

the meeting should contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** and submit 30 copies.

3. *Seating at the meeting.* Seating at the meeting will be on a first-come basis. Individuals requiring special accommodations at this meeting, including wheelchair access, should contact the DFO at least 5 business days prior to the meeting using the information under **FOR FURTHER INFORMATION CONTACT** so that appropriate arrangements can be made.

4. *Request for nominations to serve as ad hoc members of the FIFRA/SAP for this meeting.* The FIFRA/SAP staff routinely solicit the stakeholder community for nominations to serve as ad hoc members of the FIFRA/SAP for each meeting. Any interested person or organization may nominate qualified individuals to serve on the FIFRA/SAP for a specific meeting. No interested person shall be ineligible to serve by reason of their membership on any other advisory committee to a Federal department or Agency or their employment by a Federal department or Agency (except EPA). Individuals nominated should have expertise in one or more of the following areas: Cancer epidemiology, epidemiology, and biostatistics. Nominees should be scientists who have sufficient professional qualifications, including training and experience, to be capable of providing expert comments on the issues for this meeting. Nominees should be identified by name, occupation, position, address, and telephone number. Nominations should be provided to the DFO listed under **FOR FURTHER INFORMATION CONTACT** on or before June 9, 2003.

The criteria for selecting scientists to serve on the FIFRA/SAP are that these persons be recognized scientists—experts in their fields; that they be as impartial and objective as possible; that they represent an array of backgrounds and perspectives (within their disciplines); have no financial conflict of interest; have not previously been involved with the scientific peer review of the issue(s) presented; and that they be available to participate fully in the review, which will be conducted over a relatively short time frame. Nominees will be asked to attend the public meetings and to participate in the discussion of key issues and assumptions at these meetings. Finally, they will be asked to review and to help finalize the meeting minutes.

If a FIFRA/SAP nominee is considered to assist in a review by the FIFRA/SAP for a particular session, the nominee is subject to the provisions of 5 CFR part 2634, Executive Branch

Financial Disclosure, as supplemented by EPA in 5 CFR part 6401. As such, the FIFRA/SAP nominee is required to submit a Confidential Financial Disclosure Form for Special Government Employees Serving on Federal Advisory Committees at EPA, (EPA Form 3110–48 5–02) which shall fully disclose, among other financial interests, the nominee's employment, stocks, bonds, and where applicable sources of research support. EPA will evaluate the nominee's financial disclosure form to assess that there are no formal conflicts of interest before the nominee is considered to serve on the FIFRA/SAP. Selected FIFRA/SAP members will be hired as special government employees. The Agency will review all nominations. FIFRA/SAP members participating at this meeting will be posted on the FIFRA/SAP web site or may be obtained by contacting the PIRIB at the address or telephone number listed in Unit I.

## II. Background

### A. Purpose of the FIFRA/SAP

Amendments to FIFRA enacted November 28, 1975 (7 U.S.C. 136w(d)), include a requirement under section 25(d) that notices of intent to cancel or reclassify pesticide regulations pursuant to section 6(b)(2) of FIFRA, as well as proposed and final forms of rulemaking pursuant to section 25(a) of FIFRA, be submitted to a SAP prior to being made public or issued to a registrant. In accordance with section 25(d) of FIFRA, the FIFRA/SAP is to have an opportunity to comment on the health and environmental impact of such actions. The FIFRA/SAP also shall make comments, evaluations, and recommendations for operating guidelines to improve the effectiveness and quality of analyses made by Agency scientists. Members are scientists who have sufficient professional qualifications, including training and experience, to be capable of providing expert comments as to the impact on health and the environment of regulatory actions under sections 6(b) and 25(a) of FIFRA. The Deputy Administrator appoints seven individuals to serve on the FIFRA/SAP for staggered terms of 4 years, based on recommendations from the National Institutes of Health (NIH) and the National Science Foundation (NSF).

Section 104 of FQPA (Public Law 104–170) established the FQPA Science Review Board (SRB). These scientists shall be available to the FIFRA/SAP on an ad hoc basis to assist in reviews conducted by the FIFRA/SAP.

### B. Public Meeting

The FIFRA/SAP will meet to consider and review the characterization of atrazine cancer epidemiology data. Atrazine is an example of a herbicide where multiple epidemiologic studies have suggested an association with various cancer endpoints especially prostate cancer. Results of a cancer epidemiology study of manufacturing workers found a significant excess of prostate cancer, but there is strong evidence that some or all of this finding could be an effect of increased screening of workers.

The National Cancer Institute (NCI) and EPA are cooperating on a prospective cohort study of about 90,000 pesticide applicators and their spouses in the states of Iowa and North Carolina. Published results from this study did not find an excess of prostate cancer among commercial or private applicators, primarily in agricultural settings. However, these workers would be expected to have lower exposure to atrazine, at least in terms of duration of exposure compared to workers at the manufacturing plant.

Several epidemiologic studies have suggested an association between atrazine and other cancer endpoints. Considering the mixed results and the strengths and weaknesses of these studies, how should they contribute to the weight of evidence characterization in the atrazine risk assessment?

### C. FIFRA/SAP Meeting Minutes

The FIFRA/SAP will prepare meeting minutes summarizing its recommendations to the Agency in approximately 60 days. The meeting minutes will be posted on the FIFRA/SAP web site or may be obtained by contacting the PIRIB at the address or telephone number listed in Unit I.

### List of Subjects

Environmental protection, Pesticides and pests.

Dated: May 22, 2003.

**Joseph J. Merenda,**

*Director, Office of Science Coordination and Policy.*

[FR Doc. 03–13433 Filed 5–29–03; 8:45 am]

**BILLING CODE 6560–50–S**

## ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0192; FRL–7311–3]

### FIFRA Scientific Advisory Panel; Notice of Public Meeting

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

**ACTION:** Notice.

**SUMMARY:** There will be a 1-day meeting of the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (FIFRA SAP) to consider and review issues concerned with ensuring data quality for *in vitro* tests used as alternatives to animal studies for regulatory purposes.

**DATES:** The meeting will be held on July 16, 2003, from 8:30 a.m. to approximately 5 p.m., eastern daylight saving time.

*Comments.* For the deadline for the submission of requests to present oral comments and the submission of written comments, see Unit I.E. of the **SUPPLEMENTARY INFORMATION.**

*Nominations.* Nominations of scientific experts to serve as ad hoc members of the FIFRA SAP for this meeting should be provided on or before June 9, 2003.

*Special seating.* Requests for special seating arrangements should be made at least 5 business days prior to the meeting.

**ADDRESSES:** The meeting will be held at the Sheraton Crystal City Hotel, 1800 Jefferson Davis Hwy., Arlington, VA. The telephone number for the Sheraton Crystal City Hotel is (703) 486-1111.

*Comments.* Written comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION.**

*Nominations, requests to present oral comments, and special seating.* To submit nominations to serve as ad hoc members of the FIFRA SAP for this meeting, or requests for special seating arrangements, or requests to present oral comments, notify the Designated Federal Official (DFO) listed under **FOR FURTHER INFORMATION CONTACT.** To ensure proper receipt by EPA, your request must identify docket ID number OPP-2003-0192 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** Myrta Christian, Designated Federal Official, Office of Science Coordination and Policy (7201M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 564-8450; fax number: (202) 564-8382; e-mail address: [christian.myrta@epa.gov](mailto:christian.myrta@epa.gov).

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

This action is directed to the public in general. This action may, however, be of interest to persons who are or may be

required to conduct testing of chemical substances under the Federal Food, Drug, and Cosmetic Act (FFDCA), FIFRA, and the Food Quality Protection Act of 1996 (FQPA). Since other entities may also be interested, 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 DFO listed under **FOR FURTHER INFORMATION CONTACT.**

*B. How Can I Get Copies of this Document and Other Related Information?*

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP-2003-0192. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>.

EPA's position paper, charge/questions to FIFRA SAP, FIFRA SAP composition (i.e., members and consultants for this meeting) and the meeting agenda will be available as soon as possible, but no later than early July 2003. In addition, the Agency may provide additional background documents as the materials become available. You may obtain electronic copies of these documents, and certain other related documents that might be available electronically, from the FIFRA SAP Internet Home Page at <http://www.epa.gov/scipoly/sap>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public

docket that are available electronically. Once in the system, select "search," then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

Public commenters should note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments in hard copy that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

*C. How and to Whom Do I Submit Comments?*

You may submit comments electronically, by mail, or through hand

delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically.* If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. 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.

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at <http://www.epa.gov/edocket>, and follow the online instructions for submitting comments. Once in the system, select "search," and then key in docket ID number OPP-2003-0192. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail.* Comments may be sent by e-mail to [opp-docket@epa.gov](mailto:opp-docket@epa.gov), Attention: Docket ID Number OPP-2003-0192. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is

placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM.* You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail.* Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, Attention: Docket ID Number OPP-2003-0192.

3. *By hand delivery or courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID Number OPP-2003-0192. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

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

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. Provide specific examples to illustrate your concerns.
5. Make sure to submit your comments by the deadline in this document.

6. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

#### *E. How May I Participate in this Meeting?*

You may participate in this meeting by following the instructions in this unit. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP-2003-0192 in the subject line on the first page of your request.

1. *Oral comments.* Oral comments presented at the meetings should not be repetitive of previously submitted oral or written comments. Although requests to present oral comments are accepted

until the date of the meeting (unless otherwise stated), to the extent that time permits, interested persons may be permitted by the Chair of FIFRA SAP to present oral comments at the meeting. Each individual or group wishing to make brief oral comments to FIFRA SAP is strongly advised to submit their request to the DFO listed under **FOR FURTHER INFORMATION CONTACT** no later than noon, eastern daylight saving time, July 10, 2003, in order to be included on the meeting agenda. The request should identify the name of the individual making the presentation, the organization (if any) the individual will represent, and any requirements for audiovisual equipment (e.g., overhead projector, 35 mm projector, chalkboard). Oral comments before FIFRA SAP are limited to approximately 5 minutes unless prior arrangements have been made. In addition, each speaker should bring 30 copies of his or her comments and presentation slides for distribution to FIFRA SAP at the meeting.

2. *Written comments.* Although submission of written comments are accepted until the date of the meeting (unless otherwise stated), the Agency encourages that written comments be submitted, using the instructions in Unit I., no later than noon, eastern daylight saving time, July 10, 2003, to provide FIFRA SAP the time necessary to consider and review the written comments. There is no limit on the extent of written comments for consideration by FIFRA SAP. Persons wishing to submit written comments at the meeting should contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** and submit 30 copies.

3. *Seating at the meeting.* Seating at the meeting will be on a first-come basis. Individuals requiring special accommodations at this meeting, including wheelchair access, should contact the DFO at least 5 business days prior to the meeting using the information under **FOR FURTHER INFORMATION CONTACT** so that appropriate arrangements can be made.

4. *Request for nominations to serve as ad hoc members of the FIFRA SAP for this meeting.* The FIFRA SAP staff routinely solicit the stakeholder community for nominations to serve as ad hoc members of the FIFRA SAP for each meeting. Any interested person or organization may nominate qualified individuals to serve on the FIFRA SAP for a specific meeting. No interested person shall be ineligible to serve by reason of their membership on any other advisory committee to a Federal department or agency or their employment by a Federal department or agency (except the EPA). Individuals

nominated should have expertise in one or more of the following areas: Toxicology, *in vitro* test methods, biostatistics. Nominees should be scientists who have sufficient professional qualifications, including training and experience, to be capable of providing expert comments on the issues for this meeting. Nominees should be identified by name, occupation, position, address, and telephone number. Nominations should be provided to the DFO listed under **FOR FURTHER INFORMATION CONTACT** on or before June 9, 2003.

The criteria for selecting scientists to serve on the FIFRA SAP are that these persons be recognized scientists—experts in their fields; that they be as impartial and objective as possible; that they represent an array of backgrounds and perspectives (within their disciplines); have no financial conflict of interest; have not previously been involved with the scientific peer review of the issue(s) presented; and that they be available to participate fully in the review, which will be conducted over a relatively short time frame. Nominees will be asked to attend the public meetings and to participate in the discussion of key issues and assumptions at these meetings. Finally, they will be asked to review and to help finalize the meeting minutes.

If a FIFRA SAP nominee is considered to assist in a review by the FIFRA SAP for a particular session, the nominee is subject to the provisions of 5 CFR part 2634, Executive Branch Financial Disclosure, as supplemented by the EPA in 5 CFR part 6401. As such, the FIFRA SAP nominee is required to submit a Confidential Financial Disclosure Form for Special Government Employees Serving on Federal Advisory Committees at the Environmental Protection Agency (EPA Form 3110-485-02) which shall fully disclose, among other financial interests, the nominee's employment, stocks, and bonds, and where applicable, sources of research support. The EPA will evaluate the nominee's financial disclosure form to assess that there are no formal conflicts of interest before the nominee is considered to serve on the FIFRA SAP. Selected FIFRA SAP members will be hired as Special Government Employees. The Agency will review all nominations. FIFRA SAP members participating at this meeting will be posted on the FIFRA SAP web site or may be obtained by contacting the PIRIB at the address or telephone number listed in Unit I.

## II. Background

### A. Purpose of the FIFRA SAP

Amendments to FIFRA enacted November 28, 1975 (7 U.S.C. 136w(d)), include a requirement under section 25(d) of FIFRA that notices of intent to cancel or reclassify pesticide regulations pursuant to section 6(b)(2) of FIFRA, as well as proposed and final forms of rulemaking pursuant to section 25(a) of FIFRA, be submitted to a SAP prior to being made public or issued to a registrant. In accordance with section 25(d) of FIFRA, the FIFRA SAP is to have an opportunity to comment on the health and environmental impact of such actions. The FIFRA SAP also shall make comments, evaluations, and recommendations for operating guidelines to improve the effectiveness and quality of analyses made by Agency scientists. Members are scientists who have sufficient professional qualifications, including training and experience, to be capable of providing expert comments as to the impact on health and the environment of regulatory actions under sections 6(b) and 25(a) of FIFRA. The Deputy Administrator appoints seven individuals to serve on the FIFRA SAP for staggered terms of 4 years, based on recommendations from the National Institutes of Health and the National Science Foundation.

Section 104 of FQPA (Public Law 104-170) established the FQPA Science Review Board (SRB). These scientists shall be available to the FIFRA SAP on an ad hoc basis to assist in reviews conducted by the FIFRA SAP.

### B. Face-to-Face Public Meeting

The FIFRA SAP will meet to consider and review issues concerned with ensuring data quality for *in vitro* tests used as alternatives to animal studies for regulatory purposes. Many *in vitro* methods have been developed or are under development to replace animal tests. Organizations may develop *in vitro* methods using *ex vivo* tissues or biological constructs as the target tissue and fully disclose their test design and the scientific principles of the test. In other cases, *in vitro* methods may be developed by commercial sponsors for commercial marketing as Proprietary Test Methods (PTM). *In vitro* alternatives to animal testing pose unique issues regarding quality and performance. Once a new *in vitro* method is validated and accepted for regulatory use to characterize human health and environmental effects, a process is needed to provide assurance that it will continue to perform in a manner consistent with the test system

as it was originally validated.

Consistency of the *in vitro* assay system is needed with: Time, any change in ingredients or manufacturing process in the test system to be marketed, or variations in interpretation of a method described only generically in a test guideline. In addition, a process should be developed to allow "Me-too" methods to qualify for regulatory use, based on the validation originally performed for the PTM.

For this meeting, the FIFRA SAP will consider and review test guideline approaches to address performance and quality of *in vitro* methods when used as alternatives to animal studies. In addition, the panel will consider core guideline elements, and minimum performance and procedural standards for three new *in vitro* corrosivity assays.

### C. FIFRA SAP Meeting Minutes

The FIFRA SAP will prepare meeting minutes summarizing its recommendations to the Agency in approximately 60 days. The meeting minutes will be posted on the FIFRA SAP web site or may be obtained by contacting the PIRIB at the address or telephone number listed in Unit I.

### List of Subjects

Environmental protection, Pesticides and pests.

Dated: May 22, 2003.

**Joseph J. Merenda,**

Director, Office of Science Coordination and Policy.

[FR Doc. 03-13434 Filed 5-29-03; 8:45 am]

**BILLING CODE 6560-50-S**

## ENVIRONMENTAL PROTECTION AGENCY

[OPP-2003-0160; FRL-7307-1]

### Pesticide Products; Registration Approvals

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

**ACTION:** Notice.

**SUMMARY:** This notice announces Agency approval of applications to register the following four pesticide products Nut GuardV/Fruit GuardV, Novozymes Biofungicide Green-Release™ 710-140, GB34 Concentrate Biological Fungicide, and GB34 Technical Biological Fungicide containing active ingredients not included in any previously registered products pursuant to the provisions of section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.