

U.S. DEPARTMENT OF AGRICULTURE  
WASHINGTON, D.C. 20250

<b>DEPARTMENTAL REGULATION</b>		<b>Number:</b>
Advisory Committee on Biotechnology and 21 <sup>st</sup> Century Agriculture (AC21) Charter	<b>DATE:</b>	
	<b>OPI:</b> Research, Education and Economics	

## 1. AUTHORITY

The U.S. Department of Agriculture (USDA) encourages and supports the responsible development and utilization of beneficial new agricultural products, including those produced through biotechnology, and assures the safety of new products with a science based regulatory approach. USDA has complex and crucial roles in protecting public health and safety, the natural environment, and a competitive, vibrant, and diverse farm economy; ensuring the quality and availability of our food and fiber supply and contributing to long-term global food needs; and maintaining a competitive position of American agricultural products in the international marketplace. These topics are complex and of crucial concern in the conduct of agricultural biotechnology research, regulation, and commercialization. USDA believes it is important to maintain an intensive and regular dialogue to explore and understand the broad array of issues related to the expanding dimensions and importance of agricultural biotechnology. Therefore, USDA is establishing the Advisory Committee on Biotechnology and 21<sup>st</sup> Century Agriculture (AC21), in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. App., to provide information and advice to the Secretary of Agriculture on issues related to agricultural biotechnology. This Departmental Regulation supersedes DR 1043-049, dated January 16, 2009.

## 2. OBJECTIVES AND SCOPE

The purpose of this Committee is to advise the Secretary of Agriculture on the broad array of issues related to the expanding dimensions and importance of agricultural biotechnology.

## 3. DESCRIPTION OF DUTIES

a. The officers of the AC21 will have the following responsibilities:

- (1) The Chairperson or his or her designee will approve the agenda for the meetings, preside over and adjourn meetings under normal circumstances, and certify the accuracy of the minutes.

- (2) The Executive Secretary will be responsible for preparing the minutes of each meeting.
  - (3) The DFO shall have the authority and be required to adjourn any meeting under circumstances in which he or she considers adjournment to be in the public interest, and must approve the agenda in advance of any meeting of the AC21.
- b. The AC21 will meet at the call of the Chairperson with the approval of the DFO approximately four (4) times per year. Meetings may be held less frequently if the workload of the AC21 permits. A quorum will consist of a simple majority of the members of the AC21.
  - c. The functions of the AC21 will be solely advisory, and any determinations of actions to be taken as a result of the work of the AC21 will be made by the Secretary of Agriculture or other appropriate full-time, salaried USDA officials as designated by the Secretary of Agriculture.
  - d. AC21 records will consist of all papers and documents pertinent to the establishment and activities of the AC21, including its charter, agendas, minutes, and all documents related to its procedures, roster, all communication between the USDA and the AC21, and all written materials and reports considered or issued by the AC21. The records of the AC21, formally and informally established subcommittees, or other subgroups of the AC21, shall be handled in accordance with General Records Schedule 26, Item 2 or other approved agency records disposition schedule. These records shall be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552.
  - e. The AC21 will provide information and advice to the Secretary of Agriculture on topics related to the use of biotechnology in agriculture. The committee is charged with examining the long-term impacts of biotechnology on the U.S. food and agriculture system and USDA, and providing guidance to USDA on pressing individual issues, identified by the Office of the Secretary, related to the application of biotechnology in agriculture.

#### 4. AGENCY OR OFFICIAL TO WHOM THE COMMITTEE REPORTS

The AC21 will report as necessary to the Secretary of Agriculture.

#### 5. SUPPORT

Staff and support functions required for operation of the AC21 shall be supplied by Research, Education, and Economics, USDA.

#### 6. ESTIMATED ANNUAL OPERATING COSTS AND STAFF YEARS

Members of the AC21 and its subcommittees shall serve without pay, but with reimbursement of travel expenses and per diem for attendance at AC21 and subcommittee functions for those committee members who require assistance in order to

attend the meetings. The estimated annual operating cost for support of operations of the AC21 for fiscal year 2011 is \$285,591 and 0.9 staff years.

#### 7. DESIGNATED FEDERAL OFFICER

A staff member shall be supplied by Research Education and Economics to serve as the Designated Federal Official (DFO). The DFO will approve or call all of the advisory committee's meetings, prepare and approve all meeting agendas, and attend all committee meetings, adjourn any meetings when the DFO determines adjournment to be in the public interest and chair meetings when directed to do so by the official to whom the advisory committee reports.

#### 8. NUMBER AND FREQUENCY OF MEETINGS

The AC21 will meet up to four (4) times per year. Meetings will be open to the public except when a determination is made in writing by the Secretary of Agriculture or his designee that any or all portions of a meeting should be closed in accordance with 5 U.S.C. 552b (c), and applicable Federal Advisory Committee regulations.

#### 9. DURATION AND TERMINATION

This regulation shall terminate two years from the date of filing.

#### 10. MEMBERSHIP AND DESIGNATION

- a. AC21 will have a Chairperson who will be appointed by the Secretary of Agriculture, and a Designated Federal Official (DFO), who will also be the Executive Secretary of the USDA Biotechnology Coordinating Group. Members of the AC21 will be appointed by the Secretary of Agriculture. AC21 will not conduct a meeting in the absence of the Chairperson, or his or her designee, and the DFO.
- b. AC21, including the Chairperson, will consist of 20 to 25 members, plus up to seven (7) ex officio members from Federal and/or State government agencies outside of USDA. Members of AC21 will be knowledgeable in one or more of the following areas: recombinant-DNA (rDNA) research and applications using plants; rDNA research and applications using animals; rDNA research and applications using microbes; food science; silviculture and related forest science; fisheries science; ecology; veterinary medicine; the broad range of farming or agricultural practices; weed science; entomology; nematology; plant pathology; biodiversity; applicable laws and regulations relevant to agricultural biotechnology policy; risk assessment; consumer advocacy and public attitudes; public health/epidemiology; ethics, including bioethics; human medicine; biotechnology industry activities and structure; intellectual property rights systems; and international trade. Members will be selected in order to achieve a balanced representation of viewpoints to address effectively USDA biotechnology policy issues under consideration. Members shall serve for terms of up to two years, and may be

reappointed by the Secretary of Agriculture. No member may serve more than six consecutive years on the AC21.

- c. The Secretary of Agriculture shall select as Chairperson of the AC21 one of the appointed members. The term of the Chairperson shall be 2 years.
- d. USDA will identify appropriate Federal and/or State government agencies or organizations of State government officials that will be given the opportunity to name an ex officio member to the AC21. Ex officio members may participate in AC21 discussions, but may not themselves vote, or join in consensus, on any report or recommendation made by the AC21.
- e. Equal opportunity practices, in line with USDA policies, will be followed in all membership appointments to AC21. To ensure that recommendations of AC21 have taken into account the needs of the diverse groups served by USDA, membership shall include, to the extent practicable, individuals with demonstrated ability to represent minorities, women, and persons with disabilities.
- f. Additional individuals representing relevant federal and state agencies may be utilized to provide advice and expertise. Expert consultants may be called upon for advice on an ad hoc basis.

## 11. SUBCOMMITTEES

The Chairperson and the Designated Federal Official may jointly appoint such subcommittees as they deem necessary to carry out the functions of the AC21. All subcommittees, whether formal or informal, shall report back to the full AC21, and shall not directly provide advice to USDA.

## 12. RECORDKEEPING

Records shall be kept in accordance with USDA records directives and the Federal Advisory Committee Act requirements. These records shall include minutes of each meeting and reports as appropriate. The DFO shall ensure these records are made available via the General Services Administration (GSA) FACA website.

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