

EFSA Consultative Workshop

Draft Guidance on selection of comparators
for the Risk assessment of GM plants

EuropaBio comments

Brussels

31 March 2011

EuropaBio comments risk assessment of single events

General comments

- ❖ **Consistency** is needed across EFSA guidance documents:
 - Purpose and use of new guidance in light of previous guidance
 - Complementary to existing guidance
 - Clarification on status of “older” guidance

- ❖ **Clarity** on requirements for import and cultivation
 - *Comment.* Which studies are considered under ERA? It is not clear under which assessments (Food/Feed or ERA) different studies (compositional and agronomic/phenotypic) are categorized.
 - *Proposal:* EFSA to clarify the field trials/studies categorized under Food/Feed assessment, and ERA throughout the Guidance on Selection of Comparators for the Risk Assessment of GM Plants.

EuropaBio comments risk assessment of single events

Reference varieties:

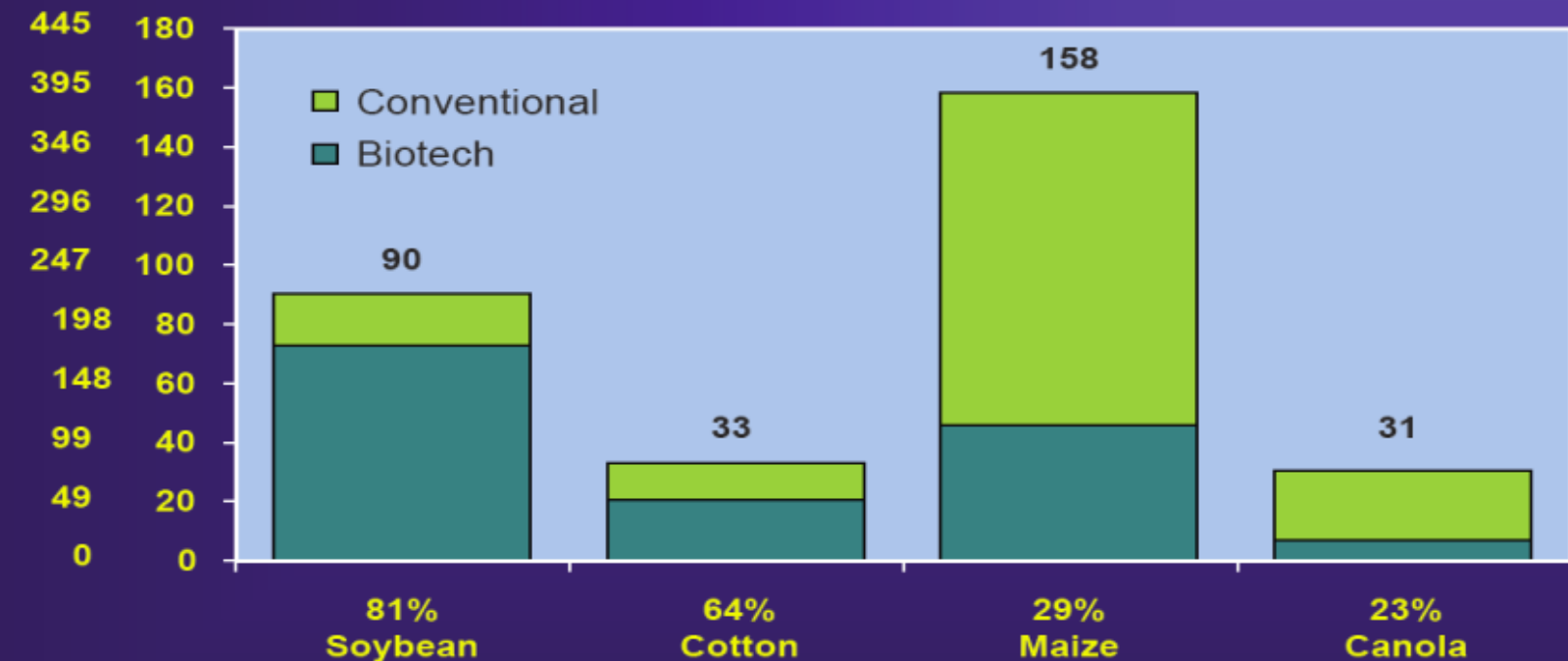
- ❖ *Comment:* discrepancy on the definition of reference varieties (set of non-GM reference varieties with a history of safe use vs representative varieties that would be normally grown in the areas where the field trials are performed) without indicating the genetic nature of the varieties
- ❖ *Proposal:* a reference range of commercially available GM (approved and safety-affirmed) and non-GM reference varieties, that are representative of the growing area, will provide a better representation of the natural variability.
For import dossiers, representative varieties relate to the area where the crops will be commercially cultivated. *De facto* these representative varieties will be GM varieties (corn, cotton, soybean and canola) these days.
- ❖ Reference to be made to ranges available in ILSI crop composition database (<http://www.cropcomposition.org/query/index.html>)

GMOs - The Global Picture

Global Adoption Rates (%) for Principal Biotech Crops (Million Hectares, Million Acres), 2010



M Acres



EuropaBio comments risk assessment of single events

Protein expression analysis:

- ❖ *Comment:* protein expression analysis is carried out to determine **exposure** to the newly expressed protein (it is not a comparative assessment). Draft guidance requires inclusion of a comparator that can provide valuable information in particular for the data on the specificity of approaches used for protein quantification
- ❖ *Proposal:* in cases where specificity can be determined using different methods, there is no need to include a comparator in the protein expression analysis