

Clean Air Act. Today's correction has no bearing on the other three rules that were finalized in our January 13, 2000 action. We believe these rules are consistent with the relevant policy and guidance regarding enforceability, RACT, and SIP relaxations.

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a "significant regulatory action" and, is therefore not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104-4), or require prior consultation with State officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or involve special consideration of environmental justice related issues as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

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

#### List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: May 9, 2000.

**Keith Takata,**

*Acting Regional Administrator, Region IX.*

Subpart F of part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

#### PART 52—[AMENDED]

##### Subpart F—California

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

**Authority:** 42 U.S.C. 7401 *et seq.*

##### **§ 52.220 [Amended]**

2. Section 52.220 is amended by removing paragraph (c)(179)(H).

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[OPP-300507A FRL-6556-2]

RIN 2070-AB78

### Vinclozolin; Order Denying Objections to Issuance of Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final order.

**SUMMARY:** EPA is denying the objections filed by the Natural Resources Defense Council to a final rule issued July 18, 1997, which announced the issuance of a tolerance for use of vinclozolin on succulent (snap) beans under section 408 of the Federal Food, Drug, and Cosmetic Act. The objections are denied because the tolerances have expired and consequently the objections are now moot.

**DATES:** This denial of the objections is effective on May 23, 2000.

**FOR FURTHER INFORMATION CONTACT:** Deanna Scher, Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-7043; fax number: (703) 308-7042; e-mail address: scher.deanna@epa.gov.

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

##### A. Does This Action Apply to Me?

This action is directed to the public in general. However, this action is of particular interest to Earthjustice Legal Defense Fund, the organization that filed objections to the vinclozolin tolerance granted for snap beans in 1997 on behalf of Natural Resources Defense Council, American Federation of Labor and Congress of Industrial Organizations, Environmental Working Group, Pineros y Campesinos Unidos del Noroeste, and Northwest Coalition for Alternatives to Pesticides. This action is also of interest to BASF Corporation, the manufacturer of vinclozolin, as well as users of vinclozolin products. Since various different entities may be interested in this action, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section."

##### B. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations" and then look up the entry for this document under the "Federal Register—Environmental Documents." You can also go directly to the Federal Register listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-300507A. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

##### II. Background

##### A. What Action Is the Agency Taking?

On September 15, 1997, the Natural Resources Defense Council ("NRDC") filed a series of objections and hearing requests in regard to EPA's issuance of a tolerance for the pesticide vinclozolin on succulent (snap) beans under section 408 of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. 346a. Because that tolerance expired on October 1, 1999, those objections are now moot and are denied on that ground.

##### B. What Is the Agency's Authority for Taking This Action?

Section 408 of the FFDCA 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 FFDCA and may not be legally moved in interstate commerce. 21 U.S.C. 331, 342. 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).

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes dietary exposure through food and drinking water and exposure other than dietary that occurs in non-occupational settings. In making safety determinations, EPA is required to consider, among other things, "available information concerning the cumulative effects of the pesticide chemical residue and other substances that have a common mechanism of toxicity." 21 U.S.C. 346a(b)(2)(D)(v).

Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ." 21 U.S.C. 346a(b)(2)(C). For pesticides that pose a threshold effect, EPA is directed to apply "an additional tenfold margin of safety . . . to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children." [hereinafter referred to as "the children's safety factor"] *Id.* This provision additionally specifies that EPA "may use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children." *Id.*

The procedure for establishing tolerance regulations is generally initiated by pesticide manufacturers through the filing with EPA of a petition requesting the establishment of a tolerance. See 21 U.S.C. 346a(d). EPA is required to publish notice of this petition as well as a summary of the petition prepared by the petitioner. *Id.* 346a(d)(3). After evaluation of the petition, EPA may issue a final tolerance

regulation, a proposed tolerance regulation, or an order denying the petition. *Id.* 346a(d)(4). Once a final tolerance regulation is issued, any person may, within 60 days, file written objections to any aspect of this regulation and may also request a hearing on issues of fact raised by the objections. *Id.* 346a(g).

EPA regulations specify that if a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor. 40 CFR 178.27. A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested. 40 CFR 178.32. EPA's regulations specify that if no hearing is requested, or a requested hearing is denied, EPA will publish in the **Federal Register** its determination on each objection submitted. 40 CFR 178.37(a).

### III. Regulatory and Procedural History

Vinclozolin is a fungicide produced by BASF Corporation. Vinclozolin is registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*, for use on various fruits and vegetables and corresponding tolerances have been established under the FFDCA. For many years prior to 1997, vinclozolin was approved for use on succulent beans in several states under an emergency exemption under FIFRA. Prior to 1997, vinclozolin was also registered for use on turf in residential areas as well as parks, school grounds, and recreational areas.

In July 1997, in response to a petition submitted by BASF Corporation, EPA issued a tolerance for vinclozolin on succulent beans (62 FR 38464, July 18, 1997) (FRL-5727-9). That tolerance contained an expiration/revocation date of October 1, 1999. In connection with the establishment of the succulent bean tolerance, BASF requested that EPA terminate BASF's vinclozolin FIFRA registrations on tomatoes, grapes, and plums including plums grown for prunes as well as on residential turf and turf in parks, school grounds, and

recreational areas (except for golf courses) and to revoke associated FFDCA tolerances. See 62 FR 43327, August 13, 1997.

On September 15, 1997, NRDC filed two objections to this tolerance and requested a hearing regarding several issues raised by its objections. NRDC's two objections were that EPA failed:

- (1) To use the statutorily mandated tenfold safety factor to account for infants' and children's exposures to and toxic risks from vinclozolin; and
- (2) To incorporate into its assessment of noncancer risks the available information on cumulative exposures to other similar chemicals. Objections at 16.

NRDC argued that EPA was required to use the tenfold safety factor because, among other reasons, there exist data gaps concerning vinclozolin's neuro-behavioral effects. Objections at 23-24.

On January 16, 1998, EPA provided an initial response to NRDC's hearing requests. EPA stated that an initial review of the hearing requests indicated that requests would have to be denied under EPA's regulations. EPA noted that the issues on which NRDC had sought a hearing "rather than being factual claims accompanied by contentions as required by the regulations, are more in the nature of interrogatories or discovery requests." EPA made clear that "[t]he purpose of an evidentiary hearing is to 'receive factual evidence relevant to material issues of fact raised by the objections,' FFDCA section 408(g)(2)(B), not to determine whether such evidence or issues of fact exist." Nonetheless, because NRDC claimed it had not had access to the full administrative record for the tolerance, EPA made that record available and gave NRDC 60 days to withdraw or revise its hearing requests. In response, NRDC, in a filing dated March 31, 1998, submitted revised hearing requests on its original objections.

Subsequent to EPA's initial response, several important developments occurred in connection with EPA's FIFRA reregistration efforts as to vinclozolin that impact the vinclozolin succulent bean tolerance. First, EPA scientists recommended that EPA use the additional tenfold safety factor for the protection of children in conducting its assessment of *in utero* acute risk to the human fetus. Second, BASF requested that EPA terminate FIFRA registrations for vinclozolin on stone fruits and strawberries and revoke the associated tolerances. See 63 FR 40710, June 30, 1998. Additionally, during the FIFRA reregistration process EPA had altered its conclusion regarding the dose at which no adverse effects had

occurred in a critical developmental study. On July 31, 1998, EPA requested both NRDC and BASF to comment on whether these developments affected the revised hearing requests. In separate letters dated September 9, 1998, BASF and NRDC took opposite positions on the viability of the hearing requests. NRDC contended that these developments "have virtually no effect on the pending objections and hearing request." BASF argued that the hearing requests were either moot or not justified.

In August 1999, NRDC filed two declarations that NRDC asserted "substantiated the data gaps described in NRDC's submissions." In a letter accompanying these declarations, NRDC stated that the declarations made an evidentiary hearing on its objections unnecessary. Accordingly, by that letter, NRDC withdrew its hearing requests and asked that EPA rule on its objections as submitted.

#### IV. Order Responding to Objections

The tolerance for vinclozolin on succulent beans to which NRDC filed objections has now expired. NRDC's objections to that tolerance are thus moot and are therefore denied.

The fact that EPA did not substantively respond to NRDC's objections during the existence of the tolerance does not mean that EPA did not consider these objections. To the contrary, NRDC's objections related directly to changes in the way EPA now assesses the risk vinclozolin poses. For example, the centerpiece of NRDC's objections was a challenge to EPA's decision in approving the tolerance that the additional tenfold factor for the protection of infants and children was unnecessary to assure to safety to infants and children. Following NRDC's objections, that decision has been revised on two occasions since the issuance of the succulent bean tolerance. First, as detailed in EPA's July 31, 1998 letter to NRDC, EPA scientists recommended that EPA use the additional tenfold safety factor for the protection of children in conducting its assessment of *in utero* acute risk to

the human fetus. That position remained unsatisfactory to NRDC and its August 1999 declarations, in essence, argued that the tenfold factor should be applied more broadly. After considering the declarations and the attached scientific literature, EPA scientists recommended that due to, among other things, the lack of neurotoxicity data, the additional tenfold factor should be used in all risk assessments for vinclozolin.

#### V. Regulatory Assessment Requirements

As indicated previously, this action announces the Agency's final decision regarding an objection filed under section 408 of FFDCA. As such, this action is an adjudication and not a rule. The regulatory assessment requirements imposed on rulemakings do not, therefore, apply to this action.

#### VI. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, does not apply because this action is not a rule for purposes of 5 U.S.C. 804(3).

#### List of Subjects in 40 CFR Part 180

Environmental protection.

Dated: May 19, 2000.

Marcia E. Mulkey,

Director, Office of Pesticide Programs.

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## DEPARTMENT OF TRANSPORTATION

### Federal Railroad Administration

#### 49 CFR Parts 209 and 230

[FRA Docket No. RSSL-98-1, Notice No. 5]

#### Inspection and Maintenance Standards for Steam Locomotives

**AGENCY:** Federal Railroad Administration (FRA), Department of Transportation (DOT).

**ACTION:** Notice of public meeting.

**SUMMARY:** On November 17, 1999, FRA published the final rule on inspection and maintenance of steam locomotives (65 FR 62828). The Inspection and Maintenance Standards for Steam Locomotives, Title 49, Code of Federal Regulations (CFR), parts 209 and 230, which took effect on January 18, 2000, sets forth new inspection and implementation requirements. FRA is holding a public meeting to explain the implementation schedule and general requirements for inspection and maintenance of steam locomotives under the rule. This meeting will also provide interested parties with the opportunity to discuss the rule and ask questions of the presenters. All parties interested in the new rule on inspection and maintenance of steam locomotives are invited to attend this meeting.

**DATES:** The meeting will be held on July 27, 2000, at 8 a.m.

**ADDRESSES:** The meeting will be held on July 27, 2000, in room 570 of the Bishop Henry Whipple Federal Building, One Federal Drive, Fort Snelling, Minnesota 55111-4007.

#### FOR FURTHER INFORMATION CONTACT:

George Scerbo, Motive Power & Equipment Specialist, Office of Safety, FRA, 1120 Vermont Avenue NW, Washington, DC 20590 (telephone 202-493-6249); or

Paul F. Byrnes, Trial Attorney, Office of Chief Counsel, FRA, 1120 Vermont Avenue NW, Washington, DC 20590 (202-493-6032).

Grady C. Cothen,

Deputy Associate Administrator for Safety Standards and Program Development.

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