OECD and Substantial Equivalence

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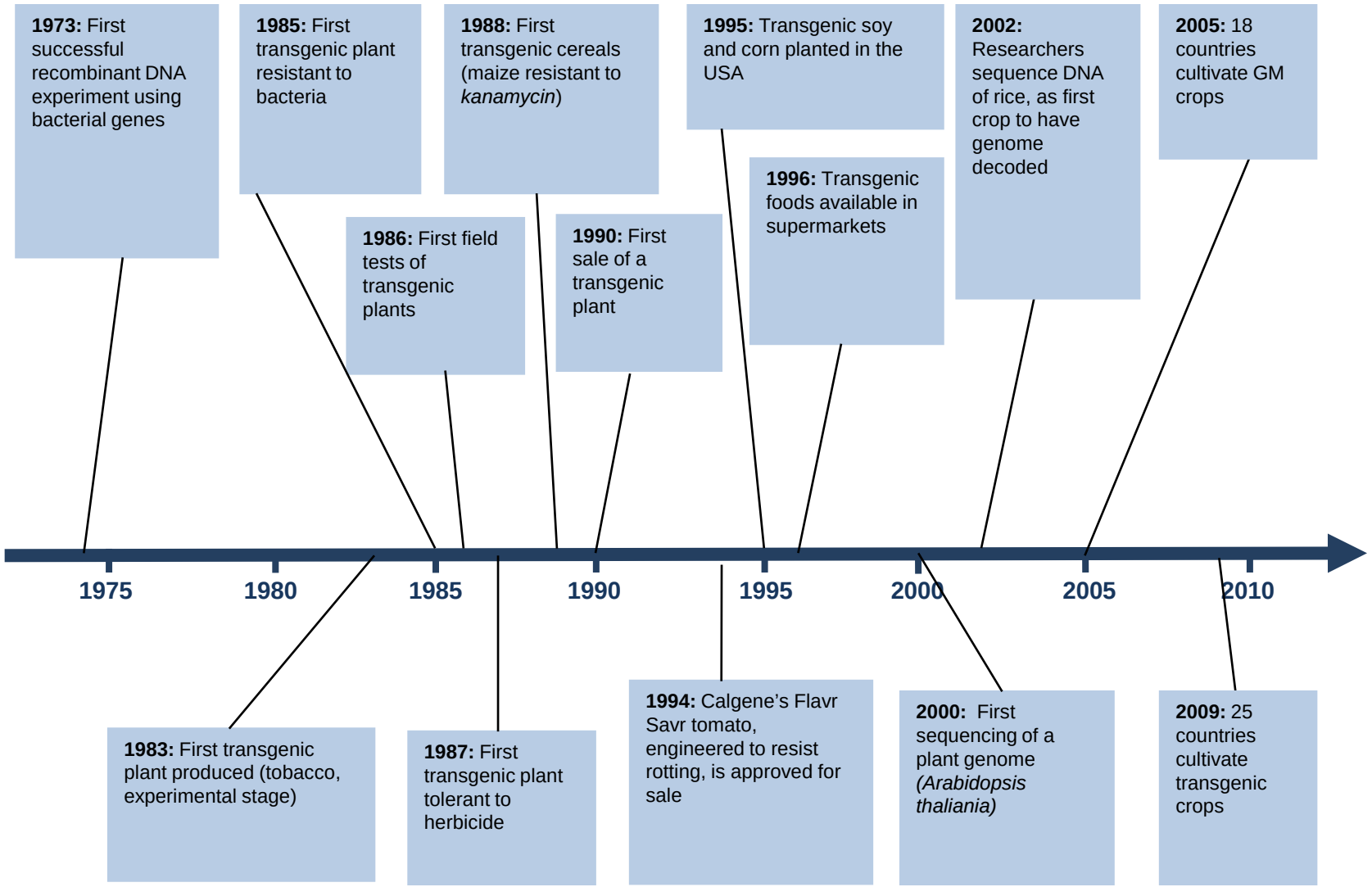
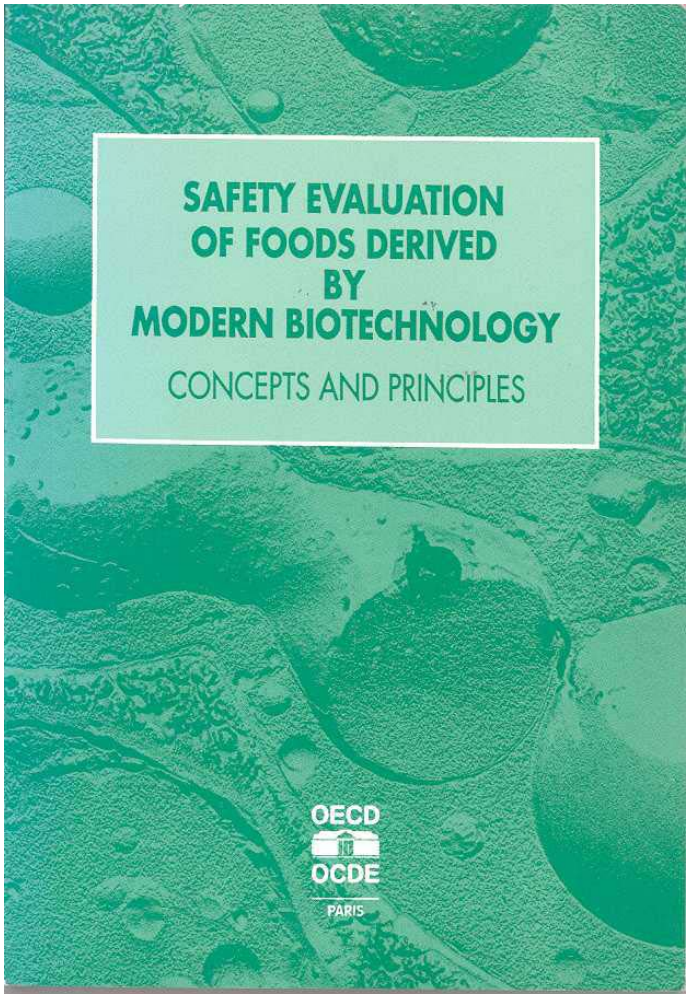
Transgenic plants: milestones



Source: Adapted from North Carolina Biotechnology Center (2010) and GNIS (2010)

1991: FAO/WHO Strategies for Assessing the Safety of Foods Produced by Biotechnology

1993: OECD Green Book


SAFETY EVALUATION
OF FOODS DERIVED
BY
MODERN BIOTECHNOLOGY
CONCEPTS AND PRINCIPLES
OECD
OCDE
PARIS

- *Principles for the application of substantial equivalence* to the assessment of foods from organisms developed by the application of biotechnology:
  - If the new of modified food component is determined to be substantially equivalent to an existing food, then further safety or nutritional concerns are expected to be insignificant;
  - Such foods, once substantial equivalence has been established, are treated in the same manner as their analogous conventional counterparts;

- Where new foods or classes of new foods or food components are less-well known, the concept of substantial equivalence is more difficult to apply; such new food or food components are evaluated taking into account the experience grained in the evaluations of similar materials (for example, whole foods or food components such as proteins, fats or carbohydrates);
- Where a product is determined not to be substantially equivalent, the identified differences should be the focus of further evaluations;

– Where there is no basis for comparison of a new food or food component, that is, where no counterpart or similar materials have been previously consumed as food, then the new food or food component should be evaluated on the basis of its own composition and properties.

- Chymosin derived from *Escherichia coli* K – 12
- *Bacillus stearothermophilus* alpha-amylase derived from *Bacillus subtilis*
- Lactic acid bacteria
- Low erucic acid rapeseed oil (LEAR oil)
- Myco-protein
- Genetically modified baker's yeast
- Tomato
- Potato
- Rice
- Animals
- Animals from transgenesis experiments
- Swine transgenesis for porcine somatotropin

Joint FAO/WHO Consultation in 1996 (FAO/WHO, 1996) recommended that the safety evaluation should be based on the concept of substantial equivalence, which is ‘a dynamic, analytical exercise in the assessment of the safety of a new food relative to an existing food’. The following parameters should be considered to determine the substantial equivalence of a genetically modified plant: molecular characterization; phenotypic characteristics; key nutrients; toxicants; and allergens.

Concept of substantial equivalence

- Starting point for safety assessment
- Comparison between the GM organism and its closest traditional counterpart
- Identification of intended and unintended differences on which further safety assessment should be focused

Kuiper et al (2001)

Concept of substantial equivalence

Mayers, Kearns et al (2002

Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from rDNA Plants (2003)

Analyses of concentrations of key components of the recombinant-DNA plant and, especially those typical of the food, should be compared with an equivalent analysis of a conventional counterpart grown and harvested under the same conditions.

Concept of substantial equivalence

OECD Task Force for the Safety of Novel Foods and Feeds (est. 1999)

Consensus Documents


Please cite this paper as:
OECD (2009), "Consensus Document on Compositional Considerations for New Varieties of Cassava (*Manihot esculenta* Crantz): Key Food and Feed Nutrients, Anti-nutrients, Toxicants and Allergens", *Series on the Safety of Novel Foods and Feeds No.18*, Environment Directorate, OECD.
Series on the Safety of Novel Foods and Feeds, No.18
Consensus Document on Compositional Considerations for New Varieties of Cassava (*Manihot esculenta* Crantz): Key Food and Feed Nutrients, Anti-nutrients, Toxicants and Allergens
OECD
Environment Directorate

- *Nutrients (Carbohydrates, proteins, lipids, minerals, vitamins)*
- *Antinutrients (Tannins, Phytic acid, Saponin, Trypsin inhibitor, etc)*
- *Toxicants*
- *Allergens*

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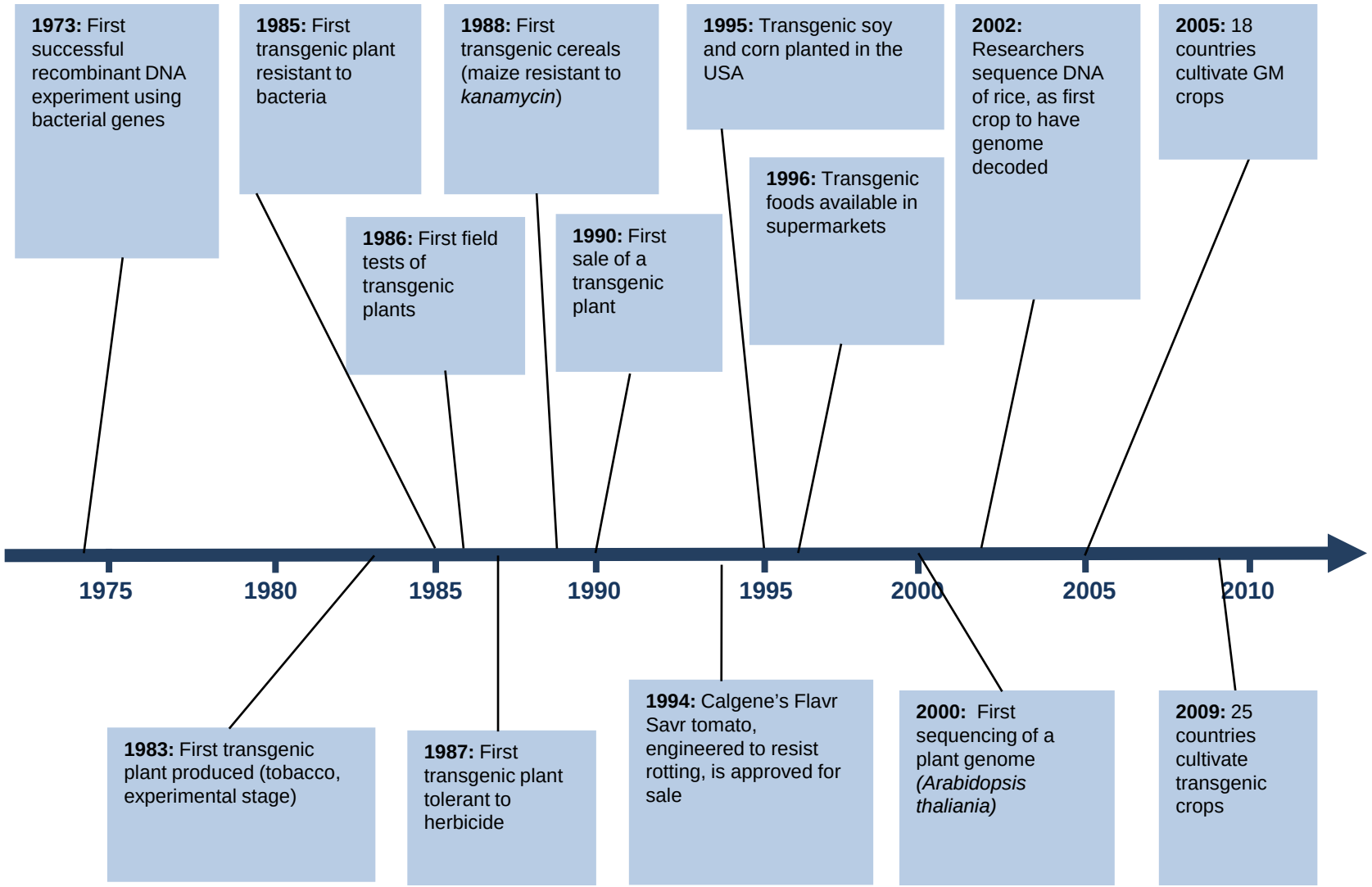

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THANK YOU !

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