

GENE FLOW AND RISK ASSESSMENT: CASE BY CASE CONSIDERATIONS.
Michael J. Horak and Thomas E. Nickson, Monsanto Company, St. Louis, MO.

A fundamental tenant of risk assessment is that risk is a function of *hazard* and *exposure*. For biotechnology-derived crops, a risk assessor considers potential *hazards* associated with the crop that could include altered pest potential and potential adverse environmental impacts including adverse effects on non-target organisms. A risk assessor also considers *exposure* by examining reasonable pathways for release into the environment, the environmental fate of the plant and trait, and potential routes of exposure to non-target organisms. The assessor would also evaluate information on potential gene flow via pollen, seed and tissue, and information on potential consequences of gene flow. The hazard and exposure information is then incorporated into the overall risk assessment.

During the risk assessment planning phase, the nature of the crop, the nature of the trait, the likely receiving, and the interactions among these factors are considered to identify potential hazards. Then comparative plant characterization data are generated on the biotechnology-derived crop. The comparative data are assessed for unintended and/or potentially adverse differences in the plant, and trait advantages to the crop that potentially affect the weediness of the crop. This information is used in an assessment of potential hazards of the crop. Concurrently, data are generated for an assessment of the potential effects to non-target organisms. The data from the hazard characterization are then considered in the context of a gene flow assessment (a portion of the exposure assessment). The gene flow assessment considers gene flow within the crop species and the likelihood of trait introgression into a sexually compatible species. Together the information from the hazard assessment and the exposure assessment, including gene flow information, are used in an overall assessment of risk.