

**STATE OF OREGON  
DEPARTMENT OF AGRICULTURE  
DIRECTOR'S OFFICE**

**Rulemaking Hearing Report  
Findings of Fact and Conclusion**

**Brent L Searle, Presiding Officer**

**HEARING DATE:** October 14, 2008  
Public comment was accepted through October 24, 2008.

**HEARING LOCATION:** OR Dept. of Agriculture, Hearing Room  
635 Capitol St. N.E., Salem, Oregon

**PROPOSED RULES:** Proposed OAR 603-052-1236. Establish a system for a coordinated joint review of any federal permit applications for growing biopharmaceutical crops in Oregon; permit requirements, review, monitoring protocols, and oversight fees; requirements for insurance.

**PUBLIC NOTICE**

A Notice of Proposed Rulemaking was published in the Oregon Bulletin of the Secretary of State on September 1, 2008. The notice was also published in the Oregonian, Eastern Oregonian, Capital Press and the Statesman Journal on September 2, 2008.

**PUBLIC HEARING**

The public hearing convened at 10:00 a.m.

Dr. Dan Hilburn, Administrator of the Plant Division, described the proposed rule and a brief history of the rule development. His complete testimony is marked as **Exhibit A**.

Dr. Hilburn described the proposed bill (SB 570) in the 2005 legislative session that would have restricted the production of biopharmaceutical crops to covered greenhouse areas and established other permit and review requirements. The bill created considerable discussion but did not pass. However, as a result of this discussion, the Oregon Department of Agriculture (ODA) and the Department of Human Services (DHS) were charged by the Governor and the Senate to convene an ad hoc committee to develop a consensus policy recommendation to address this issue.

The "Biopharm Committee" convened initially in November 2005, met a total of 11 times through October 2006, and produced a report entitled "Oregon Biopharmaceutical Committee: Policy Statement and Recommendations." The report was made available for public review and comment. The committee endorsed a moderate scope option, reflecting the interest of substantial State of Oregon involvement in federal regulatory decision about where and how biopharm crops may be grown in Oregon, without prohibiting the production outright.

In 2007, a second bill (SB 234) was introduced to make statutory changes necessary to implement the recommendations of the Biopharm Committee, providing ODA and DHS the regulatory authority to collaborate with USDA on the oversight of biopharm crops in Oregon. An advisory committee was formed in December 2007 to draft administrative rules; the draft was sent out for public comment in September 2008.

Dr. Hilburn indicated that the department supports the basic concepts and processes outlined in the proposed rule, but based on feedback from the Department of Justice, ODA's rules as written create procedural issues with DHS, as ODA cannot adopt rules that direct the activities of other agencies. DHS must adopt a similar rule in parallel with ODA's rule.

As a result of DOJ's direction, Dr. Hilburn indicated that ODA must redraft this rule and work in close coordination with DHS on the procedural aspects of the process to go forward. That would lay the groundwork for a Memorandum of Understanding with USDA for cooperative oversight of biopharm crops in Oregon.

The following persons were present at the hearing:

Rick North and Gretchen Miller, Oregon Physicians for Social Responsibility (OPSR)  
Michael Wach, Biotechnology Industry Organization (BIO)  
Terry Witt, Oregonians for Food and Shelter (OFS)  
Mitch Lies, Capital Press

In order of testimony, those who presented oral presentations are as follows:

Rick North, Project Director, Campaign for Safe Food, OPSR, (Portland, Oregon) provided oral testimony at the hearing and written testimony following the hearing (marked as **Exhibit B**). Mr. North provided an overview of OPSR's role in bringing forward the original legislative concepts in 2005 to address this topic, the organization's involvement in the Biopharm Committee and the subsequent 2007 legislation, and his role as a member of the rules committee.

Mr. North describes the interest of his organization with respect to the proposed rule as support for "enacting rules that would provide Oregon with enhanced protection from inadvertent contamination from biopharm crops that could be devastating for human health, the environment, and the economic interests of the farmers and food processors."

Mr. North urges that ODA and DHS move forward as quickly as possible so that the procedural requirements necessary can be remedied. He supports the current language of the proposed rules, with minor changes, and does not want the process "watered down in any way."

Mr. North does not believe that the U.S. Department of Agriculture (USDA) has demonstrated adequate regulatory oversight of biopharm crops, and he feels the involvement of the State of Oregon is critical: "It is absolutely necessary that Oregon go over and beyond the USDA's regulations."

Mr. North indicated that the federal "pre-emption" issue is not real. He points to numerous other states and counties that have programs, procedures, and legal requirements more stringent than the federal government on biotechnology and biopharm crop oversight and none of these has been challenged or deemed "illegal."

He does not believe that regulation of biopharm at the state level will have a chilling effect on other biotechnology research. He does not believe it necessary to wait for the USDA to finalize their pending regulatory proposal of biotechnology crops and products, nor that a Memorandum of Understanding with USDA be in place before the State of Oregon, through ODA and DHS, can adopt a rule pursuant to state law on biopharm regulation.

Mr. North reiterated his characterization of the major consensus points of the ad hoc committee regarding the proposed rules:

1. ODA and DHS be equally involved in review of biopharm applications;
2. Evaluate health, environmental, and economic considerations as part of any permit review;
3. Encourage non-food crops and containment measures;
4. Authorize DHS and ODA to enter into an MOU for confidential business information on proposed crops to ensure adequate information for review;
5. Require demonstration of adequate insurance to cover potential damages of contamination incidents and hold permit applicant responsible for costs of any remediation action; and,
6. Have opportunity for public input on a biopharm permit application – he advocates for at least 30 days notices prior to public hearing or comment deadline.

Mr. North urged the department to move ahead with the rules, making the necessary adjustments with DHS to address procedural requirements.

Dr. Michael Wach, Managing Director, Science and Regulatory Affairs, Biotechnology Industry Organization (Washington, DC), provided oral and written testimony (**Exhibit C**). Dr. Wach discussed the progress and potential applications of biotechnology in pharmaceutical area with plant-based therapeutic substances, such as producing insulin from safflower.

Dr. Wach describes ODA’s proposed rule as the “first process in the nation whereby the state can more fully participate with the federal government in certain aspects of regulatory oversight for plants producing plant-made pharmaceuticals.”

Dr. Wach commended the parties in Oregon for their progressive efforts related to biopharm regulation, but stated BIO’s perspective that the proposed rule by ODA “exceed[s] the state’s authority to act in several important ways.” USDA is charged with ensuring these plants are safe to grow, and while USDA is willing to collaborate with states in inspecting fields and some other aspects of administering permits, federal law “prohibits states from implementing laws or regulations that exceed the regulations that USDA imposes on these crops.” Dr. Wach believes this would include the prohibition in requiring the following types of information from a permit applicant:

1. the intended finished product;
2. results of allergenicity tests;
3. applicant’s analysis of risks to public health and the environment;
4. The Food and Drug Administration’s (FDA) preliminary opinion on product safety for food or feed usage;
5. evidence that the desired results and efficiencies cannot be obtained in non-food/feed crops;
6. a detailed justification of safety and containment measures beyond that required by USDA;
7. a monitoring plan beyond that required by USDA;
8. demonstration of adequate insurance to cover potential damages.

Because ODA's proposed rules require much of this information and action from a permit application, Dr. Wach believes the rules violate federal law. Further, Dr. Wach argues that state law does not specifically authorize these requirements and therefore they are unlawful requests under state law, which he argues is limited to:

1. entering into a MOU with USDA for obtaining some confidential business information (CBI);
2. limiting disclosure of CBI from the public;
3. reviewing USDA biopharm crop permit applications;
4. conducting site inspections and monitoring biopharm crop production;
5. appropriate enforcement action if there is evidence that biopharm crops are endangering agriculture, horticulture, or forest production or public health;
6. charge a permit applicant fee for the actual cost of state oversight and services up to \$10,000.

Dr. Wach also notes the difference in statute and the proposed rules, the latter of which would allow state regulators to take action if there is evidence that an "existing or proposed" biopharm crop "is likely" to endanger human health, the environment, agriculture, horticulture, or forestry. The statute uses the words "are endangering."

Dr. Wach believes the language of the state statute limits permit fees and costs of services to actual costs incurred by the state, not a flat \$10,000 fee.

Finally, Dr. Wach believes the rules are premature because a MOU with USDA does not yet exist outlining what types of collaboration may be possible, which may dictate what the rules can look like.

Terry Witt, Executive Director, Oregonians for Food and Shelter, provided oral and written comments at the hearing (marked as **Exhibit D**). Mr. Witt articulated the mission of OFS: "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."

Mr. Witt quoted his testimony provided at the 2007 legislative hearings on SB 234-A, emphasizing the process should not put unnecessary regulatory roadblocks in the way of emerging, beneficial technology that has not yet come to Oregon, and the procedures would not duplicate but utilize existing regulatory and scientific oversight at the federal level "while adding additional collaboration from the State Departments of Agriculture and Human Services."

Mr. Witt also expressed his view that the proposed rule goes beyond the scope of the statute and the expressed purpose of the rule as noted in Section 5: "The State encourages development of new agriculture and related technology in Oregon, including biopharmaceutical crop production, while protecting and maintaining public health, economic vitality, the environment, and Oregon agriculture."

Mr. Witt notes that the USDA has a pending draft rule for regulating agriculture biotechnology, and the expansion of proposed evaluation by USDA will cover many of the same issues and questions that the ODA proposed rule is seeking to address. He believes the ODA process is premature while the USDA rule is pending, and an MOU with USDA is contingent on the finalization of the USDA rule process.

Mr. Witt believes there are federal preemption issues as well and poses the question of what happens if the State recommends denial of a permit and the USDA disagrees and issues the permit - who has supremacy?

Mr. Witt also notes the difference in the fee language noted as cost recovery in the statute rather than a flat fee as proposed in the rule.

Mr. Witt raises the dilemma of how the State can determine, as the rules suggest, whether and how a “proposed” crop will cause endangerment, and what benchmarks or indicators would lead to such a determination.

Mr. Witt also raises concerns about remedial action costs that appear to be unlimited, and that public notification procedures may expose the location of a proposed crop site, which may be protected confidential business information.

He pointed out that there are no time limits on public notices, hearings, and final determinations, and that the process could be used by opponents of this technology simply to stall a permit to death.

Mr. Witt would also recommend greater clarity around confidential information and whether it is protected from a Freedom of Information Act (FOIA) request.

Mr. Witt summarized his position that the proposed rule is overly burdensome, costly, potentially illegal with respect to federal law, and premature due to the pending USDA rule. He also believes this rule would have a “chilling effect” on technology in Oregon.

He believes all the excitement around nanotechnology applies equally as well to biotechnology – they are similar in approach, applied science, and potential benefits to society.

Mr. Witt also provided a number of technical questions via e-mail to the department, including differences in definition of “biopharmaceutical” between the state and federal agencies, containment vs. confinement, noting that the FDA Early Food Safety Program is non-functional, and that “substantial risk” and other terms are undefined and subject to significant disagreement on meaning.

Other written comments on the proposed rules:

Doug Gurian-Sherman, Ph.D., Senior Scientist, Food and Environment, Union of Concerned Scientists (Washington, DC), received via e-mail.

In addition to supporting the 30-day public comment period for permit applications/review, Dr. Gurian-Sherman noted two other provisions of transparency in process that he recommended that ODA adopt as part of the rule:

1. Response to comments by the regulator (typical provision of federal environmental laws) would provide the public with assurance that the agencies have adequately considered public input. He recommends that the rule language require that the decision by the state ("letter") be made public, and include substantive response to public comments.
2. The letter that records the State's decision about the field trial should explain the reasoning of the State and be made public. For example, the State should explain why it is allowing the field trial (why it has been determined to be safe), or conversely, why it is not allowing the trial.

The department also received nearly 400 “form letters” via e-mail that were nearly identical in making the following points:

- ◆ They support the rule in general and urged its adoption;
- ◆ They recommend a 30-day notice for public hearings and comment for permit applications/review; and,
- ◆ They want to ensure that biopharmaceutical companies have adequate indemnity insurance to cover “any contamination they may cause,” and the associated “clean up.”

The e-mails were about equally split between individuals living in Oregon, and those outside the state, all across the US and Canada.

## **CONCLUSION:**

Several themes run constant through the comments and discussion around biopharmaceuticals.

1. This is a technology that holds great promise that may bring about new therapeutic products at much lower costs to the public, benefiting people worldwide. But it presents more potential risks than other biotechnology crops due to the nature of what the “product” would be, and whether the host plant is a food/feed-based plant that may have a possibility of out-crossing with regular food/feed crops.
2. This higher risk concern creates a feeling of need for regulatory agencies to take greater precautions and “control steps” to protect consumers, natural resources, and production agriculture and forestry.
3. Proponents of this technology feel that the federal regulatory regime will adequately address these risks, and that a State-level control to overlay or supersede the federal requirements is unwarranted – and even “illegal” due to federal preemption laws.
4. Skeptics, or those concerned about the technology “getting loose,” believe that the federal regulatory regime is lacking in its scope and effectiveness, and that the State needs to take a strong role in permit review, oversight, inspections, and indemnity or insurance requirements in the event of an inadvertent mishap (escape).

The fundamental matter for ODA, DHS, and the State of Oregon, is really the question of how involved in the process it desires to engage and can commit resources to administer and manage – and ultimately defend its decisions in court.

If the State issues decisions on permits -- going beyond field inspections and input on where and how a biopharm-crop may be produced in Oregon -- the State must become the legal defender of its positions, which are likely to be challenged by all sides.

A rule that is relatively “burdensome” compared to other locations will clearly serve as a deterrent to biopharm production in Oregon. This may be the desired outcome of some opposed to this technology in general.

Conversely, the inherent risks of biopharmaceutical crops create circumstances of public interest that demand attention to prevent unintended consequences. Whether the federal process is adequate, or not, is the crux of the issue.

Clearly, the process in Oregon that originated in 2005 has resulted in recommendations that the State of Oregon be involved in the regulatory oversight of biopharmaceutical crops.

The American Law Division of the Congressional Research Service in a 2004 Memorandum to the US Senate Finance Committee on this topic made these conclusions (See **Exhibit E**):

- ◆ Given the scattered federal legislative authority over biotechnology, “States will likely be able to regulate in this area unless or until Congress addresses the issue in a way that would preempt state efforts. Still a state can not pass a law that either facially discriminates against out-of-state commerce or places burden[s] on interstate commerce that are clearly excessive in relation to the local benefits received.”
- ◆ A strong state regulatory approach may pass the constitutional test if the action is 1) only an incidental burden on commerce because it is temporary; not extraterritorial; affects only a “slight” industry; and allows for an exception process. Further, the approach must be viewed as the only or the most effective way to prevent harm.
- ◆ Any state law that restricts or regulates biotechnology/biopharmaceutical crops is subject to debate and challenge in court; every situation will be “fact sensitive” to the particular issues and actions involved.

To the extent the Oregon rules process avoids interfere with interstate commerce; does not outright prohibit (or prohibit by process or practice) a product without clear scientific evidence of risk and endangerment to the public or natural resources, or ban a product or production process indefinitely; isn’t reflective of state economic “protectionism”; and, there isn’t a less discriminatory means of accomplishing the same thing, the safer the State will be from any constitutionality challenges related to federal laws.

Submitted November 10, 2008



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Brent L Searle, Presiding Officer