

UNDERSTANDING GENE FLOW AND INTROGRESSION CONSEQUENCES FOR BIOTECH CROP RISK ASSESSMENT. Thomas E. Nickson, Ecological Technology Center, Monsanto Company, St. Louis, MO, 63141.

Advances in recombinant DNA technology have enabled the development of crops with traits that would have been difficult to solely using traditional breeding techniques. Today, biotechnology-derived crops, widely known as genetically modified (GM), have been planted commercially by over 7 million farmers in 18 countries on approximately 1 billion acres. Prior to commercial planting, each product is rigorously assessed for its potential risks compared to conventional (non-GM) counterpart using a science-based, stepwise approach grounded in the principles of risk assessment ($\text{Risk} = f(\text{hazard} + \text{likelihood})$). Based on guidance developed by internationally recognized bodies, risk assessment considers the nature of the trait, the nature of the crop, the nature of the likely receiving environment and interactions among these. Prior to initiating any experimental work, the planning phase examines possible hazards as well as pathways and exposure scenarios in light of the factors noted above. Gene flow is a key aspect that must be closely examined as it represents a pathway by which a potential hazard associated with a GM trait could be realized in the environment. Potential exchange of genes to non-GM plants directly through pollen or as a consequence of movement of seed and plant parts must be carefully considered. Two important questions are asked at the outset of the risk assessment concerning gene flow: (1) is it likely that the introduced trait will change the pollination biology of the crop such that rates of gene flow will increase or decrease; and (2) what are the potential consequences associated with movement of the trait from the GM plant to a non-GM plant? This presentation describes an approach that has been developed based on a combination of published, scientifically sound guidance and over 12 years experience in assessing GM crops. The essential elements of the approach include: assessment planning, plant/crop characterization, hazard identification, hazard assessment, likelihood/exposure assessment and risk characterization. When there is reasonable certainty for a risk, possible risk management options would be proposed to mitigate or manage the potential risk. The objective of using such a rigorous approach is to develop a good understanding of gene flow including the potential for introgression of the GM trait into non-GM plants and the environmental consequences associated with spread of a GM trait beyond its intended application within agricultural fields. Assessing GM crops in this manner should ensure that their benefits outweigh their negative impacts on the environment.