

Regulatory Costs

Estimates of Full Deregulation Costs Per Allele/Crop - 2002

Company	Worldwide	US only
Novartis	\$3.5 – 7 million	
Monsanto	\$5 million	\$3.5 million
NUNZA (AgrEvo)	\$5 million	
Limagrain	\$10 million	

For Collecting Data

1) Use the specific, transgenic line:

- a) The progenitor of the proposed commercial varieties, OR
- b) The commercial hybrid, OR
- c) A near commercial hybrid with bridging data to commercial hybrid

2) Use isogenic control lines

3) Use alleles that have a simple insert that looks like the T-DNA

Molecular Biology

- Genetic Engineering Technique
- The Transformation System
- Complete description of the constructs
- Characterization of the insert
 - Southern
 - Northern
 - Western
 - ORF analysis
 - Fine mapping
- Detailed plasmid map
- Event specific PCR for tracking allele

Additional Studies

- Antibiotic resistance marker genes
 - NPT-II is classified as a “food additive” by the FDA
- Complete nutritional data
- Complete review and protein data on safety aspects
- Complete review and field trialing data to support environmental aspects
- Uses for animal feed?
- Consumer implications
- Intended evaluation research
- Socio-economic aspects (EU)