

P3-209 “Enabling Crop Deregulation with Software: a Prototype”

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Despite advances that enhance crop production by applying biotechnology to plant improvement, the results of these advances often fail to transfer from the laboratory to industry because of significant barriers to achieving non-regulated status. This motivates the goal we propose, developing software to assist in attaining biotechnology-derived specialty crop non-regulated status to help in commercializing those crops. This project will directly address the development of genetically-modified specialty crops by significantly easing the technology transfer of genetic engineering research on plant bioproduction.

This project proposes to develop a testable model and prototype software for moving specialty crops through the current regulatory system. Corn, soybeans, cotton and a few other commodity crops have been deregulated for growth and human consumption. Yet only a small number of specialty crops developed through biotechnology have been deregulated, and these were done before the current increased regulatory oversight of field trials and requirements for non-regulated status. The hurdle is nearly insurmountable in the case of plant-made pharmaceuticals or plant-made industrial proteins.

This barrier to regulatory approval for specialty crops was recognized by the USDA in the early 2000’s. The Specialty Crops Regulatory Initiative (SCRI) was formed as the outcome of a workshop held at USDA APHIS headquarters (APHIS, 2004). The workshop was organized and initially funded cooperatively by several government agencies. Thus multiple federal agencies understand the need for the type of work we seek to pursue.

The solution we propose addresses the regulatory barriers through generating a model deregulation plan, by collecting data through mining databases and literature to determine baseline plant characteristics and collecting comparative data on live transgenic plants. The ultimate goal is to unblock the road from lab to market, helping us as a society to reap what the science sows.