LEGISLATION FOR GMOs IN NORTH AMERICA: DESIGN OF CONTAINMENT FACILITIES

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Regulation of GMOs in North America is primarily targeted to field release, food, and feed applications. Under the Coordinated Framework for Regulation of Biotechnology, three US governmental agencies regulate GMOs: the Department of Agriculture, the Environmental Protection Agency, and the Food and Drug Administration (FDA). In Canada, the Canadian Food Inspection Agency (CFIA) is responsible for the regulation of importation, environmental release, and feed use of plants with novel traits which include transgenic plants. Health Canada has jurisdiction over novel foods, including food products derived from transgenic plants. Mexico regulates field experimentation with non-maize transgenic plants. Regulation governing transgenic plants and related organisms in greenhouses and other controlled environments, however, is relatively sparse. All US agencies defer to and accept the National Institutes of Health's Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines). Appendix P of the NIH Guidelines was added in 1994 to specifically address plant and plant-related organism containment.

The NIH Guidelines describe methods for conducting transgenic research in laboratory and other controlled environment settings but they stop short of offering design detail for containment facilities. Design for transgenic research borrows from containment principles found in phytosanitary and other biosafety applications. There may be a broad range of guesses and opinions among scientists and facility managers regarding what is needed. Some may harbour a misunderstanding that all GMOs must be grown in a highly contained 'clean-room,' while others may be completely unaware that certain cases require specific containment measures in order to protect the surrounding environment.

The primary goal of containment is preventing the dissemination of propagules. Designing or renovating containment facilities to meet most transgenic research programs can require little more than establishing management protocols and offering reasonable facility accoutrements. On the other hand, if the escape of research organisms poses a serious environmental, agricultural, or health threat, then engineering controls that resemble the 'clean-room' approach would be indicated.

The most qualified individuals to assess the risks are the investigators themselves acting in concert with regulators, institutional biosafety committees, and facility staff. The most qualified designers are experienced engineers and architects operating as a team with users and facility staff.