Biosafety concerns specific to the deployment of abiotic stress transgenics

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The issues

- Abiotic stress tolerant transgenics need biosafety assessments **and** regulatory approval.

- They depend on regulatory approval and biosafety assessment under current frameworks

- These frameworks are products of thinking mainly based on first generation transgenics

New products, new challenges

- Stress tolerant crops pose new questions regarding safety and impact:
  - New phenotypes (stress tolerance probably leads to more competitiveness)
  - New genetic approaches (regulatory genes, cascading effects)

- Many are developed by public research institutions with limited experience with the regulatory framework of GMOs.

Some history

- All working biosafety assessment and management systems derive from OECD guidelines produced in 1986-1995

- The working hypotheses focused on biotic stress tolerance and some ideas about compositional change

  → Based on one gene – one product model (Bt, HT, VR)

  → Very focused on molecular analysis of the expression of the transgene

  → Environmental risk assessment includes thinking about non-change in competitiveness

The new traits differ

- Genetic approaches:
  - Many traits depend on insertion of regulatory genes
  - Full list of direct and indirect effects difficult to describe
- Phenotypic effects:
  - Abiotic stress tolerance can be expected to increase competitiveness
    - Will raise the “superweed” issue
  - Concerns about impacts on previously unused environments
  - Concerns about composition of harvested products and impact on human nutrition

Current basis of biosafety assessment

Components of the package

1. Description of donor and recipient organism
2. Characterisation of the DNA to be inserted
3. **Molecular characterisation of the event**
4. **Compositional analysis of the event**
5. **Assessment of health safety of the event**
6. **Assessment of environmental safety of the event**
7. Development and validation of event-specific detection tools.

What will be different?

1. Molecular characterisation:
   - Current emphasis on demonstrating that nothing else has changed!
   - The problem of comparative analysis (controls!) with isogenics in stressed conditions
   - Problem of providing “a comprehensive molecular characterisation” of the expression of regulatory genes and their cascade
2. Compositional analysis
   - It is likely that stress tolerant crops will have significantly different composition than controls under stress

What will be different? (cont'd)

3. Health impact assessment
   - Questions about indirect effects on expression of genes with a potential health impact (allergens, toxins, micro-nutrients)
4. Environmental impact assessment
   - Questions about escape of the tolerant crop (direct weediness increase)
   - Questions about escape of the gene into wild relatives (indirect weediness increase)

The need for coordinated action

- Stress tolerance is an exploding field,
- Many approaches being brought to the field trial stage
- Many public research projects work on applications for developing countries
- Most private tech developers are heavily involved

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What has to be done fast

- An inventory of ongoing work and approaches
- A coordinated approach to biosafety assessment
- Promoting high quality regulatory submissions

- The quantum step between experimental and large scale releases
- The need to start thinking about biosafety and regulations early in the R&D process

Helpful possible actions

- Step up awareness building and training of research teams involved in this field
- Cooperation between teams on:
  - Approaches to biosafety assessment and management principles
  - Approaches to regulatory file development and management
- Dialogue with regulatory bodies on principles for biosafety assessment of stress tolerant crops
- Development of a public-private dialogue among biotech practitioners on the subject

The wider context

- Do not:
  - take for granted that your project will be positively received!
  - Assume that others will clear the regulatory environment for you
  - Assume that the benefits of your product are so obvious that they don't need explaining
  - Assume any knowledge about biotech or agriculture in those who will decide on your product
  - Assume that a scientific logic will prevail in a regulatory environment
- Positioning of stress tolerant GM crops in the global programs to address hunger and achieve sustainable development

→The need for coordinated high quality communication around this exciting new field