

603-052-1236

Biopharmaceutical Crops

(1) Definitions: As used in this rule:

(a) “Biopharmaceutical crops” means plants that have been genetically engineered using a recombinant DNA process to produce vaccines, drugs, enzymes or other medicinal compounds.

(b) “Biopharmaceutical crop permit” means a permit issued by the United States Department of Agriculture for the production of a biopharmaceutical crop.

(c) “Genetically engineered crops” means plants that have been modified using a recombinant DNA process.

(d) “Recombinant DNA process” means a process in which segments of deoxyribonucleic acid from different organisms are joined together to create recombinant DNA molecules that have the capacity to replicate in some host cell, either autonomously or as an integrated part of the host genome.

(2) As authorized by ORS 561.738 & 561.740 a system is established for joint federal-state oversight of biopharmaceutical crops in Oregon.

(3) Memoranda of understanding (MOU’s).

(a) ORS 561.740 authorizes the Director of Agriculture and an appointee of the Director of Human Services to enter into a MOU or other state-federal cooperative agreement designed to increase state input to the federal biopharmaceutical crop permitting system on issues and requirements of specific interest to the state. These rules clarify the procedures for carrying out the provisions in the statute and MOU.

(b) ODA and DHS will enter into a separate MOU or other cooperative agreement to clarify how they will interact during the joint review of a biopharmaceutical crop permit.

(4) Federal Biopharmaceutical crop Permit

Persons desiring to grow genetically engineered crops in the United States, including biopharmaceutical crops, must apply for a permit from the United States Department of Agriculture (USDA), Biotechnology and Regulatory Services (BRS). USDA evaluates proposed and existing biopharmaceutical crops (and other genetically engineered organisms) through its permitting process. As part of this process, BRS consults with relevant State agencies and provides an opportunity for review and comment by those agencies. Some of the information on permit applications for genetically engineered crops is confidential business information (CBI). USDA redacts this information from documents shared with state agencies. ORS 561.740 (2)(a) authorizes certain Oregon state officials from the departments of Agriculture and Human Services to receive CBI and keep it confidential if the application is for a biopharmaceutical crop.

(a) Non-CBI information includes, but is not limited to: company name and contact information, proposed crop, phenotype class (e.g., herbicide tolerant, novel protein produced), county where the proposed trial is to take place, proposed acreage, and proposed federal safeguards (e.g., required separation distances). Phenotype (e.g., glyphosate tolerant, Lepidoptera resistant) is usually, but not always, considered non-CBI and is generally revealed.

(b) CBI may include, but is not limited to: precise planting location, recombined genetic sequences, and sometimes the phenotype (e.g., the name of a novel protein). As provided by ORS 561.740 (2)(a), CBI revealed to State officials as part of the permitting process for a biopharmaceutical crop is not to be disclosed as public information.

(5) State Review of Federal Biopharmaceutical Crop Permit

The intent is not to duplicate the efforts of USDA, rather to allow the State to provide input on Oregon-specific issues and requirements. Oregon will utilize a case-by-case, collaborative approach for regulation of biopharmaceutical crops. 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.

The Oregon Departments of Agriculture and Human Services will work together to implement the following:

(a) Review federal biopharmaceutical crop permit applications and related information and provide feedback to USDA. This review will include CBI and non-CBI provided by the federal permit plus the intended plant made pharmaceutical, results of any allergenicity tests, protocols and tests for bio-containment, applicant's analysis of risks to public health and environment, and FDA's preliminary opinion on product safety for biopharmaceutical food or feed crops.

(b) Oregon officials reviewing biopharmaceutical crop permits for food/feed crops require evidence that the desired results and efficiencies cannot be obtained in non-food/feed crops. If biopharmaceutical production in food and feed crops is proposed, applications must include a detailed justification of safety (such as an Early Food Safety Evaluation by the FDA) and plans for one or more strict confinement procedure(s) (such as cultivation in a secured greenhouse, use of highly sterile host variety, large isolation distance from interfertile species, growth out of phenological synchrony with interfertile relatives, use of separate farm equipment, and strict monitoring, quality assurance and reporting, including full reporting of the distribution and disposition of the biopharmaceutical material).

(c) Ensure biopharmaceutical crop permit applications include a satisfactory monitoring plan and an emergency response plan. These plans will include surveillance protocols, testing methodologies, and quality assurance plans to assess if unintentional presence above authorized levels, if any, has occurred, as well as mitigation procedures in the event of a release of biopharmaceutical material.

(d) Require demonstration of adequate insurance to cover potential damages.

(6) Public Input

(a) ODA will maintain a list of interested parties requesting notification in the event the State receives a biopharmaceutical crop permit application. Notification to interested parties will be done via email. Only non-CBI will be shared with interested parties and other members of the public.

(b) If ten or more people or an association with ten or more members requests a public information meeting, ODA and DHS will conduct such a meeting pursuant to ORS 192.610 to 192.710 in the county of the proposed biopharmaceutical planting to answer questions and gather input. Notice of the meeting will be via email and will include the list of interested parties and the OSU County Extension office in the county of the proposed planting so that local growers can be invited. The meeting notice will also be posted on ODA's and DHS's website as will addresses for sending comments via postal mail or email. All input received by the end of the public information meeting will be supplied to the ODA and DHS officials reviewing the application for their consideration.

(7) State Response

(a) After thorough review, ODA and DHS will jointly issue a letter to USDA with signatures of designated officials from both agencies. If either agency has concerns, those concerns will be expressed in the joint letter. If the ODA and DHS reviewers disagree, the overall recommendation will reflect the view of the agency with the higher level of concern. The letter will recommend approval, approval with additional safeguards, or denial of the biopharmaceutical crop permit application.

(8) Monitoring

(a) In coordination with USDA, and to the extent resources are available, State officials will participate in inspecting and monitoring of biopharmaceutical crops and take action if it is determined that there is evidence an existing or proposed biopharmaceutical crop is likely to endanger human health, the environment, Oregon agriculture, horticulture, or forest production.

(b) The costs of any required remedial action, which may include crop destruction, are the responsibility of the permit applicant.

(9) State Fees

The applicant will be billed \$10,000 for state services related to the authorization and oversight of biopharmaceutical crop production, including but not limited to permit application review, site inspections, monitoring, administration and enforcement. ODA will invoice the permit applicant. DHS will receive their share of payments received via interagency transfer.