Biopharm Ad Hoc Committee
November 28, 2005
Meeting Minutes

Present
Members: Katy Coba, Thayne Dutson, Bernie Faber, Keith Harcourt, Candace Mueller, Sean Neilson, Jim Rue, Gail Shibley, Steve Strauss, Lisa Weasel
Staff: Susan Allan, Paul Cieslak, Don Hansen, Christina Hartman, Dan Hilburn, Jim Kanoff, Joel Sherman, Dave Stone
Guests: Oregon Physicians for Social Responsibility, Rick North

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Meeting called to order by Jim Rue at 1:05 p.m.

Handouts: November 28, 2005 Meeting Agenda; DRAFT Department of Agriculture and Department of Human Services Biopharm Ad Hoc Committee Workplan; Possible Stakeholder/Interested Parties List; Glossary of Biopharmaceutical Terms; Biopharmaceutical Crops, Issues for Oregon, Prepared by Dan Hilburn; Role of State Advisory Bodies in Decisions to Commercialize Biotech Crops: California's Pharma Rice Experience; The State Role in Permitting of Pharmaceutical and Industrial Crops: Colorado's Development of a Public Process; APHIS Fact Sheet – Permitting Genetically Engineered Plants that Produce Pharmaceutical Compounds, July 2005; The ProdiGene Incident; StarLink Corn; and Risk Presentation.

Introductions, Mission, Structure, Objective, Process, Timeframe
Jim Rue welcomed the members and invited introductions.

Background - Katy Coba
During the 2005 Legislative Session, legislation placing a four-year moratorium on any bio-crop production in Oregon was introduced. Although SB 570 did not make it out of committee on the House side, the topic led to discussions and the development of an interim committee, charged by the Governor's Office and the Senate, to review and develop a policy recommendation to the Governor.

Workplan Discussion
The Committee discussed the scope of their workplan and decided to limit their review to biopharming (defined as the production of pharmaceutical proteins in genetically engineered plants) recognizing the fact that there is entirely another area yet to be addressed including crops used to manufacture industrial compounds and biopharmaceuticals developed in non-plant products, such as animals.

The Committee's goal is to develop a consensus (general agreement of the Committee) policy recommendation to the Governor in respect to biopharming.

The Committee will consist of three State Board of Agriculture and Public Health Advisory Board Members and two scientists. Department of Agriculture Director, Katy Coba, and Department of Human Services, Office of Public Health Systems Administrator, Gail Shibley, will participate on the committee as non-voting ex-officio members.

Because of the relatively constrained time frame, technicality and required continuity of participation, a Committee member may not have an alternate attend in their place. Members unable to attend a meeting are asked to contact the Chair or Vice-Chair of the Committee. Permanent replacements may be made dependent upon where in the process the Committee is.

The Committee will meet monthly for the next ten months. The Department of Human Services will provide technical and administrative support for the first five meetings and the Department of Agriculture will provide support for the remaining meetings. Dave Stone will be taking the technical lead for the Department of Human Services and Dan Hilburn will take the technical lead for the Department of Agriculture.

Action:
Work plan will be updated by technical staff to reflect discussion and will be presented to the Committee at the December meeting.

Technical Workgroup Presentation

Current Federal Regulations

The U.S. Department of Agriculture's (USDA), Animal and Plant Inspection Service (APHIS), Biotechnology Regulatory Services (BRS) Program currently regulates the introduction of genetically engineered organisms to ensure the safe and confined introduction of new genetically engineered plants grown for use in making pharmaceutical and industrial compounds.

Developers interested in field-testing a pharmaceutical or industrial crop must obtain permission directly from the USDA. Permits are issued through APHIS on a case-by-case basis after a rigorous review process. While it is not required that the state be included in the review process, the Oregon Department of Agriculture also reviews the applications to see if any Oregon specific quarantines apply. Currently, the Oregon Department of Agriculture does not have staff trained specifically in genetically modified organism containment. In Oregon, the only permit issued to date was to grow alfalfa with amylase in 1995.

There is a need for Oregon's process to be reviewed to see what should be done in

addition to the review being done by the USDA. Legally, Oregon has the authority to establish control areas but does not have statutory authority over genetically modified crops.

Action:
Technical staff will contact Missouri to see what process they have in place and their legal authority.

Understanding Risk
Risk is the likelihood of harm resulting from exposure. Relative risk is the probability of harm using a new technology over the probability of harm using existing technology. Perceived risk is how risk is viewed by the public.

Two key steps are used to assess risk.

- Exposure assessment includes identifying the potential pathways, sources and exposed populations and estimating the concentrations.
- Toxicity assessment includes collecting qualitative and quantitative toxicity information and determining the appropriate toxicity values.

Once an exposure and toxicity assessment has been completed, the next step is to define the potential health risk, evaluate uncertainty and coherently summarize the information.

Uncertainties including random events and the lack of knowledge and understanding of the physical and biological system, human and ecological health and the cumulative risk to multiple sensors must also be considered. If the level of uncertainty is too high to conduct a meaningful quantitative risk assessment, a matrix can be used to define the severity of harm and the risk (probability of harm).

By taking these steps to define risk, risk management is accomplished.

Action:

- **Article by Charles Arntzen and Robert Peterson will be distributed to Committee members.**
- **List of all articles and outside sources used for the Committee will be developed.**
- **The technical workgroup will frame issues they believe the Committee needs to make an informed decision.**
- **Dave Stone will identify speakers for future meetings and technical information will be provided to the Committee before the meetings take place.**

- **BRS survey will be provided to the Committee once compiled.**
- **Specific contacts to the suggested stakeholder list will be provided to Christina Hartman.**

Meeting adjourned 3:13 p.m.

The next Biopharm Ad Hoc Committee meeting will be held on:

Monday, December 19
1:00 – 3:00 p.m.
Human Services Building, Rm. 160
500 Summer Street NE, Salem

If you would like this these minutes in an alternate format,
please contact Christina Hartman at (971) 673-1291.