VAN WERT, SALLY L., AgrEvo USA Company, 2711 Centerville Rd., Wilmington, Delaware, 19808. **An overview of the regulation of biotechnology enhanced plants in the United States.**

With the advent of biotechnology enhanced plants there has been the development of regulations and policies in the United States and other countries. In the United States the safety review system for such plants began to be elucidated in 1986 and its development is ongoing. In the United States the framework is based upon the existing laws of the United States Department of Agriculture (USDA), the United States Environmental Protection Agency (EPA) and the Food and Drug Administration Agency (FDA). The regulations and policies are based in science, are generally transparent and have some flexibility. The USDA has authority from the time that a genetically enhanced plant or seed is moved into or within the United States until a commercial submission to the Agency is approved (determination of nonregulated status). If the plant is expressing a pesticidal compound, such as is the case for "Bt plants", then the EPA also has jurisdiction once the acreage for field testing is above 10 acres. A plant pesticide must also be registered with the EPA and either a tolerance or exemption from the requirement of a tolerance granted for the introduced pesticidal compound and genetic material. The EPA regulations are currently proposed, however, applicants are complying as though they were final. The FDA has provided a policy to guide the applicant in evaluation of the food and feed safety aspects of the genetically enhanced plant. A submission to the FDA is voluntary. A summary of every biotechnology enhanced plant product commercially available in the United States has been provided to the FDA. To date more field trial and commercial approvals have been granted for genetically enhanced crops in the United States than in any other country.