

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

Testbiotech’s tabled overview, version March 2011

Starting point / First step/ technical characterization / first hypothesis on risks and hazards		
<p>Assessing unbiased data from lab and glasshouse</p> <ul style="list-style-type: none"> – genomic data – reaction to defined conditions / stress test – metabolic profiling, measuring gene activities – compositional analysis (comparison) of material exposed to varying conditions – lab data on risks for potential non target species and the food chain/ human health – Investigate combinatorial effects 	ethical and socioeconomic considerations	
<p>Initial risk and hazard identification 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>Initial ethical and socioeconomic conclusions 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>	
Following steps (if cut off criteria do not apply)		
Full publication of all data, call for comments on risk findings and ethical and socioeconomic issues		
<p>Mandatory investigations</p> <p>>multigenerational feeding studies including immunological and reproductive data¹</p> <p>>experimental release in all relevant climatic / geographical zones over several years going step by step from small scale to larger scale²</p>	<p>Further investigations according to results from step 1 (case by case)</p> <p>>Mandatory for all HT plants: close interplay with pesticide assessment / change in agricultural practises / residues in food and feed.</p> <p>>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>Generating specific data about impact for agriculture / coexistence/ sustainability</p>
First opinion on risk assessment including uncertainties and necessary reiterative investigations		
Full publication of all data, call for public comments on all preliminary findings		
Final risk assessment		
Risk analysis		
Check for effective systems for monitoring/ surveillance, also for coexistence. Identify uncertainties.		
Decision of the risk manager,		
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