



May 9, 2003

Docket No. 03-031-1
Regulatory Analysis and Development
PPD, APHIS, Station 3C71
4700 River Road Unit 118
Riverdale, MD 20737-1238

Re: Docket No. 03-031-1

To whom it may concern:

This letter is submitted by the Biotechnology Industry Organization (BIO), in response to the request for comments made by the U.S. Department of Agriculture (USDA)'s Animal and Plant Health Inspection Service (APHIS or the Agency) in the Federal Register on March 10, 2003, accompanying the announcement of the 2003 APHIS permit conditions for "Field Testing of Plants Engineered to Produce Pharmaceutical and Industrial Compounds."¹ BIO members represent the majority of those entities that will be operating under the APHIS permits described in the Federal Register notice. BIO and its member companies involved in the development and commercialization of plants engineered to produce pharmaceutical and industrial compounds are committed to the safety of these products at all stages of development and production.

BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations in all 50 U.S. states and 33 other nations. BIO members are involved in the research and development of health-care, agricultural, industrial and environmental biotechnology products, including biotechnology-derived crops intended for uses other than food or feed.

BIO fully supports the Agency's efforts to improve and enhance this permitting process. We appreciate the permitting program's flexibility, which allows the Agency to tailor permit conditions to address new information, technical innovations, and experience gained from compliance monitoring, as well as feedback from the public. We hope that APHIS will continue to address new advances in science that affect both current and future uses of the technology.

¹ 68 Fed. Reg. 11337 (March 10, 2003).

BIO members operating under the APHIS permit conditions set forth in the March 10, 2003 Federal Register notice are working hard to meet those conditions as planting season ensues. BIO members are committed to full compliance with all of their permit conditions, including those most recently announced. We also support the increased oversight and review that APHIS has pledged in this notice.

In the March 10 Federal Register notice, APHIS makes reference to plants that have been modified through biotechnology to produce industrial compounds. APHIS defines these “industrial plants” as follows:

“Industrial” plants include those genetically engineered plants that are not intended for use as food or feed, but rather are intended to produce compounds that will be extracted for industrial uses. The range of potential uses of such substances includes, for example, applications in detergent manufacturing, paper production, mineral recovery, or in purely experimental research.²

BIO supports USDA's regulatory oversight of industrial plants and agrees that, in defining this category of plants, it is appropriate to exclude plants that are intended for use as food or feed. However, BIO believes that the definition above may inadvertently include certain plants producing materials or compounds that may be otherwise regulated by FDA as food, feed or pharmaceutical products, or by EPA as plant-incorporated protectants. On the other hand, the definition should not be limited to plants that produce materials or compounds that must be extracted in order to be used for industrial purposes, but should be broad enough to include plant materials or compounds that may be used for such purposes without extraction. Finally, the definition should adequately address the range of experimental research anticipated for biotechnology-derived crops. In order to clarify these points, BIO would support the following amendments to this definition of “industrial plants” in future USDA references:

“Industrial plants” are genetically engineered plants that produce Plant-Made Industrial Products (PMIPs). PMIPs are materials or compounds that are intended solely for industrial uses. PMIPs are intended not for use for food, feed, food or feed additives or processing aids, plant-incorporated protectants, pharmaceuticals or pharmaceutical ingredients, or in experimental research for such uses. The range of potential uses of such PMIP materials or compounds includes, for example, applications in detergent manufacturing, paper production, mineral recovery, environmental remediation, or in experimental research for such uses or in basic research.

² *Id.* at 11338.

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APHIS has sought public comment on three specific areas: transparency, confinement and compliance. With regard to the first of these issues, BIO and its members are fully committed to providing APHIS and all appropriate regulatory agencies will all information necessary for the appropriate oversight of this industry. BIO members appreciate the interest that some members of the public may have in field tests of PMPs, and support the efforts that APHIS has undertaken, including this Federal Register notice, to provide greater transparency to the permitting process, consistent with the need to avoid disclosure of trade secrets and other sensitive business information. We encourage APHIS to take steps to provide the most accurate information possible regarding the types of permits being issued, whether for importation, interstate movement or field testing. We will continue to work with APHIS to provide increased transparency in the future, to aid in public understanding, and confidence, in this permitting process.

With regard to confinement, BIO and its members support permit conditions requiring the implementation of stringent Standard Operating Procedures (SOPs), focused on critical production activities (e.g., planting, harvest, etc.). Such confinement measures and SOPs should be appropriate to each stage of product development. BIO members have previously committed to submit detailed confinement plans and SOPs with all of their permit applications. We strongly encourage the Agency to treat these plans and procedures as permit conditions, subject to audit and inspection.

Finally, as mentioned above, BIO and its members support the increased oversight and regulatory review of permit compliance discussed in the March 10 announcement. The increase in field site inspections and in record auditing will allow BIO members to demonstrate the efforts they are taking to fully comply with permit conditions. BIO urges USDA to devote sufficient resources to APHIS to ensure that this type of oversight can continue in the future. Moreover, our members will ensure that APHIS receives the information needed by the Agency to fulfill its oversight responsibilities under federal law.

BIO very much appreciates the opportunity to comment on the issues set forth in the March 10 notice, and looks forward to working with APHIS and with other stakeholders to find ways of fulfilling the promise of this technology, while protecting the health and safety of the public and the environment.

Sincerely,

A handwritten signature in cursive script that reads "Michael J. Phillips".

Michael J. Phillips, Ph.D
Executive Director
Food and Agriculture