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Providing an open forum for exploring issues in agricultural biotechnology

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The National Agricultural Biotechnology Council (NABC), a consortium of thirty-four major, not-for-profit agricultural research and education institutions in the United States and Canada, is pleased to release the enclosed document entitled *Recommendations for Management Practices for Field Trials with Bioengineered Plants.* The document was prepared by a subcommittee of our organization after extensive consultation with relevant federal agencies. It is intended to guide NABC member institutions as they seek to comply with federal regulations related to research with experimental bioengineered plants under field conditions. But we hope it will be useful, too, to other institutions as they seek to conduct such experiments.

Please note that the document provides recommendations only, which are subject to the limitations expressed in the document. NABC understands that it is the responsibility of the individual institutions to ensure that their own particular management practices adhere to governmental requirements. But we also understand that there are broad, general recommendations that are applicable to all institutions conducting such research. NABC hopes that this document will be useful, and we would be pleased to receive comments and suggestions.

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Recommendations for Management Practices for Field Trials with Bioengineered Plants

Objective: To assist principal investigators, institutional biosafety committees, biosafety officers, field-research site managers, administrators and others at NABC-member institutions to coordinate their responsibilities in order to comply with federal regulations related to the confinement / containment[1] of experimental bioengineered plants under field-research conditions.

This document provides only recommendations for the benefit of NABC member institutions seeking to comply with federal regulations in this area. Each institution is responsible for adhering to applicable legal requirements, whether dictated by federal, state and/or other laws and regulations. NABC, its officers, directors, employees and representatives, assume no legal duty or responsibility for any management practices adopted by member institutions, without regard to whether such practices may be consistent or inconsistent with these recommendations. Each institution may use/adopt these recommendations to fit its own infrastructure and each institution will have total responsibility for its own field tests and any attendant liability. If any inconsistencies exist between these recommendations and current/future governmental regulations, the latter shall apply. NABC expressly disclaims any liability or legal responsibility in connection with management practices adopted by member institutions.

These recommendations are not intended, and shall not be relied upon, to constitute legal advice provided by NABC to member institutions. NABC member institutions are encouraged to seek legal advice as they, in their judgment, may consider necessary and appropriate.

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[1]USDA-APHIS uses the term "confinement," whereas EPA uses "containment"; "confinement" is used elsewhere herein.

Introduction

These recommendations for management practices (RMPs) provide a framework for administrators and scientists at NABC-member institutions involved in small-scale field-research studies (generally <10 acres) on bioengineered[2] plants. The RMPs are designed to help those involved in public-sector research to comply with federal and other regulations with respect to field trials on bioengineered plants. The recommendations may be useful also to non-NABC land-grant institutions, but that needs to be an individual decision since they have had no opportunity to review the contents[3]; as with NABC institutions, they have the responsibility to comply with any federal and other regulations. Certain regulatory agencies (USDA-APHIS-BRS, EPA, and FDA) have reviewed preliminary drafts, but the contents of this document and its recommendations are solely NABC's. Federal regulatory agencies should be contacted for clarification of legal requirements. Specific state and local requirements are not addressed. The recommendations apply only to the United States[4].

The document is intended to be broadly relevant to the testing of plant and tree crops used in agriculture, horticulture, and forestry (*i.e.* grain and cereal crops, grain and forage legumes, grasses, fruits, vegetables, tree fruits, tobacco, fiber crops, ornamentals, forestry trees, *etc*.). To date, the experience base is broadest with corn, soybean, cotton, and canola, therefore it is written with these field crops specifically in mind, although field tests have been made under the aegis of USDA-APHIS-Biotechnology Regulatory Services (-BRS) with several other species.

[2]Bioengineered" is used in this document as it is by USDA-APHIS-BRS; alternative terms include "transgenic," "genetically engineered" and "genetically modified."

[3]NABC council members reviewed these RMPs and provided comments that were considered and incorporated.

[4]The document does not cover the aspects of APHIS regulations related to movement from one contained facility (such as a laboratory) to another if the movement is into the United States or from one state to another state or territory of the US. Such considerations may be relevant to researchers receiving regulated articles from colleagues in other institutions. The shipment of bioengineered organisms from the United States to other countries will be subject to the relevant regulations of the receiving country or certain international treaties and protocols, such as the Cartagena Protocol for Biosafety.

These recommendations may be modified in the future to reflect changes in federal regulations—presumably using this document as the starting material—and additions may be made in due course to encompass more crops as the experience base expands. Although NABC intends to use its best efforts to communicate such changes to member institutions and to do so on a timely basis, NABC assumes no legal duty or responsibility in this regard. These recommendations do not apply to bioengineered plants already approved for commercial use.

Institutional Biosafety Committees (IBCs) have played a major role in achieving successful oversight of laboratory and greenhouse experimentation for over 20 years, and have been active also in field testing at many institutions. Under these RMPs, it is recommended that each institution utilize its IBC to play an equivalent role in overseeing field experimentation with bioengineered plants. It is recommended that the IBC have at least one member with experience in field experimentation, preferably with bioengineered crops. A subcommittee—composed largely of individuals with relevant experience in field research and bioengineered plants—may have an advisory role; in this document it is termed the IBC-Field Subcommittee ("IBC-F"). If an IBC-F is advantageous—*e.g.* at institutions where large numbers of bioengineered crops are under experimentation—at least the chairperson of the IBC-F should be a member of the IBC.

Each institution should establish in writing the relative roles of the principle investigator (PI), the IBC, the biosafety officer, field manager(s) and senior research administration to ensure that requirements are met for approvals from federal (see Appendix) state and local authorities, and identify the single overall responsible party.

The Recommendations

Application, institutional responsibility, approvals, training, field-site selection, record-keeping, communications, storage and disposal of biological materials, appropriate treatment of equipment

including cleaning, monitoring, testing, and reporting are processes common to all research on experimental bioengineered plants.

Application

The application(s) for approval to conduct a field test should be prepared by the PI for approval by the IBC and by federal and, if required, state and local agencies. The application must include information required by the regulatory agency, *e.g.* the transgene(s), protein(s) produced, the parent plant and relevant information from laboratory and greenhouse tests. Confinement protocols should be proposed. Listing of the relevant qualifications and experience of the PI, associates, students, and technicians who will be involved with the test, although not specifically required by USDA-APHIS-BRS, may be useful for work requiring permit authorization. The proposed field-site assignment should be made by the appropriate field-site manager or equivalent party who oversees the field area where the test will be located so as to minimize exposure to other field tests, *etc.* (see Field-Site Selection, p.7).

A communication plan—drawn up by the PI in conjunction with the field-site manager (or equivalent) and approved by an authorized institutional official—should be included in the application to the IBC or designated approval body, and be in place for immediate use in the event of accidental release of bioengineered material. It is suggested that the IBC work with the PI and the institutional public relations or publicity office in the event that public response becomes necessary.

It is recommended that the proposal be reviewed by the IBC and suggestions incorporated in the submission to the regulatory agency(s). The institution should assign responsibility for seeking approvals to a single individual, usually the PI; the responsible person must adhere to the conditions placed on the permit by the regulatory agency(s).

It may be useful for the IBC to provide a generic application form to assure consideration of all relevant aspects and minimize preparation time for the PI; however, the application forms and information required by the regulatory agencies will be dictated by said agencies.

Institutional Responsibility for Authorizations

Historically, the PI has been the party responsible for obtaining governmental authorizations. With increasing concerns over liability and quality control, some institutions have involved senior management in the process with, for example, the dean as cosignor. Each institution needs to establish its policy for who will be responsible for obtaining authorization and for implementation.

Approvals

All formal approvals (permits, notifications, consultations) required by external agencies must be obtained. Depending on the species and the generated product, small-plot field studies on experimental bioengineered plants require either notification of, or permits from, USDA-APHIS-BRS. An Experimental Use Permit (EUP) may also be needed from EPA for plant-incorporated protectants (PIPs) (*e.g. Bt* crops), usually when cumulative testing acreage exceeds 10 acres. For pharmaceutical-producing plants, early consultation with the FDA is suggested and adherence to their regulations/guidelines documented (see Appendix). Permitting procedures mandated by state and local municipalities must be followed.

The PI or other responsible institutional representative is required to determine the appropriate governmental agency(s) from which to obtain approvals. Current information on the regulatory processes of the federal agencies may be obtained from http://usbiotechreg.nbii.gov/index.asp and as follows:

- USDA-APHIS-BRS—http://www.aphis.usda.gov/ brs—biotech@aphis.usda.gov, 301-734-7324,
- EPA Office of Pesticide Programs/Biopesticides and Pollution Prevention Division—http://www.epa.gov/pesticides/biopesticides—Mike Mendelsohn, Senior Regulatory Specialist, mendelsohn.mike@epa.gov, 703-308-8715,
- FDA Center for Food Safety and Applied Nutrition (CFSAN)—http://www.cfsan.fda.gov/~lrd/biotechm.html#reg—Kathleen Jones, Kathleen.Jones@cfsan.fda.gov, 301-436-1856.

If a bioengineered plant is produced that, after consultation with the federal agencies, does not fall under the auspices of USDA-APHIS-BRS, FDA or EPA, it is recommended that the IBC review the proposal with institutional approval by a senior administrator identified by the institution.

Upon receipt of the required regulatory approvals, the responsible party will notify the other involved parties including the PI, the department chair, the agricultural experiment station director, the office of the vice-president for research and the appropriate field-site manager (or equivalents).

In addition to the above approvals, technology agreements for use of bioengineered seed or plant material provided by industry, purchased from industry, or secured from other parties for use in the field work may require formal approval from the source owner; formalizing such agreements should reduce risk to the PI and to the institution. The PI's responsibility may include adherence to additional third-party requirements for use of regulated materials.

Training

All personnel (PI, collaborating scientists, students, technicians, field workers, *etc.*) including the field-site manager (or equivalent) who are, or may be, active in the field experimentation should complete a training course prior to their first field trial. It is strongly recommended that training be required for personnel conducting field trials on pharmaceutical-producing and industrial-product crops, so as to ensure understanding of all of the issues involved, and to ensure compliance with mandated operations. The training course will be developed (or adopted[5]), implemented, and monitored by the IBC and should include:

- explanation of what bioengineered plants are,
- necessity for confinement in field experimentation,
- possibilities for breach of confinement of field experiments,
- guidance provided by this document,

[5]Many institutional members have expressed interest in being provided a training document. NABC is exploring availability of appropriate established training material; if and when available, this material will be provided as an appendix.

- protocols required by the federal agencies for reporting accidental release of bioengineered material,
- examples of specific concerns associated with particular bioengineered materials,
- procedures for cleaning dedicated equipment,
- institutional assignment of specific oversight responsibilities to specific employees,
- consequences of non-compliance with federal and/or other regulations in terms of possible institutional and individual liability.

The IBC may require that the training course be taken prior to submission of the request for federal approval or prior to initiating the field trial.

The PI should affirm to the IBC in writing that all personnel involved in her/his field trial(s) with bioengineered plants have completed the training course. When significant changes occur in regulations—as judged by the IBC—the training material will be updated accordingly and all personnel involved in field trials should take the updated course or otherwise become familiar with the changes. Smaller institutions might use training facilities made available by larger institutions. It is recommended that a yearly refresher course be taken by all individuals who continue to participate in field trials with bioengineered crops, with written confirmation provided to the IBC.

Field-Site Selection[6]

Field sites for experiments with bioengineered crop plants should be chosen carefully. The PI is urged to consult with the field-site manager (or equivalent) as early as possible in the planning of the research to confirm availability of necessary equipment resources and to verify that federally mandated setback-distance requirements may be accommodated.

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[6]Guidance for identification of a site suitable for field-testing a bioengineered plant. Set-back distances, monitoring procedures, *etc*., will be as dictated by the permit issued by the USDA and/or EPA.

Before testing bioengineered crop plants with pesticidal traits, it is crucial that PIs ensure that the PIP has a tolerance exemption that is legally applicable[7], or that the experimental design ensures that no plant or genetic material from the trial enters the food supply. Without a tolerance or tolerance exemption in place for a PIP, foods containing PIP residues are considered to be adulterated and may not be moved in interstate commerce. Proper design of the test site is needed because of the potential for the PIP to inadvertently spread from test plants into other commercial, breeding or experimental crops and into the food supply. This can occur through cross-pollination with surrounding crops, or the inadvertent mixing of seeds or other plant propagative material after harvest. To minimize the potential for such adulterants to enter the food supply, it is recommended that the PI or field site manager consult early with the EPA to ensure that appropriate physical and/or biological controls are in place to restrict the flow of genetic material, including pollen and seeds, from field tests.

The field-site manager (or equivalent person responsible for site assignment) will select the site after receiving input from the PI regarding characteristics of the bioengineered plant and objectives of the field test, taking into consideration the surrounding experimental and commercial plants and seed longevity, so as to ensure that no experimental transgenes enter commercial seed supplies. The field-site manager (or equivalent) and the PI should be aware of all regulations on follow-up procedures; any continuing use of the field site by the PI should be approved each year by the field-site manager.

On large experimental farms, when an experiment with bioengineered plants abuts an area supervised by a different field-site manager or is within the federally mandated setback distance of an area supervised by a different field-site manager, the field-site manager overseeing the bioengineered work needs to advise her/his

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[7]An example of a tolerance exemption that is not legally applicable for PIP is the *Bacillus thuringiensis* microbial pesticide exemption under 40 CFR 180.1011. This tolerance exemption is limited to pesticide products that contain *B. thuringiensis* microorganisms and does not apply to bioengineered crops with pesticidal traits. Additionally, many PIP tolerances are crop- and protein-specific.

counterpart accordingly in advance, preferably in writing. Similarly, when neighboring farms lie within the setback distance, the field-site manager should advise those farmers in advance, preferably in writing. It is suggested that a one-paragraph description of the experiment and its objectives in lay terms be provided by the PI. If a neighboring farmer requires additional information beyond that available to the field-site manager, it will be the responsibility of the PI to provide same.

NABC recommends that any site on which flooding has occurred not be used for trials with experimental bioengineered plants. Also, experiments with bioengineered plants on leased or farmers' fields that do not involve the field-site manager (or equivalent) should involve institutional oversight, as described above and provide for monitoring, at least as required by the federal permit.

Record-Keeping and Communications

Records must encompass those required by the USDA-APHIS-BRS and/or EPA permit. NABC recommends that the PI should keep all relevant records in secure hard-copy or electronic form, and suggests that each field and related operation be recorded, dated, and signed in timely fashion by the PI, or a person designated in writing by the PI. Also, a record of each current and all past trials with bioengineered plants should be prepared by the field-site manager (or equivalent) based on information provided by the PI, and kept on file for a suggested period of five years at the field-site office (or equivalent) applicable to the location of those trials and, as a backup, be regularly transferred to a central information repository (*e.g.* the office of the agricultural experiment station director and/or the institutional research office). A backup set of records—secure against loss by fire, theft, *etc.*—is advised.

Biological Materials: Storage

A dedicated facility, area, or container should be used for storage of all bioengineered materials (seeds, seedlings, and cuttings). All experimental bioengineered field-test materials covered by a federal permit should be kept in a locked facility. Each type of material—crop, transgene—will be physically separate from all others in a

locked drawer, box, cabinet, *etc*., such as to eliminate any possibility of commingling or other confusion. Seed and other plant material should be labeled so as to be identifiable as bioengineered and distinguishable from all other bioengineered material.

Biological Materials: Post-Harvest Disposal

Unused bioengineered material approved by other than USDA-APHIS-BRS notification must be disposed of in accordance with the federal permit for the specific field experiment.

The bioengineered plant material must be devitalized before movement from the field site unless such movement and the destination facility are covered under the authorization. The method of disposal chosen will depend partly on the volume and type of material and whether leachate from devitalized material poses a hazard to the environment. Methods of disposal include tillage, herbicide treatment, landfill dumping and burial, autoclaving and incineration; the authorization will dictate the process and it is recommended that it be overseen by the institutional biosafety officer.

Equipment and Cleaning

Dedicated equipment is recommended by NABC for seed processing (*e.g.*, cleaning, treatment), transportation, sowing, and harvesting of bioengineered plants for trials covered by a federal permit. Where dedicated equipment is not used, NABC recommends that a standard operating procedure for cleaning be in place with monitoring, to prevent carry-over of bioengineered material.

Dedicated equipment is not required for most USDA-APHIS-BRS field-test authorizations; however, dedicated equipment is required for trials with plants expressing pharmaceutical and industrial compounds.

All equipment used in a test with bioengineered material should be thoroughly cleaned after use in accordance with IBC-mandated protocols that are appropriate for foundation seed production or protocols for identity preservation, to prevent inadvertent movement.

USDA-APHIS-BRS provides equipment-cleaning procedures for bio-engineered crops producing pharmaceutical and industrial compounds; before equipment is used on commercial material, USDA-APHIS-BRS may inspect it (http://www.aphis.usda.gov/brs/fedregister/ BRS_20030310a.pdf).

Particular care is needed when reassigning a storage unit (container, area, or facility) so as to preclude carry-over of bioengineered material. Cleaning methods will be provided by the IBC, and the institutional biosafety officer should oversee and approve the process.

Monitoring

NABC recommends that monitoring should include checks to ensure that approved protocols are being followed. In general, it is recommended for annual crops that the field site be monitored in the following growing season. USDA-APHIS-BRS uses a number of approaches to ensure compliance with the conditions associated with its field-test authorizations, including but not limited to site inspections and auditing of records. In trials of plants producing a pharmaceutical or industrial compound, USDA-APHIS-BRS monitors five times during the test year and twice in the following year.

NABC suggests that, in the case of a perennial crop, monitoring be extended, dependent on the species: for example, three years for bioengineered alfalfa. Also, the follow-up crop should be morphologically distinct from its bioengineered predecessor to enable detection of volunteers: for example, sorghum should not follow bioengineered corn.

Monitoring records should be treated as all others (see Record-Keeping and Communications, p. 9).

Testing

The PI may wish to develop and use appropriate tests (for the transgene or its product by PCR, ELISA, *etc*.). Such tests would help to check for inadvertent presence of bioengineered material.

Reporting

A system for reporting should be established. Failure to follow protocol should be reported immediately to the IBC, to the institutional administration and other appropriate authorities, *e.g.* USDA-APHIS-BRS, EPA, FDA.

To address cases of failure to follow these guidelines, each IBC is encouraged to institute a plan of action approved by the authorized institutional administrator.

Review of Management of Bioengineered Field Trials

NABC will appoint an RMPs review committee selected from university, government, and industry professionals knowledgeable in field research, bioengineered plants, and the food/feed/fiber system. The committee will provide an on-site review of any NABC-member institution that requests it, and will provide a written report on the institution's field-test operations on bioengineered plants with recommendations for any needed improvements. The requesting institution will be responsible for the cost of the review.

All legal requirements for compliance with federal regulations are the responsibility of the institution at which the field-tests are conducted. An NABC review will provide only recommendations. NABC will assume no legal duty or responsibility for a member institution's adoption or adherence to recommended management practices or for compliance with applicable laws and regulations in connection with any such review.

Appendix

Federal Review

The federal government has a coordinated, risk-based system to ensure that new biotechnology products are safe for human and animal health and for the environment. Established as a formal policy in 1986, the Coordinated Framework for Regulation of Biotechnology describes the federal system for evaluating products developed through biotechnology (http://usbiotechreg.nbii. gov/ Coordinated_Framework_1986_Federal_Register.html).

The government agencies responsible for oversight of the products of agricultural biotechnology are USDA-APHIS-BRS, EPA, and FDA. Depending on its characteristics, a product may be subject to review by more than one of these agencies.

Further information is available at http://usbiotechreg.nbii.gov/ FAQAll.asp.

USDA-APHIS-BRS Approval Procedures[8]

Approval by Notification

The notification procedure was first added to the regulation in 1993, at which time six plant species were potentially eligible as long as they met the other eligibility criteria described in the regulation for notification. In 1997, eligibility was broadened to include almost all plant species (the exception being those that are considered weed species in the locales where the tests are to be conducted). Eligibility criteria are included in the information provided at http:// www.aphis. usda.gov/ brs/7cfr340.html#340.

Regulated articles[9] that meet the following six criteria [and performance standards defined in 340.3 Section (c)] are eligible for

[8]USDA-APHIS-BRS provides summary information on types of APHIS authorizations (permits and notifications) at http://www.aphis.usda.gov/brs/fieldtesting_importation. html. Additional explanations on the notification procedure, sample notification letters, and access to a *User's Guide* to notifications are available at http://www.aphis. usda.gov/ brs/notification.html.

[9]USDA-APHIS defines a "regulated article" as *any organism which has been altered or produced through bioengineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in 340.2 (http://www.aphis. usda. gov/brs/7cfr340. html#340.2) and meets the definition of plant pest, or is an unclassified organism and/or an organism whose classification is unknown, or any product which con-*

introduction under the notification procedure. The eligibility criteria pertain to the plant in question, whereas the performance standards refer to the way the activities will be conducted.

- The regulated article is any plant species that is not listed as a noxious weed in regulations at 7 CFR part 360 under the Federal Noxious Weed Act (7 U.S.C. 2809), and, when being considered for release into the environment, the regulated article is not considered by the Administrator to be a weed in the area of release into the environment.
- The introduced genetic material is "stably integrated" in the plant genome, as defined in 340.1.
- The function of the introduced genetic material is known and its expression in the regulated article does not result in plant disease.
- The introduced genetic material does not:
  - cause the production of an infectious entity, or
  - encode substances that are known or likely to be toxic to nontarget organisms known or likely to feed or live on the plant species, or
  - encode products intended for pharmaceutical or industrial use.
- To ensure the introduced genetic sequences do not pose a significant risk of the creation of any new plant virus, plant virus-derived sequences must be:
  - noncoding regulatory sequences of known function, or
  - sense or antisense genetic constructs derived from viral genes from plant viruses that are prevalent and endemic in the area where the introduction will occur and that infect plants of the same host species, and that do not encode a functional noncapsid gene product responsible for cell-to-cell movement of the virus.
- The plant has not been modified to contain the following genetic material from animal or human pathogens:

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tains such an organism, or any other organism or product altered or produced through genetic engineering which the Administrator determines is a plant pest or has reason to believe is a plant pest. Excluded are recipient microorganisms which are not plant pests and which have resulted from the addition of genetic material from a donor organism where the material is well characterized and contains only non-coding regulatory regions.

– any nucleic acid sequence derived from an animal or human virus, or
– coding sequences whose products are known or likely causal agents of disease in animals or humans.

Approval by Permit

All other field trials with bioengineered plants require a permit as described under 7 CFR Part 340.4. This includes trials of plants bioengineered for industrial uses, *e.g.* chemicals, materials, and medicinals[10]. A precise definition of "industrial" is available at http://www.aphis.usda.gov/ brs/fedregister/BRS_20050504a.pdf. Some traits that may be thought of as industrial may fall under notification, *e.g.* an over-expressed plant-derived product. It is recommended that first-time applicants consult USDA-APHIS-BRS to resolve any doubts.

EPA Experimental Use Permit

Before a pesticide can be marketed and used in the United States, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires that EPA evaluate the proposed pesticide to assure that its use will not pose unreasonable risks of harm to human health and the environment. The registration process involves an extensive review of health and safety information.

Plant-incorporated protectants are pesticidal substances produced by plants and the genetic material necessary for the plant to produce the substance. The genetic material and protein (*e.g. Bt* toxin)—but not the plant—are regulated by EPA.

Experimental use permits (EUPs) are issued for PIPs under Section 5 of FIFRA for the generation of information/data necessary

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10In 1993 when the procedure was introduced, plants genetically engineered for industrial uses were eligible for notification. However, at that time, such plants were typically those in which nutritional components, such as oil content, had been altered and with which USDA-APHIS had significant regulatory experience. On August 6, 2003 (http://www.aphis.usda.gov/brs/fedregister/BRS_20030806a.pdf) USDA-APHIS announced an interim rule that introductions of plants genetically engineered to encode compounds for industrial use would generally be conducted under permit. In May 2005, USDA-APHIS announced adoption as a final rule of the interim rule of August 6, 2003 (http://www.aphis.usda.gov/brs/fedregister/BRS_20050504a.pdf).

to register a pesticide under Section 3 of FIFRA. An EUP is required for testing an unregistered PIP or an unregistered use of a PIP on a cumulative total of over 10 acres. For pests that occur in different geographical situations, EUPs are required for testing PIPs on a cumulative total of over 10 acres per test. Further information is available at http://www.epa.gov/pesticides/biopesticides/pips/.

FDA Consultation

In the Federal Register of May 29, 1992 (57 FR 22984), FDA published its *Statement of Policy: Foods Derived from New Plant Varieties* (http://www.cfsan.fda.gov/~acrobat/fr920529.pdf), clarifying the agency's interpretation of the application of the Federal Food, Drug, and Cosmetic Act when applied to food and feed derived from all new plant varieties, including those bioengineered.

The 1992 policy recommended that developers consult with FDA about bioengineered foods under development. In June 1996, FDA provided additional guidance to industry on procedures for these consultations (http://www.cfsan.fda.gov/%7Elrd/consulpr.html). These procedures describe a process in which a developer who intends to commercialize a bioengineered food meets with the agency to identify and discuss relevant safety, nutritional, or other regulatory issues regarding that food and then submits to FDA a summary of its scientific and regulatory assessment of the food; FDA evaluates the submission and responds to the developer by letter.

On November 24, 2004, FDA announced the availability of *Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use* (69 FR 68381; http://www.cfsan.fda.gov/~dms/bioprgui.html), to address the possibility that material from a new plant variety intended for food use might inadvertently enter the food supply before its sponsor has fully consulted with the FDA. This draft guidance discusses the early food safety-evaluation of new proteins in new plant varieties, particularly in new bioengineered varieties that are under development for possible use as food for humans or animals. The draft guidance also describes

procedures for communicating with FDA about this evaluation. The issuance of the draft guidance was proposed in August 2002 in a Federal Register Notice (67 FR 50578) published by the Office of Science and Technology Policy as part of proposed federal actions to update field-test requirements and to establish early voluntary food safety evaluations for new proteins produced by bioengineered plants.

FDA guidance on biotechnology in general is available at http://www.cfsan.fda.gov/ ~lrd/biotechm.html.

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