

exposures to agricultural pesticides. The WPS covers both workers in areas treated with pesticides, and employees who handle (mix, load, apply, etc.) pesticides. More specifically, the provisions of the Standard are intended to:

Inform employees about the hazards of pesticides:

- By requiring provisions for basic safety training, posting and distribution of information about the pesticides.

Eliminate exposure to pesticides:

- By prohibiting against the application of pesticides in a way that would cause exposure to people.

- By requiring time-limited restrictions for workers to return to areas following the application of pesticides.

- By requiring provisions for workers and handlers to wear proper protective clothing/equipment; and mitigate exposures that occur.

- By requiring arrangements for the supply of soap, water, and towels in the case of pesticide exposure.

- By requiring provisions for emergency assistance.

II. Information Sought by EPA

EPA believes that agricultural workers, handlers and growers are best able to provide unique insights on the effects of the WPS requirements. Their input will be supplemented by data generated from other sources during the course of EPA's longer-term evaluation effort. As a follow-up to the public meetings, EPA will develop a summary of information gained. These tools will be used to develop strategies for improving the administration of the WPS. The Agency is specifically interested in hearing public comment, or receiving written comment, on the following topics.

1. Assistance from regulatory partners and others involved with the WPS.
2. Usefulness of available assistance.
3. Understanding the WPS requirements.
4. Success in implementing the requirements.
5. Difficulties in implementing the requirements.
6. Suggestions to improve implementation.

III. Registration to Make Comments

Persons who wish to speak at the public meeting are encouraged to register at the meeting location. The Agency encourages parties to submit data to substantiate comments whenever possible. All comments, as well as information gathered at the public meetings will be available for public inspection from 8 a.m. to 4:30 p.m.,

Monday through Friday (except legal holidays) at the Public Response and Program Resource Branch, Field Operations Division, Room 1132, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Information submitted as part of any comment may be claimed as confidential by marking any or all of that information as Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with the procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by the Agency without prior notice to the submitter. The Agency anticipates that most of the comments will not be classified as CBI, and prefers that all information submitted be publicly available. Any records or transcripts of the open meetings will be considered public information and cannot be declared CBI.

IV. Structure of the Meeting

EPA will open the meeting with brief introductory comments. EPA will then invite those parties who have registered to present their comments. EPA anticipates that each speaker will be permitted 5 minutes to make comments. After each speaker, Agency and state representatives may ask the presenter questions of clarification. The Agency reserves the right to adjust the time for presenters depending on the number of speakers.

Members of the public are encouraged to submit written documentation to EPA at the meeting to ensure that their entire position goes on record in the event that does not permit a complete oral presentation.

Any information may be delivered to Jeanne Heying at the address stated earlier in this Notice.

List of Subjects

Environmental protection.

Dated: July 11, 1996.

William L. Jordan,

Director, Field Operations Division, Office of Pesticide Programs.

[FR Doc. 96-18657 Filed 7-19-96; 8:45 am]

BILLING CODE 6560-50-F

[OPP-300370A; FRL-5387-4]

Plant-Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act; Reopening of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; reopening of comment period.

SUMMARY: This supplemental notice provides the public additional opportunity to comment on one aspect of EPA's approach to plant-pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). Specifically, EPA requests comment on additional information it is considering regarding the treatment, as inert ingredients, of "substances introduced into the plant along with the active ingredient to confirm or ensure the presence of the active ingredient." Based upon this new information, EPA may decide not to treat these substances as inert ingredients or as pesticide components. **DATES:** Comments identified by the docket control number [OPP-300370A] must be received on or before August 21, 1996.

ADDRESSES: Submit written comments in triplicate by mail to: Program Resources Section, Public Response and Program Resources Branch, Field Operations Division (7506C), Environmental Protection Agency, 401 M St., SW., Washington, DC. In person, bring comments to: Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number "OPP-300370A" No Confidential Business Information (CBI) should be submitted through e-mail. Electronic comments on this document may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in Unit III. of this document.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as CBI.

Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the Virginia address given above from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Bernice Slutsky, Science and Policy Staff, Office of Prevention, Pesticides and Toxic Substances (7101), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. E-627, 401 M St., SW., Washington, DC, Telephone: (202-260-6900), e-mail:

slutsky.bernice@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. Regulatory Background

In the Federal Register of November 23, 1994 (59 FR 60496) (FRL-4755-2) EPA issued proposed policies and regulations addressing substances that plants use to protect themselves against pests. EPA termed these substances "plant-pesticides." The proposed regulations were issued under FIFRA, 7 U.S.C. 136w(b) (see 59 FR 60519) (FRL-4755-3) and FFDCA, 21 U.S.C. 346a (see 59 FR 60535, 60542, and 60545) (FRL-4758-8, FRL-4755-5, and FRL-4755-4).

Because of the unique nature of plant-pesticides, EPA proposed to create a new part in the Code of Federal Regulations at 40 CFR part 174, specifically for plant-pesticides. The new part 174 would set forth the scope of regulation, regulatory requirements, criteria, and procedures applicable to plant-pesticides under FIFRA and FFDCA. In the FIFRA and FFDCA proposed rules, EPA proposed to define plant-pesticides as follows:

Plant-pesticide means a pesticidal substance that is produced in a living plant and the genetic material necessary for the production of the substance, where the substance is intended for use in the living plant (59 FR 60534, 60542, 60544, and 60545).

EPA also proposed to define inert ingredients in the context of plant-pesticides as follows:

Inert ingredient, when referring to plant-pesticides only, means any substance, such as a selectable marker, other than the active ingredient, and the genetic material necessary for the production of the substance, that is intentionally introduced into a living plant along with the active

ingredient, where the substance is used to confirm or ensure the presence of the active ingredient (59 FR 60534 and 60545).

II. Rationale

Since it published the proposed policy and regulations in November 1994, EPA has acquired additional information that has caused it to reevaluate its treatment of substances "intentionally introduced into a living plant along with the active ingredient, where the substance is used to confirm or ensure the presence of the active ingredient." Based upon this information, EPA is reconsidering whether to treat such substances and the genetic material necessary to produce them as a pesticide component (such as an inert ingredient).

FIFRA and FFDCA contain only general definitions of the relevant terms. FIFRA section 2(m) defines a "pesticide" as any substance or mixture of substances intended "for preventing, destroying, repelling, or mitigating any pest" or "for use as a plant regulator, defoliant, or desiccant . . ." (7 U.S.C. 136(u)). An "active ingredient" is defined as an "ingredient which will prevent, destroy, repel, or mitigate any pest" (7 U.S.C. 136(a)). FIFRA defines "inert ingredient" to mean "an ingredient which is not active" (7 U.S.C. 136(m)). Under the FFDCA, a substance is a "pesticide chemical" if it is a pesticide within the meaning of FIFRA (21 U.S.C. 321(q)).

Although these definitions provide some guidance, they do not clearly address whether substances added with the active ingredient to confirm or ensure the presence of the active ingredient (e.g., selectable markers) should be considered inert ingredients. When Congress created the FIFRA definitions of pesticide and inert ingredients, it did not consider how the statute would be applied to such substances since the technology that could utilize these substances as selectable markers had not yet been invented. Where a statute is ambiguous, EPA as the administering agency is entitled to make a reasonable policy choice in interpreting the statute (*Chevron, U.S.A. Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 843 n. 9, 845).

In this instance the difficulties associated with interpreting ambiguous statutory terms are compounded by the unique nature of plant-pesticides and the substances introduced to confirm or ensure their presence in the plant. Substances used to confirm or ensure the presence of a plant-pesticide in a plant are generally termed "selectable markers" and will hereafter be referred

to by the term, "selectable markers." Selectable markers are introduced into the plant or plant cells by the process of transformation at the same time as the genetic material that confers the desired trait (e.g., a pesticidal trait). A selectable marker's purpose is to provide a mechanism to distinguish cells that have successfully incorporated the genetic material for the desired trait during the transformation from the vast majority of cells that have not incorporated the trait. For example, the selection process may depend upon the cells, after they have been transformed, being resistant to an agent that is lethal to non-transformed cells. Alternatively, cells, after they have been transformed, may acquire the ability to produce a unique substance that allows them to be distinguished from cells that have not been transformed and therefore do not produce the unique substance. Usually this selection process occurs only once in the very early stages of product development.

Beyond its use for eliminating the large number of non-transformed cells, a selectable marker is generally not necessary for expression of the desired trait; i.e., selectable markers are not necessary for the pesticidal function of the plant-pesticide in the plant nor do they modify or enhance the pesticidal activity of the active ingredient. Selectable markers may even be lost from the plant during subsequent breeding with no effect on the plant-pesticidal active ingredient.

Existing regulations do not shed much light on how to treat substances introduced with the plant-pesticide active ingredient (see, e.g., 40 CFR 152.3(s), 153.2(m), 158.153(f), 177.3, and 180.1(k)). Although EPA has had extensive experience with inert ingredients in the context of traditional chemical pesticides, the unique nature of plant-pesticides makes it difficult to apply the regulatory framework that has been used with chemical pesticides.

Because of the ambiguous nature of the controlling statutory provisions and the unique nature of plant-pesticides and substances such as selectable markers, EPA believes it is reasonable to conclude that a substance used to confirm or ensure the presence of the active ingredient, and the genetic material necessary to produce that substance, are not components of a pesticide. EPA weighed a number of factors in reaching this conclusion, including the function of these substances in plants, the effects of these substances on the performance of the plant-pesticide, and the duration of that effect. Substances such as selectable markers are intentionally introduced

into plants to aid in the selection of plants or plant cells that contain the desired genetic material for the plant-pesticide. They do not have pesticidal properties themselves and are not necessary to the function of the plant-pesticide in the plant. Generally they are of no use in modifying or enhancing the pesticidal activity of the plant-pesticide and may even be lost later in the product development stage with no effect upon pesticidal activity. Substances used to confirm or ensure the presence of a plant-pesticide are frequently used only on a one-time basis very early in the development of a new plant variety, for example during the introduction of genetic material in the initial genetic transformation of plant cells or tissue. Although a substance such as a selectable marker is introduced at the same time as the active ingredient, that concomitant event does not necessarily convert selectable markers into pesticide ingredients.

The comments received in response to the 1994 proposal also helped to focus EPA's concern about the classification of selectable markers as inert ingredients. The comments addressing treatment of selectable markers as inert ingredients raised a range of issues. These issues included minimizing the potential for duplication of reviews with FDA; inappropriateness of the Agency's inert policy for chemical pesticides for substances such as selectable markers; and reservation about whether risks associated with selectable markers would be adequately addressed should they be considered inert ingredients. EPA will respond to these comments together with comments received in response to this Notice in the preamble of the final rule.

Should EPA decide that substances such as selectable markers are not inert ingredients or pesticide components, FDA rather than EPA would have direct jurisdiction over the presence of those substances in food products. This would result in a more consistent approach to the regulatory oversight of substances used to confirm or ensure the presence of a plant-pesticide, e.g., selectable markers.

Should EPA decide that substances, and related genetic material, used to confirm and ensure the presence of the plant-pesticide should not be classified as part of a pesticide, the regulatory text in the final rules under FIFRA and FFDCA would be modified to reflect this decision, including defining the plant-pesticide product as the plant-pesticide active ingredient.

III. Public Docket

A record has been established for this document under docket number "OPP-300370A" (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

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

The official record for this document, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document.

List of Subjects

Environmental protection, Biotechnology, Plant-pesticides, Plants.

Dated: July 15, 1996.

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

[FR Doc. 96-18394 Filed 7-19-96; 8:45 am]

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[FRL-5540-8]

Proposed Settlement Under Section 122(h)(1) of the Comprehensive Environmental Response, Compensation and Liability Act; in the Matter of Union Steel Products, Inc. Site

AGENCY: Environmental Protection Agency.

ACTION: Request for public comment.

SUMMARY: Notice of Settlement: in accordance with Section 122(I)(1) of the

Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended ("CERCLA"), notice is hereby given of a settlement concerning past response costs at the Union Steel Products, Inc. Site in Albion, Michigan. This proposed agreement has been forwarded to the Attorney General for the required prior written approval for this Settlement, as set forth under Section 122(g)(4) of CERCLA.

DATES: Comments must be provided on or before August 21, 1996.

ADDRESSES: Comments should be addressed to the Docket Clerk, Mail Code MFA-10J, U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois, 60604, and should refer to: In the Matter of Union Steel Products, Inc. Site, Docket No.

FOR FURTHER INFORMATION CONTACT: Kurt N. Lindland, Mail Code CS-29A, U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

SUPPLEMENTARY INFORMATION: The following parties executed binding certifications of their consent to participate in the settlement: Union Steel Products, Inc. and John Kamakian.

These parties will pay \$250,000 in settlement payments for response costs related to the Union Steel Products, Inc. Site, if the United States Environmental Protection Agency determines that it will not withdraw or withhold its consent to the proposed settlement after consideration of comments submitted pursuant to this notice.

U.S. EPA may enter into this settlement under the authority of Section 122(h) of CERCLA. Section 122(h)(1) authorizes EPA to settle any claims under Section 107 of CERCLA where such claim has not been referred to the Department of Justice. Pursuant to this authority, the agreement proposes to settle with parties who are potentially responsible for costs incurred by EPA at the Union Steel Products, Inc. Site.

A copy of the proposed administrative order on consent and additional background information relating to the settlement, including a list of parties to the settlement, are available for review and may be obtained in person or by mail from Kurt N. Lindland, Mail Code CS-29A, U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

The U.S. Environmental Protection Agency will receive written comments relating to this settlement for thirty days from the date of publication of this notice.

Authority: The Comprehensive Environmental Response, Compensation, and