

Environmental Risk Assessment of Transgenic Plants

Potential Secondary and Non-
target Effects



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Impact on non-target organisms

- ◆ Evaluate the toxicity of gene products, breakdown products, and by-products in the environment:
 - May include **indirect** effects on predators, grazers, parasites, pathogens, competitors and symbionts
 - Potential adverse effects on human health
- ◆ If the gene product is a toxin, evaluate the level of exposure and effect on soil micro flora and fauna (degradation

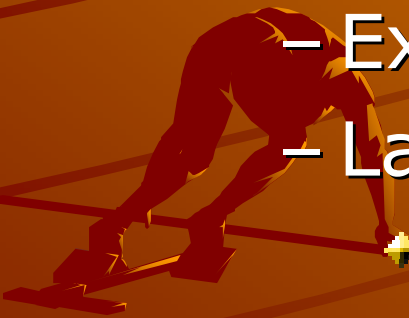
What is a non-target organism?

- ✦ Any plant, animal or microorganism that is unintentionally affected by cultivation of the novel plant



Assessing impact on non-target organisms

- ◆ The potential hazard to terrestrial wildlife, aquatic animals, plants and beneficial insects are evaluated using
 - Existing knowledge of the toxin
 - Laboratory-based, toxicology studies
 - ◆ E.g. US EPA Model
 - **Only** if detrimental effects are observed in lab assays, are field studies undertaken to evaluate population levels of the non-target



Methodology

- ✦ It is imperative that the appropriate indicator organisms be selected for non-target testing
- ✦ The potential field exposure to the transgenic plant and the toxin should be determined to enable correct levels to be used in assays
 - Tissue specificity of expression should be considered in this determination

Methodology, cont.

- ✦ The US EPA requires data on the toxicity of insecticidal proteins (*i.e.* Bt delta-endotoxins) to:
 - Birds
 - Fish
 - Honeybees and certain other beneficial insects
 - Soil invertebrates



Non-target indicator species

- ◆ Test species should be representative of the geographic region where the transgenic plant will be cultivated
- ◆ Avian test species
 - e.g. Bobwhite quail, mallard ducks
- ◆ Aquatic animals relevant to
 - (1) transgenic plants that will be grown in proximity to water sources
 - ◆ e.g. irrigation ditches, rivers
 - (2) aquatic crop species
 - ◆ e.g. rice, cranberries
 - Freshwater fish species for which considerable background data exist
 - ◆ e.g. catfish, trout, salmon
- ◆ Insectivorous or scavenging fish species may be considered where intoxicated insects or transgenic plant tissue may be consumed



Non-target indicator species

✦ Aquatic animals (cont'd):

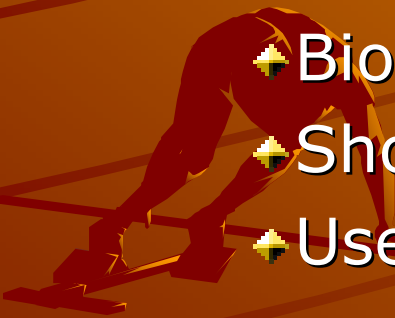
- Aquatic invertebrate species
- *Daphnia* is commonly used

- ✦ Considerable background data

- ✦ Bio-concentrator

- ✦ Short lifecycle

- ✦ Useful for assessing reproductive effects



Non-target indicator species

✦ Insect testing

- Selection of predator and parasite insect species should take into account likelihood of exposure to plant tissue, phylogenetic relationship of target and non-target species
- If novel toxin is highly specific, then insect species closely related to the target(s) are most likely to be affected

Non-target indicator species

✦ Insect testing (cont'd)

- Extrapolation of test data across species lines is problematic so tests should be conducted with representatives from a number of beneficial insect taxa

✦ E.g., the US EPA recommends a pollinator and at least two of the following – parasitic dipterans, predaceous hemipterans, predaceous coleopterans, predaceous mites, predaceous neuropterans, parasitic hymenopterans

Impact on Soil Organisms

1. Is the novel protein toxic to soil microflora and microfauna ?
2. How much novel protein is present in senescing plant tissue?
3. How long does the novel protein remain biologically active in the soil?
 - Both 2 and 3 addressed through laboratory bioassays and/or field studies
 - Representative species for



Choice of indicator species

- ✦ All sentinel species used to measure potential non-target adverse effects were proposed by US-EPA for measuring impacts of microbial pesticides
- ✦ Consider whether there are other, better species that would be more relevant to the release environment
 - Background knowledge and data available
 - Stable laboratory cultures available

Summary

- ◆ Impacts on non-target organisms are considered using existing knowledge of the toxicity of any new proteins
- ◆ Laboratory testing is performed on a range of indicator species, chose to represent likely non-target organisms
- ◆ Adverse impacts in laboratory tests are followed up in field tests
- ◆ Appropriate indicator species which can be handles in the laboratory are needed