**Regulatory Costs**

Estimates of Full Deregulation Costs Per Allele/Crop - 2002

<table>
<thead>
<tr>
<th>Company</th>
<th>Worldwide</th>
<th>US only</th>
</tr>
</thead>
<tbody>
<tr>
<td>Novartis</td>
<td>$3.5 - 7 million</td>
<td></td>
</tr>
<tr>
<td>Monsanto</td>
<td>$5 million</td>
<td>$3.5 million</td>
</tr>
<tr>
<td>NUNZA (AgrEvo)</td>
<td>$5 million</td>
<td></td>
</tr>
<tr>
<td>Limagrain</td>
<td>$10 million</td>
<td></td>
</tr>
</tbody>
</table>

**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
  - Southerns
  - Northern
  - Westerns
  - 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)