EIS No. 980485, Draft Supplement, AFS, OR, Nicore Mining Project, Implementation, New Information on Six New Alternatives, Plan-of-Operations, Mining of Four Sites, Road Construction, Reconstruction, Hauling and Stockpiling of Ore, Rough and Ready Creek Watershed, Illinois Valley Ranger District, Siskiyou National Forest, Medford District, Due: January 29, 1999, Contact: Rochelle Desser (541) 592–2166.

EIS No. 980486, Final Supplement, AFS, NV, Griffon Mining Project, Implementation, Updated Information, Revision for Expanding Gold Mining, Plan of Operations, Humboldt-Toiyabe National Forests, Ely Ranger District, White Pine County, NV, Due: January 04, 1999, Contact: James Winfrey (702) 289–3031.

EIS No. 980487, Final EIS, FHW, WI, US 12 Highway Improvement, Sauk City to Middleton, Funding and COE Section 404 Permits Issuance, Sauk and Dane Counties, WI, Due: January 04, 1999, Contact: Richard Madrzak (608) 829–7510.

Amended Notices

EIS No. 980377, Draft EIS, FHW, UT, Legacy Parkway Project, Construction from I–215 at 2100 North in Salt Lake City to I–15 and US 89 near Farmington, Funding and COE Section 404 Permit, Salt Lake and Davis Counties, UT, Due: January 08, 1999, Contact: Tom Allen (801) 963–0182. Published FR 10–02–98—Review Period extended.

EIS No. 980421, Draft EIS, COE, OR, WA, Columbia and Lower Willamette River Federal Navigation Channel, Improvement Channel Deepening, OR and WA, Due: February 05, 1999, Contact: Steve Stevens (503) 808–4768. Published FR 10–23–98 Review Period Extended.

Dated: December 1, 1998.

William D. Dickerson,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 98–32347 Filed 12–3–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPP–00568; FRL–6048–2]

Pesticides; Science Policy Issues Related to the Food Quality Protection Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: To assure that EPA's science policies related to implementing the Food Quality Protection Act (FQPA) are transparent and open to public participation, EPA is soliciting comments on three draft science policy papers—''Proposed Threshold of Regulation Policy When a Food Use Does Not Require a Tolerance,'' ''Assigning Values to Nondetected/Nonquantified Pesticide Residues in Human Health Dietary Exposure Assessments'' and ''A Statistical Method for Incorporating Nondetected Pesticide Residues into Human Health Dietary Exposure Assessments.''

DATES: Written comments for each science policy paper, identified by separate docket control numbers provided in the ADDRESSES section, should be submitted by February 4, 1999.

ADDRESSES: The docket number for ''Proposed Threshold of Regulation Policy When a Food Use Does Not Require a Tolerance'' is OPP–00569, for ''Assigning Values to Nondetected/Nonquantified Pesticide Residues in Human Health Dietary Exposure Assessments'' is OPP–00570, and for ''A Statistical Method for Incorporating Nondetected Pesticide Residues into Human Health Dietary Exposure Assessments'' is OPP–00571. By mail, submit written comments identified by the docket control number listed for each to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St.. SW, Washington, DC 20460. In person, deliver comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically to: opp-docket@epa.gov. Follow the instructions under Unit V. of this document. No Confidential Business Information (CBI) should be submitted through e-mail.

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 will be included in the public docket by EPA without prior notice. The public docket is available for public inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: For ''Proposed Threshold of Regulation Policy When a Food Use Does Not Require a Tolerance'' contact Vivian Prunier, Environmental Protection Agency (7506C), 401 M St., SW., Washington, DC 20460. Office location and telephone number: 1921 Jefferson Davis Highway, 7509C, Arlington, VA, 22207, 703–308–9341, fax: 703–305–5884, e-mail: prunier.vivian@epa.gov.

For ''Assigning Values to Nondetectable Pesticide Residues in Human Health Dietary Exposure Assessments'' and ''A Statistical Method for Incorporating Nondetectable Pesticide Residues into Human Health Dietary Exposure Assessments'' contact by mail: Kathleen Martin, Environmental Protection Agency (7509C), 401 M St., SW., Washington, DC 20460. Office location, telephone number, fax and e-mail: 1921 Jefferson Davis Highway, 7509C, Arlington, VA, 22207, 703–308–2857, fax: 703–305–5147, e-mail: martin.kathleen@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Electronic Availability

A. Internet

Electronic copies of this document, a table entitled ''TRAC Science Policy Area #3: Exposure Assessment—'No Residues Detected,''' and the three science policy papers are available from the EPA Home page at the **Federal Register** — Environmental Documents entry for this document under ''Laws and Regulations'' (http://www.epa.gov/fedrgstr/).

B. Fax-on-Demand

For Fax-on-Demand, use a faxphone to call 202–401–0527 and select item 6024 for ''Proposed Threshold of Regulation Policy When a Food Use Does Not Require a Tolerance,'' item 6025 for ''Assigning Values to Nondetected Pesticide Residues in Human Health Dietary Exposure Assessments'' and item 6026 for ''A Statistical Method for Incorporating Nondetected Pesticide Residues into Human Health Dietary Exposure Assessments.''

II. Background

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. Effective upon signature, the FQPA significantly amended the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). Among other changes, FQPA established a stringent

health-based standard (''a reasonable certainty of no harm'') for pesticide residues in foods to assure protection from unacceptable pesticide exposure; provided heightened health protections for infants and children from pesticide risks; required expedited review of new, safer pesticides; created incentives for the development and maintenance of effective crop protection tools for farmers; required reassessment of existing tolerances over a 10 year period; and required periodic re-evaluation of pesticide registrations and tolerances to ensure that scientific data supporting pesticide registrations will remain up-to-date in the future.

Subsequently, the Agency established the Food Safety Advisory Committee (FSAC) as a subcommittee of the National Advisory Council for Environmental Policy and Technology (NACEPT) to assist in soliciting input from stakeholders and to provide input to EPA on some of the broad policy choices facing the Agency and on strategic direction for the Office of Pesticide Programs (OPP). The Agency has used the interim approaches developed through discussions with FSAC to make regulatory decisions that met FQPA's standard but that could be revisited if additional information became available or as the science evolved. As EPA's approach to implementing the scientific provisions of FQPA has evolved, the Agency has sought independent review and public participation, often through presentation of many of the science policy issues to the FIFRA Scientific Advisory Panel (SAP), a group of independent, outside experts who provide peer review and scientific advice to OPP.

In addition, as directed by Vice President Albert Gore, EPA has been working with the U.S. Department of Agriculture (USDA) and another subcommittee of NACEPT, the Tolerance Reassessment Advisory Committee (TRAC), chaired by the EPA Deputy Administrator and the USDA Deputy Secretary, to address FQPA issues and implementation. TRAC comprises more than 50 representatives of affected user, producer, consumer, public health, environmental, states and other interested groups. The TRAC has met five times as a full committee from May 27 through September 16, 1998.

The Agency has been working with the TRAC to ensure that its science policies, risk assessments of individual pesticides, and process for decision making are transparent and open to public participation. An important product of these consultations with TRAC is the development of a framework for addressing key science policy issues. The Agency decided that the FQPA implementation process would benefit from initiating notice and comment on the major science policy issues.

The TRAC identified nine science policy issue areas they believe were key to implementation of FQPA and tolerance reassessment. The framework calls for EPA to provide one or more documents for comment on each of the nine issues by announcing their availability in the **Federal Register**. In addition to comments received in response to these **Federal Register** notices, EPA will consider comments received during the TRAC meetings. Each of these issues is evolving and in a different stage of refinement. Accordingly, as the issues are further refined by EPA in consultation with USDA and others, they may also be presented to the SAP.

In accordance with the framework described in a separate notice published in the **Federal Register** of October 29, 1998 (63 FR 58038)(FRL–6041–5), EPA is issuing a series of draft documents concerning nine science policy issues identified by the TRAC related to the implementation of FQPA. This notice announces the availability of three draft documents identified above, all of which relate to science policy area #3 (Exposure Assessment—Interpreting ''No Residues Detected'') as described in the framework notice published in the **Federal Register** of October 29, 1998 (63 FR 58038). A table entitled ''TRAC Science Policy Area #3: Exposure Assessment—'No Residues Detected''' that accompanies this notice summarizes these papers and shows how they interrelate.

III. Summary of Draft Papers

A. ''Proposed Threshold of Regulation Policy When a Food Use Does Not Require a Tolerance''

EPA is considering a new policy regarding the use of the pesticide on or in or near food does not result in residues that are detected in food. Currently, EPA considers that a specific use of a pesticide chemical will result in a pesticide residue in or on a food if the pesticide is used in a manner which has a reasonable likelihood to produce residues in food. Before registering a pesticide for such use under FIFRA, EPA ordinarily requires the establishment under FFDCA of a tolerance or an exemption from the requirement to establish a tolerance (tolerance exemption). In practice, EPA has applied this science policy in such a manner that an agricultural pesticide use is deemed to result in residues in or on food unless the use is shown to result in essentially zero residues.

EPA is deliberating whether to adopt a policy that would set forth conditions under which the Agency would determine that there is no requirement to establish a tolerance for an agricultural pesticide or a pesticide otherwise used in the vicinity of food in certain circumstances where use of the pesticide does not result in detection of residues of a pesticide in a food. If EPA adopts such a policy, the Agency would regulate qualifying pesticide uses solely under FIFRA. The Agency would not perform the analyses required under section 408 of FFDCA as to such use. However, if use of a pesticide registered in accordance with such a policy were to result in detected residues, then food that bears or contains such residues would be adulterated under FFDCA and may not be sold.

Under the policy being considered, the determination could be based on either of the following criteria:

1. *Threshold of Regulation based on ''essentially zero'' risk*. There would be no requirement for a tolerance or tolerance exemption under FFDCA if: (i) Using a reliable and appropriately sensitive analytical method to measure residues in the commodity, there are no detected residues in the commodity under expected conditions of use when the commodity enters interstate commerce; and (ii) using reasonably protective criteria, the estimated potential dietary risk of any theoretically possible residues is so small as to not be of concern.

2. *Threshold of Regulation based on ''essentially zero'' exposure*. EPA will evaluate data concerning the amount of residue resulting from the use of a pesticide in foods (other than milk, meat, poultry or eggs derived from animals fed pesticide-treated feed) to determine whether there is ''no reasonable expectation of finite residues'' in these foods, and therefore, there would be ''essentially zero'' exposure. If EPA makes such a determination, no tolerance would be established under FFDCA section 408.

EPA is considering adopting the Threshold of Regulation policy because it would allow the Agency to grant new food uses or to permit the continuation of existing food uses that pose ''essentially zero'' dietary risk. The policy would make Agency resources available for pre-market review of safer pesticides to replace pesticides that do not meet the new safety standard of the Food Quality Protection Act on 1996 (FQPA). It also would support a reasonable transition for agriculture by

retaining some pesticide uses that might otherwise be discontinued and by expanding the number of potential replacements for high risk food use pesticides.

B. ''Assigning Values to Nondetected/ Nonquantified Pesticide Residues in Human Health Dietary Exposure Assessments''

When residue data are submitted in support of establishing or reassessing a tolerance for a particular food use, in some cases a portion of the measurements of the levels of pesticide residue present on food shows no detection of residues. These ''nondetects'' (NDs) do not necessarily mean that the pesticide is not present at any level, but simply that any amount of pesticide present was below the level that could be detected or reliably quantified using a particular analytical method.

The primary science policy issue concerning NDs is what value EPA should assign to them in calculating dietary exposure and risk from a pesticide. This science policy paper describes the value that EPA generally will assign to NDs under different circumstances when EPA conducts a dietary exposure and risk estimate for a pesticide food use. First, EPA will assign a value of zero to the proportion of the data set corresponding to the percentage of the commodities which were not treated with the pesticide. For the remainder of the data points for pesticide-treated commodities, EPA will use the following assumptions:

(1) If a valid Limit of Detection (LOD) exists, EPA will use ½ LOD as the assigned value for NDs when conducting dietary exposure and risk assessments.

(2) If an LOD is not available, but a valid Limit of Quantitation (LOQ) exists, EPA will use ½ LOQ for the NDs.

(3) If neither an LOD nor an LOQ is available, EPA will use the full Lower Limit of Method Validation (LLMV) for the NDs.

(4) If unquantified residues are found between the LOQ and LOD, EPA will use ½ LOQ for those NDs.

In adopting this science policy, EPA's goal is to avoid underestimating exposure to potentially sensitive or highly exposed groups such as infants and children while attempting to approximate actual residue levels as closely as possible. Both biological information and empirical residue measurements support EPA's belief that this science policy is consistent with these goals. Recognizing, however, that these assumptions may, in some cases, either overestimate or underestimate exposure, EPA's policy will be to perform a ''sensitivity analysis'' to determine the impact of different assumptions, e.g., assuming NDs = LOQ or NDs = zero, on the Agency's assessment of risk. If the Agency risk assessment changes as a result of these alternate substitutions, the sensitivity analysis will have demonstrated that the Agency risk assessment is sensitive to assumed concentrations for the NDs and may request that additional data and/or an improved analytical method be developed and submitted.

C. ''A Statistical Method for Incorporating Nondetected Pesticide Residues into Human Health Dietary Exposure Assessments''

As mentioned for the previous document, the primary science policy issue concerning NDs is what value EPA should assign to them in calculating dietary exposure and risk from a pesticide. In adopting this science policy, EPA has the same goal as for its policy for assigning values to NDs. In addition, just as for that policy, available biological information and empirical residue measurements indicate that this science policy will be protective of public health, including potentially sensitive or highly exposed groups such as infants and children.

This science policy document describes a statistical method which may be used for determining the distribution of non-detectable residues below the LOD where some of the residues of the data set are undetectable. This method is fully described in EPA's *Guidance for Data Quality Assessment: Practical Methods for Data Analysis* issued in July 1996 (EPA/600/R–96/084, which has been peer reviewed by EPA program offices, regional offices and laboratories. The method, referred to as ''Cohen's method,'' would be available in situations where the treated NDs comprise less than half the data set and the rest of the data are normally or lognormally distributed. Generally, these values would be expected to be less than ½ the LOD but greater than zero. When properly employed, such methods can provide a scientifically sound basis for more accurately estimating dietary exposure and risk than assuming that ND values represent ½ LOD. This document is intended to be used chiefly by persons conducting probabilistic human health exposure assessments for purposes of registration or reregistration of pesticides. This guidance will help assure that dietary exposure assessments accurately portray exposures and risks to the U.S. population and subpopulations of special concern such as infants and children. Such assessments will play an increasingly important role in the evaluation of risks posed by pesticides and will improve the Agency's ability to make regulatory decisions that fully protect public health and sensitive subpopulations, including infants and children.

D. Public Comments on the Science Policy Issue: ''Exposure Assessment -- Interpreting No Residues Detected''

The Agency received several comments as part of the discussions with the Tolerance Reassessment Advisory Committee on issues relating to some aspects of the science policies in the three papers being made available today. In particular, a coalition of farm, food, manufacturing and pest management organizations, called the Implementation Working Group (IWG), argued that EPA's risk assessment methodology tended to overstate possible exposure to pesticide residues in food by assigning inappropriate values to samples on which no residue had been detected. The IWG recommended that: (1) One half the LOQ should be used as a ''general reasonable default'' for residue levels in samples which are known or believed to have been treated but which fall below the LOQ; (2) for certain use patterns (e.g., seed treatments and applications to dormant fruit and nut trees), EPA should assign a value of zero to residues falling below the LOQ; and (3) EPA should avoid taking regulatory action against a pesticide use, due to its dietary risk, when the risk is attributable in any extent to the amount of residues estimated to be present for ND values. These recommendations are addressed both in the texts of the papers and in the identification of issues for public comment in this notice.

IV. Questions/Issues for Comment

While comments are invited on any aspect of the above three papers, EPA is particularly interested in comments on the following questions and issues.

A. ''Proposed Threshold of Regulation Policy When a Food Use Does Not Require a Tolerance''

1. Is the proposed Threshold of Regulation policy a reasonable approach for dealing with food uses which result in no detected pesticide residues?

2. Are the data and criteria that the Agency would use for determining that a use results in ''essentially zero'' exposure appropriate?

3. Are the data and criteria that the Agency would use for determining that a use results in ''essentially zero'' risk appropriate?

4. Would this policy have any implications for international trade?

5. Should existing tolerances be revoked if the Threshold of Regulation policy is adopted and certain tolerance are determined not to be needed?

B. ''Assigning Values to Nondetectable Pesticide Residues in Human Health Dietary Exposure Assessments''

1. Under what circumstances would either ½ LOD or LOQ for NDs significantly underestimate or overestimate dietary exposure? Does any available information demonstrate that this method either underestimates or overestimates dietary exposure?

2. Should EPA consider a different approach for incorporating nondetectable samples into risk assessments depending on the type of risk assessment being performed (i.e., chronic risks, acute risks, short-term risks (Section 18's))?

3. Are the methods for determining LOD and LOQ adequately defined?

4. Would this policy have any implications for international trade?

C. ''A Statistical Method for Incorporating Nondetectable Pesticide Residues into Human Health Dietary Exposure Assessments''

1. Are other methods available which may be preferable to the methods described in this paper for statistically estimating the distribution or mean values of nondetectable residue samples?

2. Under what circumstances, if any, would use of Cohen's method not be considered reliable or appropriate?

V. Public Record and Electronic Submissions

A record has been established for these policy guidances under docket control numbers ''OPP–00569,'' ''OPP–00570,'' and ''OPP–00571'' (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 public inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the Virginia address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@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 5.1/6.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control numbers ''OPP–00569,'' ''OPP–00570,'' or ''OPP–00571.'' Electronic comments on this document may be filed online at many Federal Depository Libraries.

VI. Contents of Docket

Documents that are referenced in this notice document will be inserted in the docket under the docket control numbers ''OPP–00569,'' ''OPP–00570,'' or ''OPP–00571.'' In addition, the documents referenced in the framework notice, which published in the **Federal Register** on October 29, 1998 (63 FR 58038) have also been inserted in the docket under docket control number OPP–00557.

List of Subjects

Environmental protection, Administrative practice and procedure, Agricultural commodities, pesticides and pests.

Dated: November 30, 1998.

Lynn R. Goldman,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

[FR Doc. 98–32344 Filed 12–3–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[OPP–34154; FRL–6048–7]

Iprodione; Availability of the Reregistration Eligibility Decision Document for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of and starts a 60-day public comment period of the Reregistration Eligibility Decision (RED) document for the active ingredient iprodione. The RED for this chemical is the Agency's formal regulatory assessment of the health and environmental database of the subject chemical and presents the Agency's determination regarding which pesticidal uses are eligible for reregistration.

DATES: Written comments on the RED decisions must be submitted by February 2, 1999.

ADDRESSES: Three copies of comments identified with the docket control number ''OPP–34154'' and the case number (noted below), should be submitted to: By mail: Public Information and Records Integrity Branch, Information Resources and Services Division (7502), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, deliver comments to: Room 119, Crystal Mall 2 (CM #2), 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under ''SUPPLEMENTARY INFORMATION'' of this document. No Confidential Business Information (CBI) should be submitted through e-mail.

Information submitted as a comment in response to this notice 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 docket. Information not marked confidential will be included in the public docket without prior notice (including comments and data submitted electronically). The public docket and docket index, including printed paper versions of electronic comments, which does not include any information claimed as CBI will be available for public inspection in Rm. 119 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Technical questions on the RED document should be directed to the following Chemical Review Manager:

Chemical Name	Case No	Chemical Review Manager	Telephone No.	e-mail Address
Iprodione	2335	Dennis Deziel	703–308–8173	Deziel.Dennis@epamail.epa.gov