

REGULATION OF BIOTECHNOLOGY, A PERSPECTIVE

David C. Nunenkamp, Deputy Secretary, CDFA

California is the birthplace of the US biotechnology industry, the base of 40% of all biotech companies, accounts for 47% of national R & D spending on biotech, and generates 53% of the nation's biotech revenues.

Yet the regulation of agricultural biotechnology is a hot, negative issue generated by fear mongers. Fear can lead to both great achievements and to tragic decisions and to poorly written and misguided public policy. The issues of concern surrounding biotechnology and food are understandable. Our government has done a dismal job of assuring consumers of the long-term safety of food made from genetically modified plants. People want to know if there are health risks associated with eating plants and animals who's DNA has been manipulated. They want to understand the effects on nature if these modified species enter the natural environment. Scientists have provided conflicting answers. The federal Food and Drug Administration has been missing in action – meanwhile, the use of genetically engineered crops has exploded. An estimated 70 percent of food products contain some ingredient derived from a gene-altered plant.

States with large Ag sectors are intensely interested in the economic promise of Ag biotechnology, recognize that the economic benefits could/will be jeopardized if public anxiety or market access for conventional crops is threatened, have an important stake in the oversight of Ag biotechnology not only to protect health and safety but to protect the economic interests, and most perfect that stake through a partnership with the federal regulatory program.

The federal Coordinated Framework for Regulation of Biotechnology established as a formal policy, based upon a coordinated, risk-based system to ensure new biotechnology products are safe for the environment and human and animal health. The "Framework" is predicated upon health and safety laws developed to address specific product classes. Separate but coordinated reviews are made by USDA, EPA, and FDA [depending upon the gene and host crop].

From the perspective of the California Department of Food and Agriculture (CDFA), the regulation of agricultural biotechnology is strictly a federal issue. Significant national and international implications and ramifications have resulted from the regulation of this industry and the perceived lack of regulation based on the unwarranted fears generated by activists opposed to the introduction of any genetically modified organism. The regulation of Ag biotechnology cannot and should not be compounded by individual states or local legislative units.

Details of the program and current dissatisfaction are discussed in the presentation.