

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Parts 152, 156, 167, 168, 169, 172, and 174****[EPA-HQ-OPP-2006-1003; FRL-8118-2]****RIN 2070-AJ32****Plant-Incorporated Protectants; Potential Revisions to Current Production Regulations****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Advance Notice of Proposed Rulemaking (ANPRM).

**SUMMARY:** In light of the differences between plant-incorporated protectants (PIPs) and other types of pesticides, EPA is considering amendments to the current pesticide establishment and production regulations promulgated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and to other related FIFRA regulations as needed for producers of PIPs. PIPs are pesticidal substances that are intended to be produced and used in a living plant, or the produce thereof, and the genetic material necessary for the production of such a pesticidal substance, and also include any inert ingredient contained in the plant, or the produce thereof. Given these characteristics, it is possible that PIPs may not be produced in the manner contemplated when the current establishment and production regulations were promulgated for other types of pesticide. In this ANPRM, the Agency provides a list of the general regulatory provisions applicable to PIPs that EPA is considering amending and solicits public comment on the completeness of the list and the scope of any potential changes to these regulations. EPA also is soliciting information that may be useful to EPA as it reviews these regulations and developing the proposed rules. In addition to soliciting comments through this ANPRM, EPA intends to solicit stakeholder input through two public meetings during the comment period of this ANPRM.

**DATES:** Comments must be received on or before June 13, 2007.**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2006-1003, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200

Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

*Instructions:* Direct your comments to docket ID number EPA-HQ-OPP-2006-1003. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at <http://www.regulations.gov>, 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 [regulations.gov](http://www.regulations.gov) or e-mail. The [regulations.gov](http://www.regulations.gov) website is an "anonymous access" system, 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 [regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the 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.

*Docket:* All documents in the docket are listed in the docket index available in [regulations.gov](http://www.regulations.gov). To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the [regulations.gov](http://www.regulations.gov) web site to view the docket index or access available documents. Although listed in the index, some information is not publicly available, e.g., 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 in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Stephen Howie, Hazard Assessment Coordination and Policy Division (7202M), Office of Science Coordination and Policy, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-4146; fax number: (202) 564-8502; e-mail address: [howie.stephen@epa.gov](mailto:howie.stephen@epa.gov).

**SUPPLEMENTARY INFORMATION:****I. General Information***A. Does this Action Apply to Me?*

You may be potentially affected by this action if you manufacture, import, process, or use PIPs. In order to identify potentially impacted industries the analysis relies on North American Industrial Classification System (NAICS) codes. Potentially affected entities may include, but are not limited to:

- Pesticide and Other Agricultural Chemical Manufacturing (NAICS code 325320). This industry comprises establishments that are producing PIPs intended for distribution and sale as pesticides.

- Crop Production (NAICS code 111). These are establishments such as farms, orchards, groves, greenhouses, and nurseries, primarily engaged in growing crops, plants, vines, or trees and their seeds.

- Colleges, Universities, and Professional Schools (NAICS code 611310). This industry comprises establishments primarily engaged in furnishing academic courses and granting degrees at baccalaureate or graduate levels. Furthermore, they may comprise establishments where research on PIPs occurs and where PIPs may be grown.

- Research and Development in the Physical, Engineering, and Life Sciences (NAICS code 54171). This industry comprises establishments primarily engaged in conducting research and experimental development in the physical, engineering, or life sciences, such as agriculture, environmental,

biology, botany, biotechnology, forests, and other allied subjects.

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

1. *Docket.* EPA has established a docket for this action under docket ID number EPA-HQ-OPP-2006-1003. Publicly available docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

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

- i. Identify the document 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

### *A. What Action is the Agency Taking?*

PIPs are “pesticidal substances that are intended to be produced and used in a living plant, or the produce thereof, and the genetic material necessary for the production of such a pesticidal substance. PIPs also include any inert ingredient contained in the plant, or the produce thereof.” (40 CFR 174.3) By definition, PIPs are primarily distinguished from other types of pesticides because they are intended to be produced and used in the living plant. Other types of pesticides are primarily produced in a facility and used through physical application, e.g., spraying or dusting of the plant. Since PIPs were not defined when the existing regulations associated with pesticide establishments and pesticide production were promulgated, the existing regulations may not adequately address this distinction.

The Agency is therefore considering amending the current FIFRA regulations associated with pesticide establishments and pesticide production to better address PIPs and PIP production given the unique characteristics of PIPs compared to other types of pesticides.

EPA is soliciting comments from interested stakeholders on the issues and questions identified in this ANPRM. EPA intends to use this information in reviewing these regulations and developing its proposed rules.

### *B. What is the Agency's Authority for Taking this Action?*

EPA has regulatory authority to promulgate regulations under FIFRA sections 3(a), 8(a), 25(a), and 25(b) (7 U.S.C. 136a(a), 136f(a), 136w(a), and 136w(b)).

PIPs are pesticides under FIFRA section 2 because they are introduced into plants with the intention of “preventing, destroying, repelling, or mitigating any pest...” (7 U.S.C. 136(u)).

Under FIFRA section 7, any person who manufactures, prepares, compounds, propagates, or processes any pesticide is a “producer.” “Produce,” as further described in 40 CFR 167.3, also means to package, repackage, label, relabel, or otherwise change the container of any pesticide. FIFRA section 7 requires that producers of pesticides register the establishments where production occurs and requires that producers report their annual production (7 U.S.C. 136e). In addition, producers of pesticides are required under FIFRA section 8(a) to maintain records with respect to their operations, and to make such records

available for inspection (7 U.S.C. 136f(a)). Under FIFRA section 9 appropriately credentialed inspectors have the authority to conduct inspections at pesticide producing establishments or other places where pesticides are being held for distribution or sale for the purpose of inspecting and obtaining samples (7 U.S.C. 136g).

### *C. Why is the Agency Considering Amending the Regulations?*

EPA believes that the existing regulations need to be amended to better address apparent differences between PIPs and other types of pesticides in the application of FIFRA's production and production-related requirements. The existing regulations were written for pesticides that are generally produced and used in a more traditional manner, e.g., spraying or dusting onto the plants. PIPs are produced and used in a living plant, which raises questions regarding how that “production” should be regulated under the existing authorities of FIFRA. In general, EPA's experience with PIPs is that they present different and potentially lower risk situations compared to chemical pesticides. However, EPA needs to ensure that appropriate PIP production data are available to manage any potential risk a PIP might pose.

The United States Government published in the **Federal Register** issue of June 26, 1986 (51 FR 23302) a document entitled, *Coordinated Framework for Regulation of Biotechnology* (“Coordinated Framework”), which describes in broad terms the Federal Government's approach to regulating biotechnology products. In that document, the Federal Government concluded that it could appropriately regulate the products of biotechnology under existing laws, but recognized that, in some cases, new regulations might be needed. Consistent with the Coordinated Framework, EPA regulates PIPs under its pesticide authorities. In the **Federal Register** issue of July 19, 2001 (66 FR 37771) (FRL-6057-7), EPA published a rule that established a regulatory framework for PIPs. That rule clarified the relationship between plants and PIPs under FIFRA, exempted from FIFRA requirements PIPs derived entirely through conventional breeding between sexually compatible plants, established a new part in the Code of Federal Regulations specifically for PIPs (40 CFR part 174), provided requirements for reporting of adverse effects, and set forth certain procedures for CBI. In that **Federal Register** document, EPA also anticipated the future need for proposing regulations tailored

specifically to PIPs so that the regulatory framework would better fit their unique characteristics (66 FR 37807). EPA indicated that it would continue to apply existing regulations to PIPs, except where superseded by the regulations in the July 19, 2001 Final Rule, until the Agency could develop additional regulatory provisions specifically tailored to PIPs.

Since the mid-1990s, EPA has approved a number of PIP experimental use permits (EUPs) under FIFRA section 5, as well as seed increase and commercial use registrations under FIFRA section 3. During this time, EPA has registered facilities involved in the production of PIPs as pesticide producing establishments under FIFRA section 7. These have included, for example, sites of the original transformation (where plant tissue was transformed by the insertion of PIP genetic material) and seed processing facilities.

FIFRA section 7 requires that producers of pesticides register the establishments where the pesticide is produced and report the amount of pesticide produced. EPA's experience to date has demonstrated, particularly in the area of pesticide production, that the existing regulations (e.g., 40 CFR part 167) may need to be better tailored to address PIPs. For example, existing regulations require pesticide production quantities to be reported in terms of volume or weight (gallons or pounds), measurements that are not useful when considering a pesticidal substance produced within a plant. Other questions concern the manner in which PIPs are increased within a living plant. Such increase occurs at many stages from product development through use, which raises questions concerning where pesticide production occurs, and what establishments must register and report their production. Clarification of this matter would help to ensure that appropriate persons comply with production related requirements, and that other persons do not face unnecessary regulatory burden. To that end, EPA is reviewing the existing regulations in 40 CFR chapter I, subchapter E and considering potential regulatory changes to address the apparent differences between PIPs and other types of pesticides.

### III. Current Regulations Under Review

EPA is considering amending the following existing regulations related to pesticide establishment and production to better address PIPs and PIP production:

1. *Registration of establishments where PIPs are produced* (FIFRA section

7 and 40 CFR 167.20). Current regulations require any producer of a pesticide to register the "production" site with EPA. The statutory and regulatory definitions of "produce" include several activities, including manufacturing, preparing, compounding, propagating, or processing any pesticide or packaging, repackaging, labeling, and relabeling the container of any pesticide.

2. *Reporting by registered production establishments* (FIFRA section 7 and 40 CFR 167.85). Current regulations require a producer operating a producing establishment to report annually the types and amount of each pesticidal product that was produced, sold, or distributed the previous year and to estimate the amount that will be produced during the current year.

3. *Recordkeeping and inspection authority* (FIFRA sections 8 and 9 and 40 CFR 169.2 and 169.3). EPA's statutory authority under FIFRA section 8, and the regulations promulgated thereunder, require pesticide producers, registrants, and applicants for registration to maintain certain records related to pesticide production (i.e., including information regarding the production, receipt, and shipment of pesticides) and to provide these records upon request to appropriately credentialed inspectors. FIFRA section 8 also provides authority for appropriately credentialed inspectors to conduct inspections to access such information. Furthermore, under FIFRA section 9 appropriately credentialed inspectors have the authority to conduct inspections at pesticide producing establishments or other places where pesticides are being held for distribution or sale for the purpose of inspecting and obtaining samples.

4. *Labeling on PIP containers* (FIFRA section 2 and 40 CFR 156.10). The statute and current regulations provide requirements for labeling of pesticides, including name of the product, identity of the producer, net content, product registration number, establishment registration number, ingredient statement, hazard and precautionary statements, directions for use, and use classification. Currently, PIPs are labeled for FIFRA section 5 EUPs and FIFRA section 3 seed increase registrations only.

5. *EUPs for field testing of unregistered PIPs* (FIFRA section 5 and 40 CFR part 172). FIFRA allows for field testing of unregistered pesticides under an EUP. Any pesticide production activity related to an EUP, either the production of a pesticide for use in an EUP or by being produced as a result of an EUP, is subject to FIFRA production

establishment and recordkeeping requirements.

6. *Production of unregistered PIPs for export* (FIFRA section 17 and 40 CFR 168.65–168.85). FIFRA exempts pesticides intended solely for export from certain FIFRA requirements, including product registration requirements. Products intended for export only are therefore not subject to the product safety evaluation required of products intended for domestic distribution and sale. However, they must still comply with the producer establishment registration, reporting and recordkeeping requirements of FIFRA sections 7 and 8 and are subject to certain labeling requirements, e.g., their label must include the statement: "Not Registered for Use in the United States of America."

### IV. Request for Comments

EPA is seeking public comment on the completeness of the list of current regulations that need to be reviewed for applicability to PIPs and PIP producers (see Unit III.), and is soliciting related information to use in reviewing these regulations and developing its proposed rules. These issues are especially challenging for PIPs, since based on statutory and regulatory definitions, the borders between production and use are unclear. EPA is seeking public input to help inform decisions on how best to ensure appropriate compliance without imposing unnecessarily burdensome reporting or labeling requirements on PIP registrants, producers, distributors, and users.

1. EPA would like comments in response to the following questions with respect to the regulations referenced in Unit III.:

a. *Registration of establishments* (Unit III.1.). Given that PIPs by definition are intended to be produced and used in a living plant, what activities should the Agency consider to be part of "production" as that term is defined in FIFRA (which includes manufacturing, preparing, compounding, propagating, or processing any pesticide or packaging, repackaging, labeling, and relabeling the container), and what establishments should be registered to help EPA manage any potential risks associated with PIPs? What other types of facilities, if any (e.g., growers involved in seed production), involved in the development of PIP-containing varieties should be subject to these requirements? Please explain the reason for your response.

b. *Production reporting* (Unit III.2.). What production reporting, by whom and in what units (e.g., volume, weight, number of seeds, etc.) would be

appropriate? Should reporting units be dependent on the reproductive methodology of the crop (e.g., seeds, bulbs, or tubers)? Given your response to Unit IV.1.a., what types of production reporting would provide the Agency with information valuable for compliance assurance purposes and for managing any potential risks associated with a violation?

c. *Recordkeeping and inspection* (Unit III.3.). What establishments or other locations are appropriate to be inspected for records and samples, and what records would be appropriate for producers of PIPs to maintain?

d. *Labeling* (Unit III.4.). Please comment on current labeling practices for PIPs. Are current labeling practices sufficient? For example, do grower agreements offer sufficient information and compliance assurance to ensure registered PIPs are used in a manner that protects human health and the environment? Are there circumstances where labeling different from that currently in practice for PIPs may be appropriate?

e. *Experimental use permits* (Unit III.5.). Are there aspects of production in association with PIP EUPs that are different from production associated with other types of pesticides used in EUPs? If there are differences, how should they be addressed for PIP EUPs?

f. *Production for export* (Unit III.6.). What conditions would ensure that a PIP is intended for export only, and what would be necessary for such a PIP to meet the requirements of FIFRA?

2. Are there other characteristics not described in this document unique to PIPs that may affect the application of the existing regulations associated with pesticide establishments and pesticide production to PIP producers?

3. Are there additional sections of FIFRA implementing regulations related to pesticide establishment and production regulations that should be modified to more effectively address the unique characteristics of PIPs?

#### V. Do Any Statutory or Executive Order Reviews Apply to this Action?

Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), the Office of Management and Budget (OMB) has determined that ANPRMs are considered "significant regulatory actions" under section 3(f) of the Executive Order. The Agency therefore submitted this document to OMB for the 10-day review period afforded under this Executive order. Any changes made in response to OMB comments during that review have been documented in

the docket as required by the Executive order.

Since this ANPRM does not impose or propose any requirements, and instead seeks comments and suggestions for the Agency to consider in possibly developing a subsequent proposed rule, the various other review requirements that apply when an agency imposes requirements do not apply to this action.

As part of your comments on this ANPRM, you may include any comments or information that you have regarding this action. In particular, any comments or information that would help the Agency to assess the potential impact of a rule on small entities pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*); to consider 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); to consider environmental health or safety effects on children pursuant to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997); or to consider human health or environmental effects on minority or low-income populations pursuant to Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994). The Agency will consider such comments during the development of any subsequent notice of proposed rulemaking as it takes appropriate steps to address any applicable requirements.

#### List of Subjects in 40 CFR Parts 152, 156, 167, 168, 169, 172, 174

Environmental protection, Pesticides and pests, Plant-incorporated protectants, Reporting and recordkeeping requirements.

Dated: March 22, 2007.

Stephen L. Johnson,  
Administrator.

[FR Doc. E7-6151 Filed 4-3-07; 8:45 am]

BILLING CODE 6560-50-S

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

[DA 07-1350; MB Docket No. 04-319; RM-10984]

#### Radio Broadcasting Services; Clinchco, VA and Coal Run, KY

AGENCY: Federal Communications Commission.

ACTION: Proposed rule, denial.

**SUMMARY:** This document denies a petition for rule making filed by East Kentucky Broadcasting Corp. ("Petitioner") proposing to substitute Channel 221C3 for Channel 276A at Coal Run and modify the license of Station WPKE-FM to reflect the channel upgrade. To accommodate the channel upgrade, Petitioner proposes to substitute Channel 276A for Channel 221A at Clinchco, Virginia and modify the license of Station WDIC-FM to reflect the channel substitution. However, Petitioner's proposed site is unacceptable due to major terrain obstruction that prevents the requisite 70 dBu signal over the entire community of license.

**FOR FURTHER INFORMATION CONTACT:** Robert Hayne, Media Bureau, (202) 418-2177.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Report and Order, MB Docket No. 04-319, adopted March 16, 2007, and released March 20, 2007. The full text of this Commission decision is available for inspection and copying during regular business hours at the FCC's Reference Information Center, Portals II, 445 Twelfth Street, SW., Room CY-A257, Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY-B402, Washington, DC 20554, telephone 1-800-378-3160 or <http://www.BCPIWEB.com>.

This document is not subject to the Congressional Review Act. (The Commission, is, therefore, not required to submit a copy of this Report and Order to the Government Accountability Office pursuant to the Congressional Review Act, see 5 U.S.C. 801(a)(1)(A) because the proposed rule is denied.) Federal Communications Commission.

John A. Karousos,  
Assistant Chief, Audio Division, Media Bureau.

[FR Doc. E7-6258 Filed 4-3-07; 8:45 am]

BILLING CODE 6712-01-P