
Breakout Sessions: Summary of Discussions and Recommendations

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The NABC-17 workshop discussions focused on *Bioremediation, Phytosensing, and Ecores-toration; Gene-to-Product Development; and Regulation, Consumer Acceptance and Risk Management*. For the first two topics, the following aspects were discussed: opportunities for innovative applications, obstacles to innovative applications, how public policies could overcome the obstacles, and how research and development could be advanced. For the third topic, discussants focused on the public's beliefs and attitudes about agricultural biotechnology, actions that industry could undertake to address consumers' fears and concerns. Participants were encouraged by the facilitators to focus on non-food applica-tions for genetically modified (GM) plant technologies in defining appropriate evaluation criteria. The workshop discussants focused largely on impediments to commercializa-tion and public acceptance of non-food products of biotechnology. The predominant observations were that the companies involved in commercialization of new, non-food technologies tend to be small, such that the regulatory process is particularly burdensome. Broad-ranging recommendations listed below focused on industry, the regulatory agen-cies, public acceptance and associated policy needs, and the role of public-sector entities such as universities and the government:

ROLE OF INDUSTRY

- Improve communications between and among scientists in the private and public sectors, and with consumers and policymakers. Pro-actively seek partnerships with groups who share mutually desired outcomes who would help with funding, regulatory approval, commercial development, and market acceptance of geneti-cally modified products.

¹This summary draws upon a verbal report on the workshop discussions delivered at the end of the conference by Lori Garkovich (University of Kentucky) who received input from fellow-facilitators Kim Jensen (University of Tennessee), Bill Park (University of Tennessee) and Randy Weckman (University of Kentucky).

- Create more effective messages that fairly and adequately address the costs and benefits of biotechnology, emphasizing how GM products can help address critical public concerns (*e.g.*, improvement of environmental quality).
- Acknowledge public concerns and fears by explaining how the current research, development and regulatory processes already guard against potential problems.

REGULATORY AGENCIES

- A strong theme of the conference was that regulatory policies should be focused on the product rather than the process used to produce it. Therefore, participants recommended redesigning the regulatory process by basing decisions on a broader, different, and more clearly defined set of criteria and developing new roles for participants in the process.
- Regulatory decision processes should be transparent and should utilize cost, benefit, and liability analyses that include a cost accounting throughout the life cycle of the product to determine the speed and priority of regulatory reviews.
- Regulators should clearly define what steps must be completed and what information is necessary for approval of a genetically engineered product. Small companies in particular lack the intellectual infrastructure and financial capital to effectively negotiate a regulatory approval process that is still dynamic and often lacks clarity with respect to criteria for decision-making.
- As part of redefining the regulatory process, agencies should evaluate current definitions and standards for key concepts used in the evaluation and approval process and consider their applicability to GM plants with respect to site remediation, risk assessment, liability and adventitious presence.
- Dialogues with regulatory agencies and multiple stakeholders should be opened in an effort to identify common ground, and encourage regulators to become proactive spokespersons in explaining the decisions they render.

CONSUMER ACCEPTANCE AND PUBLIC POLICIES

- For the smoothest path to commercialization to occur, a shift to a “market-driven” rather than a “science-driven” focus needs to guide the research and development process. In particular, because of issues related to GM foods, other GM technologies must be developed with a clear understanding of consumer acceptance and risk-benefit analyses. These needs are compounded when one considers international cultural, social and political environments.
- A knowledge/information gap exists between scientists who develop technologies and those who will use them. With respect to the technologies addressed at NABC 17, there is a clear opportunity to educate the public about potential risks and benefits. With bioremediation in particular, the purchaser is likely to be a government agency but perhaps still subject to the same perceptions as the general consumer.

- It is also recommended that an informed public-policy discussion begin to assure that planning and funding for bioremediation activities be placed up-front into site-planning for industrial and commercial construction sites. These activities should include preference for phytoremediation practices, where possible, at federally funded cleanup sites, tax incentives to promote the use of phytoremediation, and allocation of pollution fines or Superfund monies for this activity.
- Strategies should be employed to build on existing public support for technology applications such as the following: animal vaccines and veterinary uses, agricultural crop phytosensing to improve the efficiency of crop production, and research on plant-made pharmaceuticals (PMPs) directed at “orphan” diseases and health needs in developing countries.
- A clear recommendation to encourage continued public acceptance of PMPs is to focus such research on crops that cannot cross with other food/feed species, such as *Nicotiana* plants developed by the Kentucky Tobacco Research and Development Center.

ROLE OF UNIVERSITIES, GOVERNMENT AND PUBLIC-SECTOR ORGANIZATIONS

- Workshop participants recognized the role of public research institutions as a driving force in creating knowledge for development of new technologies. It is recommended that the reward system of universities be reoriented to encourage intellectual efforts directed towards the commercialization pipeline.
- Continued coordination and communication with regard to university-owned technologies, as conceptualized by the Public Intellectual Property Resource for Agriculture (PIPRA), is strongly recommended. The PIPRA initiative recognizes the collective strength of public research institutions with respect to the number of patents controlled. Most importantly, PIPRA not only serves in clarifying issues related to freedom to operate, but also promises to inform and streamline the regulatory approval process.
- Creation of a repository of novel GM organisms was recommended to ensure their preservation for possible future use. Development of many products is in abeyance due to the current climate of regulatory requirements and consumer acceptance, which collectively result in less venture capital investment.
- The workshop participants advocated study by a newly commissioned National Research Council committee to examine scientific, regulatory and liability issues related to non-food, non-energy uses of GM plants. The charge should include evaluating the roles of phytoremediation and PMPs in enhancing environmental quality and human health and to make recommendations on regulatory aspects.
- Increase funding to regulatory agencies sufficient to address the greater challenge posed by biotechnology research and its commercial products.

- Universities also need to expand the scope of work of their Offices of Technology Transfer to include seeking potential partners for GMO research at the beginning so that commercialization issues (such as market applications) can be incorporated into the research and development process.
- Universities should promote science literacy by developing K–12 science education modules to introduce students to biotechnology and working with state curriculum committees to include biotech issues in science curricula.
- A recurring theme of the conference was that public-sector entities like NABC, universities, and government agencies should strive to improve communications between/among scientists, industry, public and policymakers, with particular emphasis on risks and benefits of new technologies. It is considered that the extension services of land-grant universities could be important forces in reinvigorated communications efforts. These efforts should acknowledge public concerns and fears by explaining how the current research, development and regulatory processes already guard against potential problems.