copy of the stay request filed with the Hearing Clerk shall be submitted to the Office of Pesticide Programs Docket Room. A stay may be requested for a specific time period or for an indefinite time period. The stay petition must include a citation to this final rule, the length of time for which the stay is requested, and a full statement of the factual and legal grounds upon which the petitioner relies for the stay. In determining whether to grant a stay, EPA will consider the criteria set out in the Food and Drug Administration's regulations regarding stays of administrative proceedings at 21 CFR 10.35. Under those rules, a stay will be granted if it is determined that: (1) The petitioner will otherwise suffer irreparable injury; (2) The petitioner's case is not frivolous and is being pursued in good faith; (3) The petitioner has demonstrated sound public policy grounds supporting the stay; and (4) The delay resulting from the stay is not outweighed by public health or other public interests.

Under FDA's criteria, EPA may also grant a stay if EPA finds such action is in the public interest and in the interest of justice.

Any person wishing to comment on any stay request may submit such comments and objections to a stay request, to the Hearing Clerk, on or before March 11, 1996. Any subsequent decisions to stay the effect of this Order, based on a stay request filed, will be published in the Federal Register, along with EPA's response to comments on the stay request.

V. Regulatory Requirements

A. Executive Order 12866

Under Executive Order 12866, the Agency must determine whether the regulatory action is "significant" and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under the order, a "significant regulatory action" is an action that is

likely to result in 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, and the environment, public health or safety, of State, local, or tribal governments or communities"; (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 the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. EPA has determined that this final rule is not a "significant" action under E.O. 12866. EPA is taking this action because it has determined that the food additive regulation for trifluralin is not needed. Therefore, the Agency expects that no economic impact will result.

B. Regulatory Flexibility Act

The regulatory action has been reviewed under the Regulatory Flexibility Act of 1980, and, as stated above, EPA expects that it will not have any economic impacts, including impacts on small entities.

C. Paperwork Reduction Act

This Order does not contain any information collection requirements subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq.

List of Subjects in 40 CFR Part 185

Environmental protection, Administrative practice and procedures, Agricultural commodities, Food additives, Pesticides and pests, Reporting and recordkeeping.

Dated: January 19, 1996.

Lynn R. Goldman,
Assistant Administrator for Prevention,
Pesticides and Toxic Substances.

Therefore, 40 CFR part 185 is amended as follows:

PART 185—[AMENDED]

1. The authority citation for part 185 continues to read as follows:

Authority: 21 U.S.C. 346a and 348.

§ 185.5900 [Removed]

2. By removing § 185.5900 *Trifluralin*.

[FR Doc. 96-1402 Filed 1-25-96; 8:45 am]

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