

## Some elements for stepwise risk analysis for genetically engineered plants based on a “risk assessment per se”

Testbiotech’s tabled overview, version March 2011

<b>Starting point / First step/ technical characterization / first hypothesis on risks and hazards</b>		
<p>Assessing unbiased data from lab and glasshouse</p> <ul style="list-style-type: none"> <li>– genomic data</li> <li>– reaction to defined conditions / stress test</li> <li>– metabolic profiling, measuring gene activities</li> <li>– compositional analysis (comparison) of material exposed to varying conditions</li> <li>– lab data on risks for potential non target species and the food chain/ human health</li> <li>– Investigate combinatorial effects</li> </ul>	ethical and socioeconomic considerations	
<p><b>Initial risk and hazard identification</b> developing first hypothesis for later steps</p> <p>stop authorisation process and field trials for crops being persistent or invasive, showing technical deficiencies such as genetic instability.</p>	<p><b>Initial ethical and socioeconomic conclusions</b> developing questions for further considerations</p> <p>stop authorisation process and field trials for crops that require non-sustainable cultivation methods, do not meet criteria for coexistence or do not render significant improvements.</p>	
<b>Following steps (if cut off criteria do not apply)</b>		
Full publication of all data, call for comments on risk findings and ethical and socioeconomic issues		
<p><b>Mandatory investigations</b></p> <p>&gt;multigenerational feeding studies including immunological and reproductive data<sup>1</sup></p> <p>&gt;experimental release in all relevant climatic / geographical zones over several years going step by step from small scale to larger scale<sup>2</sup></p>	<p><b>Further investigations</b> according to results from step 1 (case by case)</p> <p>&gt;Mandatory for all HT plants: close interplay with pesticide assessment / change in agricultural practises / residues in food and feed.</p> <p>&gt;Mandatory for all IR plants: Tests for synergistic effects in non target organisms. Tests for effects in all relevant levels of the food web and food chain.</p>	<p><b>Generating specific data about impact for agriculture / coexistence/ sustainability</b></p>
<b>First opinion on risk assessment including uncertainties and necessary reiterative investigations</b>		
Full publication of all data, call for public comments on all preliminary findings		
<b>Final risk assessment</b>		
<b>Risk analysis</b>		
Check for effective systems for monitoring/ surveillance, also for coexistence. Identify uncertainties.		
<b>Decision of the risk manager,</b>		
including socio- economic and ethical findings		

1 Necessary from scientific point of view (to assess risks for human, livestock and wildlife), but controversial from ethical perspective

2 Necessary from scientific point of view but controversial because of environmental risks created by experimental releases