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September 22, 2006

Oregon Department of Agriculture  
**Biopharm Comments**  
c/o ODA Plant Division  
635 Capitol Street NE  
Salem, OR 97301-2532

**To: Oregon Department of Agriculture, Oregon Department of Human Services  
and Members of the Biopharming Ad Hoc Committee**

The Biotechnology Industry Organization (BIO) and Oregonians for Food & Shelter (OFS) appreciate the opportunity to comment on the draft policy document prepared by the Oregon Biopharming Ad Hoc Committee.

BIO is the national trade association for the biotechnology industry, representing more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and 31 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products, with over 300 biotechnology-derived drugs in clinical development addressing cancer, heart disease, Parkinson's, Alzheimer's and other intractable diseases.

OFS is a member-funded, state grass roots coalition representing more than 11,000 natural resource based individuals, businesses and trade organizations in Oregon, including BIO. OFS's mission is "to promote the efficient production of quality food and fiber, while protecting human health, personal property and the environment, through the integrated, responsible use of pest management products, soil nutrients and biotechnology." This is OFS's 26th year of service to Oregon's natural resource base and the businesses and communities it supports.

New advances in biotechnology make it possible to turn plants into "factories" that produce therapeutic proteins for use in the manufacture of drugs, medicines and therapies. Plant-made pharmaceuticals (PMPs) are the result of an innovative application of biotechnology to plants to enable them to produce therapeutic proteins that could ultimately be used by the medical community to combat life-threatening illnesses. BIO and OFS and its members are committed to protecting human health and the environment by ensuring the safety of PMPs during all stages of

development and production through a close working relationship with state and federal regulatory authorities to assure that applicable requirements are both rigorous and enforceable.

BIO and OFS applaud the commitment the State of Oregon has shown to new technologies and research through initiatives such as the Oregon Nanoscience and Microtechnologies Institute. That commitment is also evident in the thoughtful approach the Committee has taken to the issues involved with the cultivation of PMPs. It is BIO's and OFS's position, however, that the Committee's recommendations as a whole are premature at this point.

The U.S. Department of Agriculture (USDA) established its Biotechnology Regulatory Services (BRS) division in 2002 to place increased emphasis on USDA's regulatory responsibilities for biotechnology. Prior to that time, plant products of biotechnology were regulated under the general authority of USDA's Animal and Plant Health Inspection Service (APHIS). APHIS has a long history of regulating agricultural biotechnology products, overseeing the safe conduct of more than 10,000 field tests of plants produced through biotechnology.

Since 2002, BRS has been consistently reviewing and strengthening the requirements for PMP field trial permits, as well as the rigor of the division's oversight of permit compliance. These modifications to the PMP permitting requirements are based on the experience that BRS personnel have developed over years of dealing with these types of field trials. It is anticipated that PMP permit requirements will continue to be strengthened over the next several planting seasons. Doing so at the federal level promotes needed uniformity and a level regulatory playing field across the entire U.S. This puts no state in a position of advantage or disadvantage.

Additionally, BRS announced in 2004 that it was undertaking substantial revisions to its regulations for all plants developed through biotechnology, including PMPs. These regulations will reflect new authority that USDA was granted under the Plant Protection Act of 2000 and, according to public statements made by BRS, will fundamentally alter certain aspects of the current permitting system, including that used for PMP permits. The promulgation of these new regulations is being accompanied by the preparation of a Programmatic Environmental Impact Statement (PEIS), which will examine the potential environmental impacts of this rule-making. The PEIS process includes the opportunity for public comment. Additionally, the rulemaking itself will be subject to public notice and comment. We understand that BRS currently anticipates publication of the draft PEIS by winter of 2006 – prior to the 2007 growing season.

In the interests of regulatory economy, the State of Oregon would be best served by directing its resources towards participating in the ongoing federal policy revisions and rulemaking processes, rather than moving ahead prematurely with a policy that would unnecessarily stifle new and valuable technology. Until the State has a better understanding of the types of permit requirements that will be implemented at the federal level, as well as any unique issues that might require review at the state level, adopting policies at the state level may well prove an unnecessary expenditure of time, effort and limited financial resources.

Moreover, a number of the specific recommendations do not appear to be designed to address Oregon-specific issues, but are much more broadly based. It would be more appropriate to submit these approaches to BRS for nationwide consideration rather than to seek to impose them at the state level. If, based on its years of experience with these field trials, BRS does not determine that certain specific measures need be taken to protect agriculture and the environment nationwide, there may be little basis to require such measures in a particular state.

Additionally, several of the proposed recommendations are likely to disproportionately stifle research and development efforts by small companies and academics. Requiring a researcher to post a bond or demonstrate financial responsibility for potential inadvertent release would create an insurmountable burden, essentially preventing those researchers from operating in the State. It would be particularly onerous and detrimental to future research programs at State universities, as their research budgets have been slashed and are already overtaxed. This requirement is neither science- nor risk-based, and is not based on any evidence of harm to human health or the environment caused by any PMP planting.

As the Committee recognized, any adventitious presence from PMP field trials is likely to pose no significant impacts on human or environmental health. The State of Oregon does not require the posting of bonds or other demonstration of financial responsibility for other agricultural activities. Even a suggestion that a financial requirement would be necessary would erroneously portray PMPs as needlessly dangerous to agriculture and human health.

Another proposed recommendation would work a similar hardship on small companies and academic researchers. As the Committee has recognized, the creation of an extensive permit review system for PMP field trials would require significant State expenditures, and would likely become a resource burden for the State. However, due to the small size of this industry, and the high percentage of small companies and academic researchers in the field, application fees high enough to pay for services would inevitably be more expensive than most researchers could bear. Given the extensive regulatory oversight administered by BRS, the cost involved with extensive State oversight would be an unnecessary expense, whether paid for by researchers or the State.

Another proposed recommendation suggests that the State enter into an agreement or Memorandum of Understanding (MOU) with BRS regarding certain information and authority sharing. While all interested stakeholders agree that increased collaboration among the state and federal governments should be encouraged, several provisions of the proposed MOU will require careful legal scrutiny. With regard to the sharing of confidential business information (CBI), such cooperation will depend on the State Department of Agriculture's ability to adequately protect the information. This will, in turn, depend on State law, which would be beyond the scope of any MOU. Similarly, the proposed MOU provision that would authorize the State to modify, restrict or veto a permit would appear to conflict with the scope of BRS's authority as set forth in the federal Plant Protection Act of 2000.

Changes made by ODA to their CBI statues in 1999 when promulgating the Pesticide Use Reporting System insured confidentiality of that information. Perhaps this is a template ODA can use to expand CBI protection to include confidential PMP information.

BIO and OFS support the careful and balanced approach the Committee has taken with regard to this issue. We highly support the State's efforts to encourage new technologies, to strengthen its communications with the public regarding the role new technologies play in Oregon, and to increase the State's interaction with federal authorities regarding PMPs.

However, in order to make the most effective use of both State and federal resources, BIO and OFS suggest that the State take no further action on regulatory components of this policy until the completion of the current federal rulemaking. During the course of that rulemaking, the State

will have the opportunity to more fully explore all its recommendations, and to receive feedback from not only BRS, but from a multitude of other interested states and other stakeholders. Once that process is complete, the State will be in a position to better understand whether any additional action may be necessary.

With no existing PMP problems in Oregon and no PMP planting permits even requested for the near future, the State can afford to take some extra time to deal with this issue using a scientifically based, uniform and federally coordinated approach that protects the public, the environment, Oregon's research community, the economy and the societal benefits this technology will likely bring.

Again, BIO and OFS appreciate the opportunity to present their views on this important issue, and offers any help and technical expertise our organizations can provide in the future.

Respectfully,

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