RECOMMENDATIONS FOR MANAGEMENT PRACTICES FOR FIELD TRIALS WITH TRANSGENIC PLANTS

October 5, 2005
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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 transgenic plants under field-research conditions.

This document provides only recommendations; each institution is responsible for adhering to legal requirements dictated by federal, state and/or other regulatory agencies. 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 will apply.

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 transgenic\(^2\) plants\(^3\). 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; as with NABC institutions, they have the responsibility to comply with any federal and other regulations. The current version of this document applies only to the United States\(^4,5,6\). It is intended to be broadly relevant to the testing of plant and tree crops

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\(^1\)USDA-APHIS uses the term “confinement,” whereas EPA uses “containment”; “confinement” is used elsewhere herein.

\(^2\)Also termed “genetically engineered” or “genetically modified” plants: recombinant DNA technology (including anti-sense and knock-out manipulations) has been used to express at least one foreign gene that modifies a molecular process, conferring a novel trait.

As a related issue, USDA-APHIS defines a “regulated article” as any organism which has been altered or produced through genetic engineering, 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/cfr340.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 contains 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.

\(^3\)Certain regulatory agencies (USDA-APHIS-BRS, EPA and FDA) reviewed the document, but this does not imply endorsement by them. Government research agencies in the United States Department of Agriculture (USDA) endorse this document as useful for providing guidance for field-testing.

\(^4\)It is our understanding that the United States [USDA-Animal and Plant Health Inspection Service (APHIS)] and Canada (Canadian Food Inspection Agency) are in discussions on best practices to meet their respective regulations. A future edition of this document may consider Canada and Mexico as well as the United States.

\(^5\)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 genetically engineered organisms from the United States to other countries will
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.). Since the experience base is broadest with corn, soybean, cotton, and canola, it is written with these field crops specifically in mind. Periodic modifications will be made 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. These recommendations do not apply to transgenic plants already approved for commercial use.

The RMPs are designed to help those involved in public-sector research meet federal regulations to confine field trials on transgenic plants. Their generation reflects a sense of responsibility on the part of not-for-profit NABC-member institutions to safeguard the food supply and the environment, and to maintain credibility with the regulatory agencies and the public at large.

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 transgenic plants. It is recommended that the IBC have at least one member with experience in field experimentation, preferably with transgenic crops. A subcommittee—composed largely of individuals with relevant experience in field research and transgenic 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 transgenic 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 A) 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 transgenic plants.

**APPLICATION**

The application(s) for approval to conduct a field test should be prepared by the principal investigator (PI) for approval by the IBC and by federal and, if required, state and local agencies. The application should include information required by the regulatory agency, e.g. the transgene(s), protein(s) produced, the parent plant and relevant information from laboratory and be subject to the relevant regulations of the receiving country or certain international treaties and protocols, such as the *Cartagena Protocol for Biosafety*.

NABC council members reviewed these RMPs and provided comments that were considered and incorporated. The RMPs were provided for review to the Biotechnology Regulatory Services (BRS) of USDA-APHIS, the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA) and their responses considered and incorporated. The RMPs are being shared with professional plant-research societies.
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, 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).

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 transgenic 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 transgenic species and the generated product, small-plot field studies on experimental transgenic plants require either notification of, or permits from, USDA-APHIS. 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 A). 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(ies) 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](http://usbiotechreg.nbii.gov/index.asp) and as follows:

- USDA-APHIS Biotechnology Regulatory Services (BRS)—[http://www.aphis.usda.gov/brs](http://www.aphis.usda.gov/brs)—Rebecca Bech, Associate Deputy Administrator, Rebecca.A.Bech@aphis.usda.gov, 301-734-7324,
If a transgenic plant is produced that, after consultation with the federal agencies, does not fall under the auspices of USDA-APHIS, 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 transgenic 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 adopted7), implemented, and monitored by the IBC and should include:

- explanation of what transgenic plants are,
- necessity for confinement in field experimentation,
- possibilities for breach of confinement of field experiments,
- guidance provided by this document,
- protocols required by the federal agencies for reporting accidental release of transgenic material,
- examples of specific concerns associated with particular transgenic 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.

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7Many 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.
The PI should affirm to the IBC in writing that all personnel involved in her/his field trial(s) with transgenic 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 transgenic crops, with written confirmation provided to the IBC.

**FIELD-SITE SELECTION**

Field sites for experiments with transgenic 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. In the case of a trial with transgenic plants regulated by EPA, unless an applicable pesticide-tolerance exception is in place under Title 40 of the Code of Federal Regulations, trials of crops containing PIPs (e.g. insecticidal traits) must be fully contained so that no plant or genetic material from the trial enters the food or feed supply. 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 transgenic 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 transgenic 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 transgenic work needs to advise her/his 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.

It is recommended that any site on which flooding has occurred not be used for trials with experimental transgenic plants. Field-testing of experimental transgenic plants which involves flooding (e.g. paddy rice) will require special considerations to ensure confinement.

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8 Guidance for identification of a site suitable for field-testing a GM plant. Setback distances, monitoring procedures, etc., will be as dictated by the permit issued by the USDA and/or EPA.

9 An example of an inapplicable tolerance exemption would be the *Bacillus thuringiensis* microbial pesticide exemption under 40 CFR 180.1011. This tolerance exemption is limited to pesticide products that contain *B. thuringiensis per se*, but does not apply to transgenic crops with pesticidal traits.

10 Since this specifically applies to EPA, their terminology is used here.
In the planning of field trials with transgenic plants in areas of the United States potentially affected by tropical storms, consideration should be given to the potential impact of high winds on movement of pollen, seed, etc.

Experiments with transgenic 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**

The PI should keep all relevant records in secure hard-copy or electronic form. With transgenic plants producing pharmaceuticals or industrial products, the record-keeping protocol in the USDA-APHIS requirements (http://www.aphis.usda.gov/brs/fedregister/BRS_20030310a.pdf) must be adhered to. Records must encompass those required by the permit, and may include:

- site location and distance from other experimental or commercial plants (transgenic and non-transgenic),
- all dates including planting, flowering and pollen-shed, post-planting to pre-harvest treatments, observations, tests, harvesting, and placement in storage,
- location and method of disposal,
- monitoring and treatments at the site (see Monitoring) appropriate to the normal dormancy period of the crop under consideration (usually 1–2 years) as specified in the permit conditions,
- standard methods of record-keeping should be developed by the IBC.

It is suggested 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.

A record of each current and all past trials with transgenic 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 transgenic materials (seeds, seedlings, and cuttings). All experimental transgenic 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 co-mingling or other confusion. Seed and other plant material should be labeled so as to be identifiable as transgenic and distinguishable from all other transgenic material.

**BIOLOGICAL MATERIALS: POST-HARVEST DISPOSAL**

Unused transgenic material approved by other than USDA-APHIS notification must be disposed of in accordance with the federally dictated protocol for the specific field experiment; however, in the application for federal regulatory approval—from USDA-APHIS and/or EPA—it may be desirable to seek permission for saving transgenic material for future use, as a contingency against accidental loss of the transgenic material.
The regulated article 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 for seed processing (e.g., cleaning, treatment), transportation, planting, and harvesting of transgenics for trials covered by a federal permit. However, if dedicated equipment is not economically feasible, a standard operating procedure for cleaning should be in place with monitoring, to eliminate carry-over of transgenic material.

All equipment used in a test with transgenic 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 provides equipment-cleaning procedures for transgenic crops producing pharmaceutical and industrial compounds; before equipment is used on commercial material, USDA-APHIS 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) from one transgenic to another so as to preclude carry-over. Cleaning methods will be provided by the IBC, and the institutional biosafety officer should oversee and approve the process.

**MONITORING**

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 performs random monitoring, and, in trials of plants producing a pharmaceutical or industrial compound, monitors five times during the test year and twice in the following year. Required institutional monitoring in the growing and the following seasons will be as stated by USDA-APHIS permit. It is suggested that, in the case of a perennial crop, monitoring be extended, dependent on the species: for example, three years for transgenic alfalfa. The follow-up crop should be morphologically distinct from its transgenic predecessor to enable detection of volunteers; for example, sorghum should not follow transgenic corn.

The PI will oversee all institutional monitoring required by federal regulations, and may wish to check for changes in susceptibility to disease and/or insects, growth characteristics, and weediness, and inspection for volunteers of the same species throughout at least the following season.

Monitoring records should be treated as all others (see Record-Keeping and Communication).

**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 transgenic material. (Note: USDA-APHIS does not yet require testing.)
**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, 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.

**CONFINEMENT/CONTAINMENT**

The objective is to minimize the persistence (or establishment and spread) of the regulated article in the environment, whether by pollination or growth of volunteer propagules such as seeds or viable vegetative structures. The chief factors for consideration are biological and physical methods of confinement, both of which categories are based on the plant species (mainly whether self-pollinating or out-crossing via wind or other pollen-transfer agent) and the transgene(s) and expression product(s). The objective is the elimination or minimization of gene flow from the test site to other plants, especially food/feed crops. Limitation of access for insects, birds, animals, and human intruders needs to be addressed: geographical isolation, fences, nets and pesticides should be used as appropriate.

**INSTITUTIONAL REVIEW OF ADHERENCE TO RMPs**

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

APPENDIX A: 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, 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/.

USDA-APHIS Approval Procedures

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

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– 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:
  – 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 transgenic plants require a permit as described under 7 CFR Part 340.4.
This includes trials of plants genetically engineered for industrial uses, e.g. chemicals, materials,
and medicinals.12 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 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

12 In 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
Act when applied to food and feed derived from all new plant varieties, including those genetically engineered.

The 1992 policy recommended that developers consult with FDA about genetically modified foods under development. In June 1996, FDA provided additional guidance to industry on procedures for these consultations (http://www.cfsan.fda.gov/~lrd/consulpr.html). These procedures describe a process in which a developer who intends to commercialize a genetically modified food meets with the agency to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered 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.

In the Federal Register of January 18, 2001 (http://www.cfsan.fda.gov/~lrd/fr010118.html), FDA issued a proposed rule that would require that developers submit a scientific and regulatory assessment of the genetically modified food 120 days before being marketed. In the premarket notification proposal, FDA recommends that developers continue the practice of consulting with the agency before submitting the required premarket notice. Links to FDA guidance on early food-safety evaluations are available at http://www.cfsan.fda.gov/~lrd/biotechm.html.

**APPENDIX B**

These *Recommendations for Management Practices for Field Trials with Transgenic Plants* were prepared by the following committee of the NABC council:

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