The Stakeholder Forum on Agricultural Biotechnology:

AN OVERVIEW OF THE PROCESS

Approved by the Stakeholder Forum

May 2003

Sponsored by the Pew Initiative on Food and Biotechnology

IN EARLY 2001, the Pew Initiative on Food and Biotechnology (PIFB) was established, through a grant from the Pew Charitable Trusts to the University of Richmond, to introduce a neutral party to the debate on agricultural biotechnology. From its inception, the PIFB had two separate programs: a research and education campaign, and a consensus project referred to as the "Stakeholder Forum." The research and education campaign uses reports, conferences, and public debates to increase awareness about the many complex issues embedded in discussions about agricultural biotechnology. This report concerns only the activities of the Stakeholder Forum, which concluded in May 2003.

The Stakeholder Forum was composed of leaders with expertise and interest in the federal regulatory system governing agricultural biotechnology. Forum participants included representatives of the biotechnology industry; environmental and consumer advocacy organizations; the farming and ranching communities; food processing and marketing companies; and academia. (See Appendix A for a list of participants.)

Over the two-year period, Stakeholder Forum members sought to develop consensus recommendations that would enhance the ability of U.S. policies, programs, and regulations governing agricultural biotechnology products to protect public health and the environment. Members paid particular attention to the ability of the regulatory system to: address the health and environmental issues associated with future products of biotechnology; provide a clear pathway to market for those products; and inspire consumer confidence. The Forum met in plenary session 11 times. Also, at least 46 work group meetings and/or conference calls, each of which involved a subset of the larger Forum membership, were held over the course of the two years.

The Forum's goal was very ambitious: consensus on a package of regulatory reforms described in sufficient detail to enable an agreement on implementation. That package was to address animal and plant applications of biotechnology, public health and environmental concerns, and the regulatory system at the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA). Forum members generally agreed to outcomes, principles, and components for a regulatory system for agricultural biotechnology that protects public health and the environment. In the end, however, the group could not reach agreement on the full range of issues in sufficient detail to achieve its goal. Forum members concluded that an imprecise or incomplete package of recommendations would not serve a useful purpose, but they decided to keep open the prospect of future agreement and collaboration.

Forum members agreed that the dialogue process was very constructive despite the lack of consensus. Members engaged in candid and substantive discussions, and had an opportunity to carefully examine and debate the strengths and weaknesses of the current regulatory system. The Forum process provided a valuable opportunity for members to be exposed to different ideas and perspectives, learn from each other,

and forge new relationships. Some of the key factors that contributed to the constructive dialogue included appropriate time for deliberation, adequate funding for travel and outside expertise, and the use of professional facilitators. Moving forward, Forum members are confident that the relationships they built will inform the actions of their individual organizations and enhance the substance and quality of the ongoing debate shaping the future of this technology. Forum members agreed it would be desirable to come back together in 12-18 months to revisit how the regulatory agencies are addressing agricultural biotechnology issues and see if there is an opportunity to pursue consensus recommendations at that point.

Stakeholder Forum members wanted to set forth, for the public record, a description of the dialogue process they undertook. This document thus explains the roles of the organizers, how participants were chosen, the schedule of meetings, and the scope of the discussions. This report was developed and approved by Stakeholder Forum members at their final meeting in May 2003.

Process Roles

The Pew Initiative on Food and Biotechnology convened the Stakeholder Forum and provided financial and staff support, serving as a neutral facilitator and the sole funder of the Forum's plenary sessions and work group meetings.

The Stakeholder Forum's consensus-based process was run by professional mediators from RESOLVE, a nonprofit organization specializing in environmental dispute resolution, mediation, consensus building, facilitation, and policy dialogue. RESOLVE mediators facilitated the Forum's plenary and work group discussions, assisted Stakeholder Forum members in developing approaches and potential recommendations, prepared meeting summaries, and handled logistical arrangements. (See Appendix B for a list of staff members from the PIFB and RESOLVE.)

While the PIFB and RESOLVE provided process assistance to the Stakeholder Forum, Forum members themselves were responsible for the content of the deliberations. Forum members defined the scope of their discussions; chose the substantive topics for each meeting; set meeting agendas; sought assistance as needed from the outside experts of their choosing; and developed together various draft approaches and potential recommendations.

Stakeholder Selection

Staff members from the PIFB and RESOLVE worked together at the outset of the process to identify potential Stakeholder Forum members. The selection process involved consultations with leaders and experts from a broad range of relevant

interests, including agricultural groups, trade associations and individual companies, consumer and environmental advocacy groups, Congressional staff, and state and federal agencies. It also involved a small focus group meeting consisting of individuals representing the biotechnology industry, food processors, commodity traders, environmental groups, growers, and consumer advocates. (See Appendix C, Contributors and Other Participants, for a list of participants in this focus group meeting.) During these consultations, the organizers sought advice regarding the range of interests that should be represented on the Forum, specific organizations that could represent those interests, and individuals within those organizations who would be productive participants. The PIFB and RESOLVE also used these consultations to receive advice on issues and approaches that would be useful to consider in a consensus process.

On the basis of these meetings, PIFB and RESOLVE staffers determined that, to foster dialogue and negotiations, Forum membership should be limited to about 20. As such, it was recognized that not all opinions shaping the ongoing debate about agricultural biotechnology were directly involved in the Forum, nor were federal agencies included. However, in the course of their deliberations, Forum members actively sought out, heard from, and engaged in discussions with individuals representing a broader range of opinions than those represented around the table.

Ultimately, the individuals invited to join the Forum were chosen because of their experience with agricultural biotechnology and their willingness to work together in a collaborative, consensus-oriented process. Also, the members represented interests that would be substantially affected by the issues addressed in the deliberations and by the recommendations developed. Members were expected to bring the views of their organizations, as well as others with similar interests, to the Forum process. Members also committed to seek broader support for any recommendations developed by the Forum.

As the first plenary session was being organized, PIFB and RESOLVE staffers met with experts with hands-on regulatory experience in agricultural biotechnology decisions and policies, to seek their input on useful ways to organize the many issues raised during the consultation and stakeholder selection process. (See Appendix C for a list of participants in this “scoping” meeting.) The group did not make any specific recommendation other than that the Stakeholder Forum had a large variety of issues that merited exploration and discussion and that Forum members, to be effective, would need to quickly determine the issues of greatest concern to them and then maintain a focus on those issues.

During the first two plenary meetings, Forum members discussed the balance and scope of the interests represented at the table. As a result, three new members joined the group, bringing the number of Forum members up to 21 at one point.

The Dialogue Process

The Stakeholder Forum commenced in May 2001 with an inaugural meeting in Washington, DC. Originally, the Forum was scheduled to meet five times over 16 months. However, Forum members ultimately met in a total of 11 facilitated plenary sessions over a two-year period. The meetings were held in five locations around the United States. Numerous work group meetings and conference calls were also held between plenary sessions. All told, Stakeholder Forum members spent more than 7,000 person-hours actively engaged in dialogue meetings, not including time spent preparing for and traveling to meetings. (Appendix D contains a list of the Forum's meetings and conference calls.)

At the initial meeting, members adopted a number of operating procedures, which served to safeguard the members' interests and foster open and constructive dialogue. For example, the members agreed to conduct themselves in a manner that promotes joint problem solving and collaboration, and to consider the input and viewpoints of the other participants. Also, the Forum was conducted as a nonpublic, confidential process. Under these operating procedures, Forum members had the opportunity to develop a common understanding of the complex and controversial issues surrounding biotechnology regulation, explore their respective interests, and clarify options to help inform public policy. (The group's operating procedures are contained in Appendix E.)

During the first few meetings, Forum members worked to define the issues of greatest importance to them and to target their work toward seeking consensus on those concerns. For example, as discussed later in this report, the group chose to focus on regulatory issues rather than science or marketing issues, and on domestic regulatory issues rather than international regulatory issues. At the second meeting, Forum members developed a draft of essential components and characteristics of a regulatory system. They reworked this document over the next several months, but ultimately decided to leave it as a working draft rather than formulate it into a consensus recommendation. This document informed the Forum's work throughout the process. (Appendix F contains this working draft.)

In order to hold in-depth discussions on key issues, Stakeholder Forum members organized into three major work groups: the Animals Work Group, the Environmental Protection Work Group, and the Food Safety Work Group. Materials, proposed approaches, and draft recommendations that were developed by these work groups were, throughout the process, reviewed, discussed, and/or modified by all members of the Forum during plenary meetings.

The Stakeholder Forum also involved the participation of nearly 100 outside legal, scientific, business, and policy experts in varying ways. The Forum commissioned extensive original research and analysis of critical issues by leading independent

experts representing a diversity of viewpoints. Experts prepared dozens of in-depth analytical memoranda that addressed key legal, policy, and scientific issues. Forum members also benefited from the ongoing participation of numerous outside experts in plenary and work group sessions, where they made presentations, answered questions, engaged in debate, and reacted to Forum members' ideas. The experts' independent research and analysis provided Forum members with valuable information that they believe will also make a significant contribution to the broader policy debate. (A list of the experts and contributors is set out in Appendix C.)

On two occasions the Forum conducted workshops in which experts were invited to formally contribute to the group's deliberations and decisions. The first was a two-day workshop on transgenic animals that included, in addition to several Forum members, 13 experts who were not Forum members. (See Appendix D for a list of meeting participants.) The second was a one-day planning meeting with members of the National Research Council's Committee on Agricultural Biotechnology, Health, and the Environment. This planning meeting, which included 25 non-Forum participants, was entitled "Exploring Genetic Modification of Plants: New Approaches and Implications for Definitions." (See Appendix C for a list of planning meeting participants.)

Toward the end of the dialogue process, Forum members held several meetings with federal agency staff, in order to test the feasibility of draft recommendations and clarify technical issues. Members of the Animals Work Group met with individuals from the FDA's Center for Veterinary Medicine. Members of the Environmental Protection Work Group met with individuals at both the EPA and the USDA. (The meeting dates are listed in Appendix D.)

Scope of the Discussions

Forum members' discussions centered around "agricultural biotechnology products," which the members roughly defined as plant, animal, and microbial products modified by the techniques of recombinant DNA and used in agricultural systems in the production of food, fiber, feed, landscape plants, pharmaceuticals, and industrial products. The products considered by the group included those in the marketplace today (e.g., corn, cotton, and soybean varieties into which herbicide-tolerance and insect-control genes have been inserted) and, even more important, those anticipated in the marketplace over the next 10 years (e.g., pharmaceuticals, industrial chemicals, and nutritionally enhanced foods derived from transgenic plants or animals).

At the outset of their discussions, members of the Stakeholder Forum agreed that:

1) agricultural biotechnology products will continue to be developed for introduction into the U.S. and global marketplace;

2) the U.S. system of governance of agricultural biotechnology products must ensure that the public interest is protected; and

3) public trust in the U.S. system of governance requires credible regulation and sensible public policies.

In addition, Stakeholder Forum members acknowledged and confirmed that the protection of public health and the environment should be the primary goals of any regulatory framework for agricultural biotechnology. Public health and safety are paramount considerations, and the regulatory system should ensure that the use of agricultural biotechnology has no adverse impact on them. Environmental protection is also important, and the system should minimize adverse environmental effects. Stakeholder Forum members also recognized that some level of risk and uncertainty will exist in any regulatory system.

In proceeding with discussions on how best to protect public health and the environment and ensure public confidence in the regulatory system, the Stakeholder Forum sought approaches that achieved these goals while:

1) not unnecessarily hampering innovation in agricultural biotechnology;

2) learning from experiences with the increasingly broad and complex array of agricultural biotechnology applications; and

3) providing a significant measure of stability and predictability for both technology developers and the interested public.

U.S. policies, programs, and regulations governing food safety and environmental protection were the target of the deliberations and anticipated recommendations of the Forum. At the core of the deliberations were questions regarding the credibility and effectiveness of the systems of oversight, both public and private, for the governance of agricultural biotechnology products.

The most relevant federal laws included the Federal Food, Drug, and Cosmetic Act; the Plant Protection Act; the Federal Insecticide, Fungicide, and Rodenticide Act; and the Toxic Substances Control Act. The most relevant federal departments and agencies included the the FDA, USDA, and EPA. Forum members discussed the strengths and weaknesses of the existing regulatory system, including perceived gaps in the system, and how it will handle future products of agricultural biotechnology.

Forum members agreed that an effective and comprehensive public policy regarding agricultural biotechnology should consider the science of risk assessment and the factors affecting risk management and consumer confidence, including transparency, inclusiveness, public understanding, commercial viability, and consumer choice. Oversight of an agricultural biotechnology product can span a long progression of

time and evolution, including: (1) research and development or pre-approval, (2) approval for commercialization, (3) commercialization and introduction into marketplace, and (4) post-commercialization, including monitoring, enforcement, and reassessment.

Although the global marketplace, trade agreements, and other international policies, programs, and regulations have implications for the U.S. system of governance, the Stakeholder Forum chose to direct its attention to the domestic regulation of agricultural biotechnology products. Stakeholder Forum members recognized and were mindful of the interplay between domestic and international governance during their deliberations.

Appendix A Stakeholder Forum Members

The 18 Stakeholder Forum members who signed off on this report at the end of the dialogue process are as follows:

Richard Caplan
Environmental Advocate
U.S. Public Interest Research Group
Washington, DC

Harold D. Coble
Past President
Council for Agricultural Science and Technology
Raleigh, NC

Steve Daugherty
Director, Government and Industry Relations
Pioneer Hi-Bred International, Inc.
Des Moines, IA

Carol Tucker Foreman
Distinguished Fellow and Director, Food Policy Institute
Consumer Federation of America
Washington, DC

Rebecca J. Goldburg
Senior Scientist
Environmental Defense
New York, NY

Robert M. Goodman
Professor, College of Agricultural & Life Sciences
University of Wisconsin-Madison
Madison, WI

Duane Grant
Wheat and Potato Farmer and Board of Directors
National Association of Wheat Growers
Rupert, ID

Gregory Jaffe
Director, Biotechnology Project
Center for Science in the Public Interest
Washington, DC

Robbin Johnson
Sr. Vice President, Corporate Affairs
Cargill Incorporated
Wayzata, MN

Andrew G. Jordan
Director, Technical Services
National Cotton Council
Memphis, TN

Margaret G. Mellon
Director, Food & Environment Program
Union of Concerned Scientists
Washington, DC

Kathleen Merrigan
Assistant Professor and Director, Agriculture, Food & Environment Program
Friedman School of Nutrition Science & Policy
Tufts University
Boston, MA

Bill Northey
Corn Grower
Innovative Farms
Spirit Lake, IA

John Pierce
Director, Biochemical Sciences & Engineering, Central Research and Development
DuPont
Wilmington, DE

Jerry Pommer
Director, Quality Systems
Trans Ova Genetics
Hull, IA

Linda Strachan
Director, Governmental Affairs
Monsanto
Washington, DC

Austin P. Sullivan, Jr.
Sr. Vice President, Corporate Relations
General Mills, Inc.
Minneapolis, MN

Roger West
Cattle Rancher and Chairman, Science and Technology Committee
National Cattlemen's Beef Association
Gainesville, FL

Several other individuals deserve mention for their contributions to the Stakeholder Forum. First and foremost, Raymond Dobert of Monsanto, who was technically an alternate for Linda Strachan, provided active and helpful service on the Environmental Protection Work Group.

Other individuals served as members of the Stakeholder Forum at various points in time. David Frederickson, then of the Minnesota Farmers Union, served as a Forum member for the first year of the process. Mr. Frederickson was then elected President of the National Farmers Union and, in taking the helm of that organization, was unable to continue his participation in the Forum.

Similarly, Margaret Wittenberg, Vice President of Governmental and Public Affairs at Whole Foods Market, Inc., was an active member of the Forum from the beginning until December 2002, when Whole Foods withdrew from the Forum.

The representatives of a few organizations changed during the course of the process. Kate Fish, for example, Vice President of Public Policy at Monsanto, participated from the beginning of the process until March 2002, when Linda Strachan took over for her. Likewise Dave Faber, President of Trans Ova Genetics, participated from the outset until November 2001, when Jerry Pommer formally took his place. Jane Brooks, Vice President of the Biotechnology Network at DuPont, participated in the first plenary session, and thereafter John Pierce represented DuPont on the Forum.

Several individuals in addition to Raymond Dobert served as alternates for Forum members at various points in the process. These included Jessica Adelman, Cargill; Tom Carrato, Monsanto; Darrell Hanavan, Colorado Wheat Growers; E. Keith Menchey, National Cotton Council; and Nora Murphy, Tufts University. In addition, several individuals provided technical expertise to members during one or more plenary meetings. These included Shirley Boyd, Cargill; William A. Gillon, Butler, Snow, O'Mara, Stevens, & Cannada (for the National Cotton Council); Karil Kochenderfer, Grocery Manufacturers of America; and Terry Medley, DuPont.

Finally, it should be noted that Forum members and organizers wanted very much to have a small-business owner as a member of the Forum, but were unsuccessful in maintaining their consistent participation. Jerry Caulder, former Chairman and CEO of Akkadix Corporation, advised the PIFB and RESOLVE in setting up the exploratory meetings and took part in planning the first plenary meeting, and John Ryals, then President and CEO of Paradigm Genetics, Inc., participated in the second plenary. A panel of small-business owners also made presentations at the May 2002 meeting.

Appendix B PIFB and RESOLVE Staff

The Pew Initiative on Food and Biotechnology

Michael Rodemeyer
Executive Director

Keith Pitts
Director of Public Policy

Serina Vandegrift
Assistant Director of Public Policy

The Pew Initiative on Food and Biotechnology was established in 2001 to be an independent and objective source of credible information on agricultural biotechnology for the public, the media, and policymakers. Funded through a grant from The Pew Charitable Trusts to the University of Richmond, the PIFB advocates neither for nor against agricultural biotechnology. Instead, the Initiative is committed to providing information and encouraging debate and dialogue so that consumers and policymakers can make their own informed decisions. The Honorable Dan Glickman, former Secretary of Agriculture and Member of Congress, and The Honorable Vin Weber, former Member of Congress, serve as Executive Advisors for the PIFB. For more information, see www.pewagbiotech.org.

RESOLVE

Abby Dilley
Senior Mediator and Project Director

Paul De Morgan
Senior Mediator

Robert Fisher
Senior Mediator

Jennifer Peyser
Associate

Jennifer Thomas-Larmer
Editorial Consultant, Larmer Consulting

RESOLVE is one of the premier public policy dispute resolution organizations in the United States and internationally, with expertise in the full range of alternative dispute resolution and consensus-building processes and a commitment to understand-

ing how these tools can enhance public decision making. RESOLVE has particular expertise in the application of mediation and other consensus building processes to complex environmental, natural resources, health, land-use, transportation, and other public policy issues. RESOLVE is a nonprofit organization founded in 1977 and operating from offices in Washington, DC, Portland, OR, and Denver, CO.

Appendix C Contributors and Other Participants

This appendix lists the individuals (other than Forum members) who took part in various meetings relating to the Stakeholder Forum, as noted.

Initial Focus Group Planning Session, February 28, 2001

Jane Brooks, DuPont
Steve Daugherty, Pioneer Hi-Bred International, Inc.
Rebecca Goldburg, Environmental Defense
Mary Howell-Martens, Finger Lakes Community College
Michael Jacobson, Center for Science in the Public Interest
Robbin Johnson, Cargill Incorporated
Bill Northey, National Corn Growers Association
Keith Triebwasser, Procter & Gamble

Early Scoping Meeting, March 19, 2001

Jim Aidala, former Assistant Administrator, EPA
Sharon Friedman, U.S. Forest Service and former OSTP-CEQ Staff Member
Lynn Goldman, former Assistant Administrator, EPA
Eric Olsen, former Chief of Staff, USDA
William Schultz, former Deputy Commissioner, FDA
Skip Stiles, former Legislative Director, House Committee on Science
Michael Taylor, former Deputy Commissioner, FDA and Asst. Secretary for Food Safety, USDA
Caren Wilcox, former Deputy Assistant Secretary for Food Safety, USDA

Workshop on Transgenic Animals, January 30–31, 2002

Mel Coleman, Jr., Coleman Natural Products, Inc.
Fred Degnan, King and Spalding, LLP
Dave Faber, Trans Ova Genetics
Andrew Fish, FoxKiser
Eric Hallerman, Virginia Polytechnic Institute and State University
Eric Hentges, National Pork Board
Jennifer Kuzma, National Research Council
John Matheson, FDA, Center for Veterinary Medicine
Eric Olsen, Patton Boggs, LLP

Bernard Rollin, Colorado State University
Larisa Rudenko, Integrative Biostrategies, LLC
Steven Stice, University of Georgia
Kim Waddell, National Research Council

National Research Council Planning Meeting, August 15, 2002

CABHE Members

Barbara Schaal, Washington University
David Andow, University of Minnesota
Neal First, University of Wisconsin-Madison
Richard Harwood, Michigan State University

Participants

Michael Arnold, University of Georgia **(speaker)**
Gary Comstock, Iowa State University
Carole Cramer, Virginia Polytechnic Institute and State University **(speaker)**
Donald Duvick, Iowa State University
Yann Echelard, Genzyme Corporation **(speaker)**
Eric Flamm, FDA
Randal Giroux, Cargill Incorporated
Mich Hein, Epicyte Pharmaceutical
James Holland, North Carolina State University **(speaker)**
Robert Horsch, Monsanto
Ed Korwek, Hogan & Hartson, LLP **(speaker)**
John Matheson, FDA, Center for Veterinary Medicine
Jose Piedrahita, North Carolina State University **(speaker)**
Larisa Rudenko, Integrative Biostrategies, LLC
Michael Schechtman, USDA
Michael Taylor, Resources for the Future
Rod Townsend, Pioneer Hi-Bred International, Inc.

Stakeholder Forum Members

Harold Coble, Council for Agricultural Science and Technology
Steve Daugherty, Pioneer Hi-Bred International, Inc.
Duane Grant, National Association of Wheat Growers
Gregory Jaffe, Center for Science in the Public Interest
Margaret Mellon, Union of Concerned Scientists

NRC Staff

Jennifer Kuzma
Kim Waddell
Mike Kisielewski
Seth Strongin

Consultants to the Stakeholder Forum

Stan Abramson, Arent Fox Kitner Plotkin and Kahn, PLLC
Jim Aidala, JSC, Inc.
Tom Bundy, former Assistant General Counsel, USDA
Fred Degnan, King and Spalding, LLP
Andrew Fish, FoxKiser
Lynn Goldman, John Hopkins University
Eric Olsen, Patton Boggs, LLP
Larisa Rudenko, Integrative Biostrategies, LLC
William Schultz, Zuckerman Spaeder, LLP
Michael Taylor, Resources for the Future

Contributors/Presenters at Various Plenary and Work Group Meetings

Charles Arntzen, Arizona Biomedical Institute, Arizona State University
Bill Brown, National Audubon Society
Julie Caswell, University of Massachusetts
Mel Coleman, Jr., Coleman Natural Products, Inc.
Elliot Entis, Aqua Bounty Farms
Dave Faber, Trans Ova Genetics
Roy Fuchs, Monsanto
Eric Hallerman, Virginia Polytechnic Institute and State University
Mich Hein, Epicyte Pharmaceutical
Eric Hentges, National Pork Board
Rick Hellmich, Agricultural Research Service, Iowa State University
Nick Hether, Gerber
Bill Horan, Horan Brothers Agricultural Enterprises
John Howard, ProdiGene
Tom Howard, Gala Design
Phil Hutton, EPA, Office of Pesticide Programs
Ed Korwek, Hogan & Hartson, LLP
Jennifer Kuzma, National Research Council
Belinda Martineau, author, formerly with Calgene, Inc.

John Matheson, FDA, Center for Veterinary Medicine
Tom McGarity, University of Texas School of Law
Joseph Mendelson, Center for Food Safety
Elizabeth Milewski, EPA, Office of Pollution Prevention and Toxic Substances
Marcia Mulkey, EPA, Office of Pesticide Programs
Stuart Pape, Patton Boggs, LLP
Jane Rissler, Union of Concerned Scientists
Bernard Rollin, Colorado State University
Ron Rosmann, Rosmann Family Farms
Michael Schechtman, USDA, Agricultural Research Service
Sid Shapiro, University of Kansas School of Law
Isi Siddiqui, CropLife America
Mark Silbergeld, Consumers Union
Steven Stice, University of Georgia
Skip Stiles, consultant
Kim Waddell, National Research Council
Jim White, USDA, Animal and Plant Health Inspection Service
Trudy Witbreuk, Embassy of Australia

Appendix D List of Stakeholder Forum Meetings

The following are the dates of the meetings and conference calls convened by the Stakeholder Forum and its work groups. The dates listed indicate in-person meetings, unless noted with a "cc" for "conference call."

Plenary Meetings

May 30-31, 2001 (Washington, DC)
August 28-30, 2001 (Sundance, UT)
November 28-30, 2001 (Warrenton, VA)
March 4-6, 2002 (Tucson, AZ)
May 6-8, 2002 (Chaska, MN)
June 13-14, 2002 (Chantilly, VA)
August 1-2, 2002 (Washington, DC)
October 2-4, 2002 (Tyngsboro, MA)
December 18-19, 2002 (Washington, DC)
January 24, 2003 (Washington, DC)
May 22-23, 2003 (Washington, DC)

Food Safety Work Group

Meetings and Conference Calls
December 20, 2001 (cc)
January 10, 2002 (cc)
March 4, 2002
April 8-9, 2002
April 26, 2002 (cc)
June 12, 2002
July 19, 2002
September 5, 2002
October 24, 2002 (cc)

Animals Work Group

Meetings and Conference Calls
December 21, 2001 (cc)
January 30-31, 2002
March 4, 2002
March 11, 2002 (cc)
May 31, 2001 (cc)
June 7, 2002 (cc)
June 12, 2002
June 24-25, 2002
July 26, 2002 (cc)
August 27-28, 2002
September 12, 2002 (cc)
January 23, 2003

Environmental Protection Work Group

Meetings and Conference Calls
December 18, 2001 (cc)
January 28-29, 2002
March 4, 2002
April 8-9, 2002
June 12, 2002
July 24-25, 2002
September 10-11, 2002 (cc)
September 23, 2002 (cc)
October 24, 2002 (cc)
December 3, 2002 (cc)
February 4, 2003 (cc)
February 20, 2003

Conference Calls of Ad Hoc Work Groups

June 15, 2001 (cc)
July 9, 2001 (cc)
October 24, 2001 (cc)
October 25, 2001 (cc)
October 29, 2001 (cc)
March 14, 2002 (cc)
May 21, 2002 (cc)
July 1, 2002 (cc)
July 3, 2002 (cc)
July 10, 2002 (cc)
July 15, 2002 (cc)
September, 13, 2002 (cc)
December 10, 2002 (cc)
January 22, 2003 (cc)
May 7, 2003 (cc)
May 14, 2003 (cc)

Meetings with Agency Staff

March 4, 2003, with EPA's Office of Pollution Prevention and Toxic Substances

March 5, 2003, with the Biotechnology Regulatory Service of the USDA's Animal and Plant Health Inspection Service

April 4, 2003 with the FDA's Center for Veterinary Medicine

Appendix E Operating Procedures

At the outset of the Stakeholder Forum process, Forum members discussed and agreed to abide by the following operating procedures. These procedures were not revised after the second plenary session.

1) PURPOSE

The purpose of the Pew Initiative on Food and Biotechnology Stakeholder Forum is to develop consensus recommendations that will enhance the ability of U.S. policies, programs, and regulations governing agricultural biotechnology products to ensure protection of human health and the environment. [Note: Later in the process, Forum members agreed that another primary purpose of the Forum was "to enhance public trust in the regulatory system governing agricultural biotechnology."]

2) PARTICIPATION

A. *Interests Represented*. The Members of the Stakeholder Forum represent interests that would be substantially affected by the issues to be addressed in these deliberations and by the recommendations to be developed. The Members were chosen because of their experience with agricultural biotechnology and willingness to work together in a collaborative, consensus process. In order to foster creative problem solving, Members are encouraged to voice their individual viewpoints and ideas. In order to broaden and strengthen the chances of success for the anticipated final consensus recommendations, Members are expected to bring the views of their constituent groups, as well as others with similar interests, to the Forum process. Members also will be asked to inform their constituents and others of major activities and agreements as part of the process.

B. *Principles for Involvement/Assumptions of the Deliberations*. Members of the Stakeholder Forum have agreed to the following assumptions.

Assumption 1: Agricultural biotechnology products will continue to be developed for introduction into the U.S. and global marketplace.

Assumption 2: The U.S. system of governance of agricultural biotechnology products must ensure that the public interest is protected.

Assumption 3: Public confidence in the U.S. system of governance requires credible regulation and sensible public policies.

C. *Additional Parties*. Additional parties may join the Forum discussion only with the agreement of the Stakeholder Forum membership and the Sponsor.

D. *Attendance at Meetings*. Each Stakeholder Forum Member must make a good faith effort to attend each full meeting. Attendance at 4 of the 5 anticipated sessions is expected. Attendance at the final meeting is mandatory. If a Member cannot make one of the meetings, an alternate can be sent to take notes and to respond to questions. The Member must provide advance notice of the name and background of the alternate. The alternate should be knowledgeable about biotechnology issues and the topics to be discussed at the meeting. The alternate is not allowed to determine consensus or lack thereof. It is the responsibility of the Member and the alternate to exchange information and keep each other well-informed and briefed concerning the deliberations. All alternates are bound by these Operating Procedures.

E. *Withdrawal from the Stakeholder Forum*. Any Member may withdraw from the Forum at any time without prejudice. If a Member wishes to withdraw from the Stakeholder Forum, he or she is requested to give the group the reasons for withdrawing. The decision to replace a Member will depend on factors such as how far along the group is in the decision-making process, whether the addition of a new member would be disruptive, and whether the loss of the interests represented by the withdrawing Member creates a serious imbalance on the Stakeholder Forum in terms of expertise and/or interests.

3) DECISION MAKING

A. *Product*. The intended product of the process is a written agreement describing recommendations to enhance the ability of U.S. policies, programs, and regulations governing agricultural biotechnology products to ensure protection of human health and the environment.

B. *Consensus*. The Stakeholder Forum will operate by consensus. Recommendations or other documents will be considered to have achieved consensus if there is no dissent by any Member of the Stakeholder Forum. For the final report containing the recommendations of the Stakeholder Forum, consensus will be defined by the following, “As a package of ideas and recommendations, all Stakeholder Forum Members can live with and support the overall direction of the recommendations.” On issues or ideas viewed as important by Stakeholder Forum Members but where consensus

cannot be reached, the Stakeholder Forum will articulate the areas of agreement and disagreement and the associated reasons why the differences of opinion exist.

C. *Procedural Decision Making*. The Stakeholder Forum also will strive to operate via consensus on procedural matters, such as forming work groups, structuring sessions, and concluding discussions.

D. *Absence of Consensus*. In the event consensus cannot be achieved, either procedurally or concerning the finalization of a report containing recommendations, the Facilitator, in consultation with the Sponsor, will propose a means of moving forward. Agreement will be sought on proposals, but are not essential for action. Reports from subgroups of Members (so called "majority-minority reports") describing the work of the Forum may be issued only if agreed by all Members. The Sponsor may use the ideas and products developed by the Forum as a basis for making recommendations to improve the existing regulatory infrastructure as the Sponsor may independently choose to develop or advocate. If the Sponsor refers to the Forum's role in developing any ideas or products, the Sponsor will include a disclaimer indicating that the ideas or products do not represent the views of, and have not been endorsed by, the Forum or individual Members, unless a Member gives the Sponsor permission.

4) ORGANIZATIONAL STRUCTURE

A. Roles and Responsibilities

i. *Pew Charitable Trusts and Pew Initiative on Food and Biotechnology – "Sponsor."* The sole sponsor of the Forum is the Pew Charitable Trusts and the Pew Initiative on Food and Biotechnology (PIFB), of which the Forum is one component. The Sponsor will serve as a financial and staff resource for the operations of the Forum. The Sponsor will serve as a neutral participant in all Forum and work group meetings and will assist the Facilitator in carrying out the facilitator's role. The Sponsor will provide or obtain technical assistance, including preparing resource and other materials as requested by the Forum. The Sponsor will keep the Members of the Forum informed of the public activities of the PIFB. Keith Pitts will serve as the primary point of contact at PIFB for the Forum.

ii. *Facilitator.* A neutral Facilitator will chair the meetings and work with all of the Members to ensure that the process runs smoothly. The Facilitator serves at the will of the Forum and may be replaced by another as determined by the Forum and the Sponsor. The role of the Facilitator usually

includes developing draft agendas, focusing meeting discussions, working to resolve any impasses that may arise, preparing meeting summaries, assisting in the location and circulation of background materials and documents the Forum develops, and other functions as the Forum requests. Abby Dilley, Robert Fisher, and Paul De Morgan of RESOLVE will serve as the Facilitator.

iii. *Work Groups*. The Forum is expected to conduct its deliberations primarily through the whole group. Under special circumstances and as a last resort work groups may be formed, as approved by the Forum and the Sponsor, to address specific issues and to make recommendations to the Forum. Work groups are open to any Member or the Member's designee, plus such other individuals as the Forum believes would enhance the functioning of the work groups. Work groups are not authorized to make decisions for the Forum as a whole. All Members will be notified of all work group meetings. Designees and other individuals participating in work groups must agree to be bound by these Operating Procedures.

iv. *Caucus Groups*. Any Member may request a break at any time for purposes of caucus within a party or between parties. Members requesting a caucus will be asked for a realistic estimate of the time needed. Caucuses will meet in closed session. Any Member may request that the Facilitator excuse others from a session to discuss confidential information with the Facilitator. The Facilitator also may be excused from a session.

v. *Resource Participants and Other Key Representatives Interacting with the Stakeholder Forum*. Resource participants, technical consultants, and other key representatives interacting with the Forum may attend meetings as observers by invitation with the agreement of the Members and the Sponsor. Invited guests may not participate in discussions at the table unless the Members agree otherwise and must agree to be bound by the same ground rules as the Members. The Members will decide how the Forum will interact with individuals and groups not participating in the Forum, including Congress and the federal executive branch, to identify potential resources for the Forum and to assess topics or approaches under consideration.

B. Administrative Procedures

i. *Documentation and distribution of deliberations and decision making.* The purpose of this section is to preserve and protect the integrity of the Forum process until it is completed. Forum meetings, including work group meetings, will not be electronically recorded by any person. Draft meeting summaries will be prepared by the Facilitator after each meeting,

and approved by the Forum. The meeting summaries will serve as a means of characterizing the discussions at each meeting and will not attribute statements to specific Members or interest groups. Meeting summaries are for use by the Members and the Sponsor and will not be made available to the public. Meeting summaries approved by the Forum may be shared with constituents as long as they agree to be bound by these Operating Procedures. All proposals and draft recommendations will be treated as confidential. At each meeting the Forum will determine what information or documents may be made public following the meeting. All other products produced by the Forum will be confidential, unless otherwise agreed by the Members, until the conclusion of the Forum. Agreement on final recommendations will be indicated by an appropriately authorized signature of each Member.

ii. *Meeting organization*. All sessions of the Forum will be closed, unless opened to the public by the full agreement of the Members. Meeting agendas will be drafted by the facilitator in consultation with the Forum and the Sponsor. Agendas will be reviewed at the beginning of each meeting, refined as necessary, and approved by consensus of the Members attending the meeting.

iii. *Expenses and reimbursements*. The Sponsor has dedicated funds to cover the estimated travel expenses of the Members. The Facilitator will handle travel arrangements and reimbursing Members for reasonable expenses for travel to Forum meetings. As there is a limited amount of money available for travel and the meeting schedule will be established, Members are expected to plan their travel in advance to realize cost savings.

iv. *Electronic Equipment*. Members and other participants are requested not to bring beepers or cellular telephones into the meetings.

5) SAFEGUARDS FOR THE PARTIES

A. *Good Faith*. All parties agree to act in good faith in all aspects of the Forum deliberations, to conduct themselves in a manner that promotes joint problem solving and collaboration, and to consider the input and viewpoint of other participants. Members agree not to use specific offers, positions, or statements made by another Member during nonpublic discussions for any other purpose not previously agreed to in writing by the Members involved. Personal attacks will not be tolerated. Negative generalizations are not productive and have the potential to impede the ability of the Forum to reach consensus. All Members will be given an equal opportunity to be heard with

the intention of encouraging the free and open exchange of ideas, views, and information prior to achieving consensus.

B. *Confidentiality.* To foster open and frank dialogue, the Forum is a nonpublic, confidential process. All Members, the Facilitator, and the Sponsor agree not to divulge information shared by others in confidence. The identity of the Members will be public. In addition, the information and documents determined by the Forum at each meeting to be public may be distributed publicly.

C. *Public Statements.* The Members recognize that how the Forum process and the Members' views are described publicly may affect the ability of the Forum to reach consensus. Therefore, whenever possible, Members will refer inquires regarding the overall progress of the process to the Facilitator or the Sponsor. If a Member does engage in discussions with the media or others, the Member may describe the purpose of the Forum, the scope of topics under discussion, and their own views. Members will not describe or characterize the position of any other Member, nor will any Member seek to place blame on any other Member, even if that Member withdraws from the process or the process is discontinued. References to the Forum on a Member's website will include a link to the Sponsor's website.

D. *Sharing of Relevant Information.*

   i. Members agree not to withhold relevant information that is readily available, as long as providing information that is not readily available does not cause an undue burden and the party explains the reasons for objecting to providing the information. If a Member believes they cannot or should not release relevant information, they will provide the substance of the information in some form (such as by aggregating data, by deleting non-relevant confidential information, by providing summaries, or by furnishing it to a neutral consultant to use or abstract) or a general description of it and the reason for not providing it directly.

   ii. Members will provide information called for by this paragraph as much in advance of the meeting at which such information is to be used as is reasonably convenient.

   iii. Neither the Forum nor the Sponsor can protect confidential business information (CBI). If information required for deliberations can only be derived from CBI, then the information may only be received by the Forum in aggregate form so as to protect specific CBI from release.

E. *Rights in Other Forums.* Participation in the Forum process does not limit the rights of any Member. Members will make a good faith effort to notify

one another in advance if another action outside the process will be initiated or pursued that will affect the terms of proposals, recommendations, or agreements being discussed.

6) SCHEDULE

The Forum is expected to meet five (5) times over the course of 16 months. Unless extended by the Members and the Sponsor, the deliberations will conclude in August 2002. [Note: 11 plenary sessions were ultimately held and the Forum concluded in May 2003.]

Appendix F* Essential Components and Characteristics of a Regulatory System

In order to protect public health and the environment without unduly burdening the development of innovative, productive, and sustainable agricultural practices, Forum members agreed that a set of fundamental building blocks, or components, needs to be in place in the regulatory system. These components include adequate legal authority, adequate resources, a safety-driven approach to risk assessment, and appropriate risk management. Furthermore, in order to ensure continuous improvement, and to build and maintain public confidence in the regulatory system, members agreed that the system must be adaptive, efficient, equitable, transparent, and participatory. These components and characteristics are discussed in this section.

1) COMPONENTS

A. *Adequate Legal Authority*
Forum members agreed that federal law must provide for a comprehensive and understandable regulatory system that is endowed with sufficient authority to make and enforce protective decisions. The regulatory system must have a broad enough scope to address the full range of human and environmental safety issues associated with specific products of agricultural biotechnology. It also needs to have adequate authority to both obtain the data required for decision making and enforce decisions in a timely fashion.

B. *Adequate Resources*
The regulatory system must be adequately funded. The relevant agencies must have enough funding to:

- provide comprehensive oversight,
- retain qualified staff,
- conduct independent reviews when appropriate,
- conduct research and testing when appropriate,
- provide for public participation in decision-making processes, and
- make timely decisions.

C. *Safety-Driven Risk Assessment*
In order to ensure public confidence in the regulatory system, the regulatory process for each product must begin with an assessment of the product's potential risks to public health and the environment. A science-based, safety-

* Forum members used this working draft to guide their assessment of the current regulatory system and possible approaches for changing it. The document served as a useful analytical tool during the discussions, but it is not a consensus recommendation.

driven risk assessment involves generating information on the potential for risk and rigorously studying and analyzing the product. The assessment process should be receptive to both new and historical information regarding the level of hazard posed by the product.

Regulatory needs can and should drive scientific discovery to aid in the development of the knowledge base underpinning the regulatory process. Policy makers should encourage, through open debate and the public funding of research, the continuing evolution of the knowledge base underpinning regulatory processes and decisions. Although scientific knowledge continues to change, scientific uncertainty should not preclude regulators from making decisions. Also, the scientific bases for regulatory decisions should be stated plainly.

D. *Appropriate Risk Management*

Risk management—the process of making decisions based on risk assessments —should be applied to regulatory decision making regarding agricultural biotechnology. In general, benefit considerations should not enter regulatory decision making until a product meets a basic threshold of safety for public health that has been set by Congress or the relevant government agency. Once that threshold has been met, products of agricultural biotechnology should be regulated relative to the risks posed by other food or agricultural products and processes.

Depending on the regulated product and the statute under which it is regulated, risk management may include a consideration of benefits and policy concerns. These considerations may include economic, nutritional, and other benefits; public concerns; and any circumstances that may affect compliance with regulatory restrictions. The preferred risk management strategy protects public health and the environment at a minimal cost and with minimal market impact. It uses management techniques that are risk-based, accurate, verifiable, understandable, and not misleading. When considering risks and benefits, products of agricultural biotechnology should not be compared solely to the status quo, but also to other available and reasonable alternatives.

2) CHARACTERISTICS

A. *Adaptive*

Forum members agree that, over time, the regulation of agricultural biotechnology products to protect public health and the environment should adapt as needed. This adaptation should take place as:

- scientific knowledge of agricultural biotechnology and its attendant risks and benefits expands;

- measurement and detection capabilities improve;
- product attributes change; and
- experience with the regulatory system is gained.

As this adaptation takes place, the decision-making criteria used by regulators should always be clear to all interested parties. Also, the criteria should be subject to review and revision as new data arise or experience and understanding warrant.

B. *Efficient*
To be efficient, regulators must clearly, and in advance, specify the scientific and other information required from an applicant in order for the regulatory analysis to be conducted. Enough specificity must be provided so that the applicant knows what is expected, and where, when, and how the information should be provided. Regulators should require regulated parties to submit only that information that is necessary to help achieve the goals of regulation. When more than one agency is involved, a lead agency should be identified, and all agencies should coordinate their efforts with each other. Agencies need to share information provided for their respective reviews, coordinate any additional information requests, and ensure that any regulatory conditions imposed on an approved product are not inconsistent or contradictory. Also, regulating agencies should conduct their reviews in as timely, cost-effective, and productive a manner as possible.

C. *Equitable*
The level of regulation, and the regulatory parameters chosen, should be based on the relative risk to public health and the environment posed by products of agricultural biotechnology. In addition, the regulatory system should treat similar products in a consistent manner and make decisions based on established criteria, independent of the process used to produce the product, unless that process itself raises unique safety concerns.

Regulators should be mindful that costly and complex regulations have the potential to stifle the consideration of novel solutions and deny new and innovative companies the ability to gain market access. The regulatory system should compare biotechnology approaches to other approaches used in agriculture, as well as food safety and environmental issues, in promulgating their regulations.

D. *Transparent*
The regulatory requirements for bringing agricultural biotechnology products to market and for monitoring those products after they reach the marketplace must be clear, understandable, and open to public review. Registrants and the public are entitled to a predictable regulatory environ-

ment and should have access to information about the regulatory process and any changes made to it. As individual products move through the regulatory process, all interested parties should have access to health and safety data and other product data that is not confidential business information. Agency decisions, and the underlying rationale used in making them, should be open for public comment and input.

E. *Participatory*
Regulatory agencies should ensure that opportunities are available for citizens and members of the affected and interested public to be involved in the agricultural biotechnology regulatory system, including post-marketing monitoring. These opportunities could include, for example, public hearings, opportunities to comment on policies and rules, opportunities to comment to advisory committees, and timely access to relevant information, as appropriate. In most instances, the public should have the opportunity to offer formal input. Regulatory agencies should analyze and respond to the issues raised, including those criticizing agency decisions, in a timely manner.