

Safety Assessment Process to Register GM Products

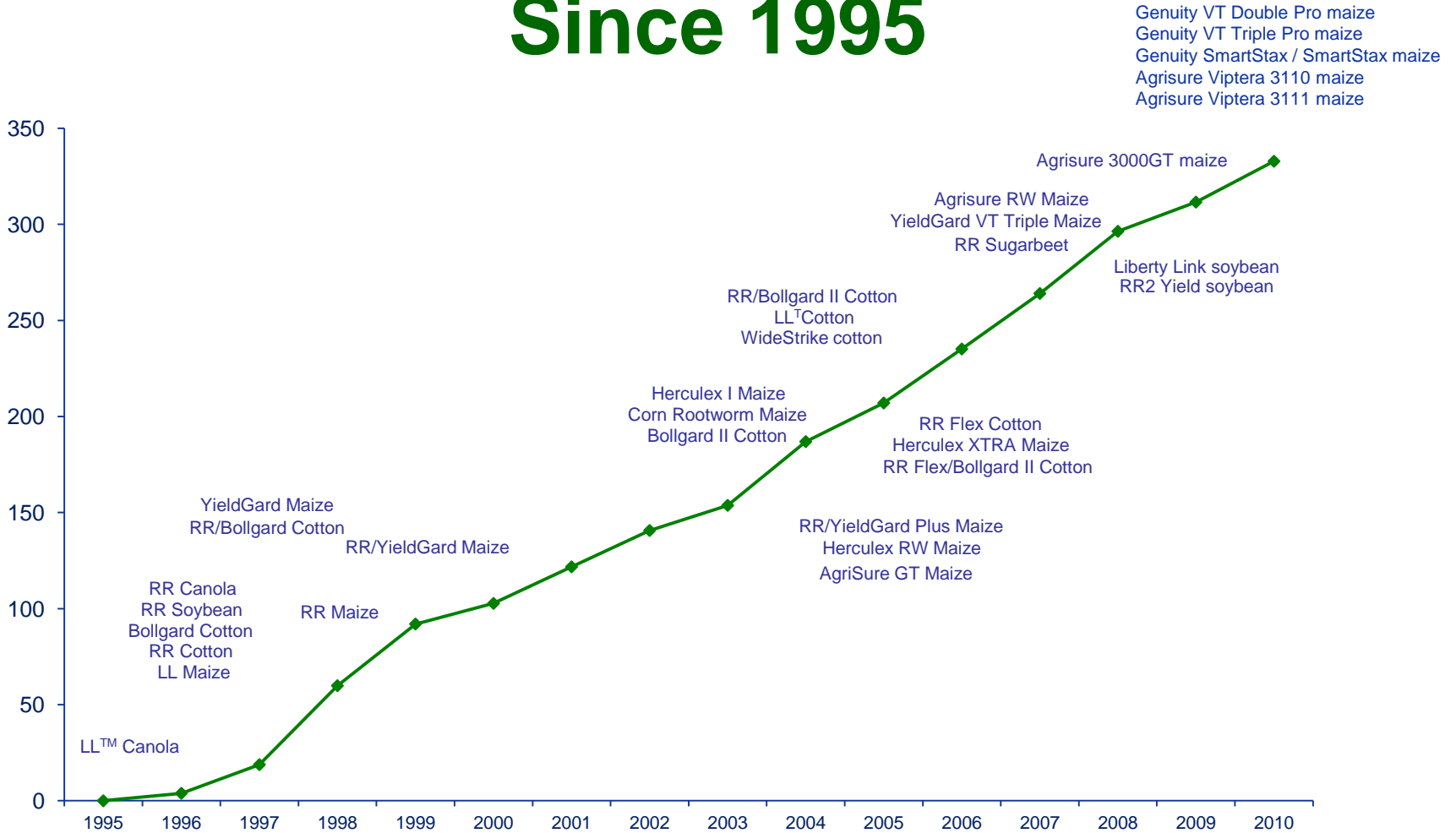
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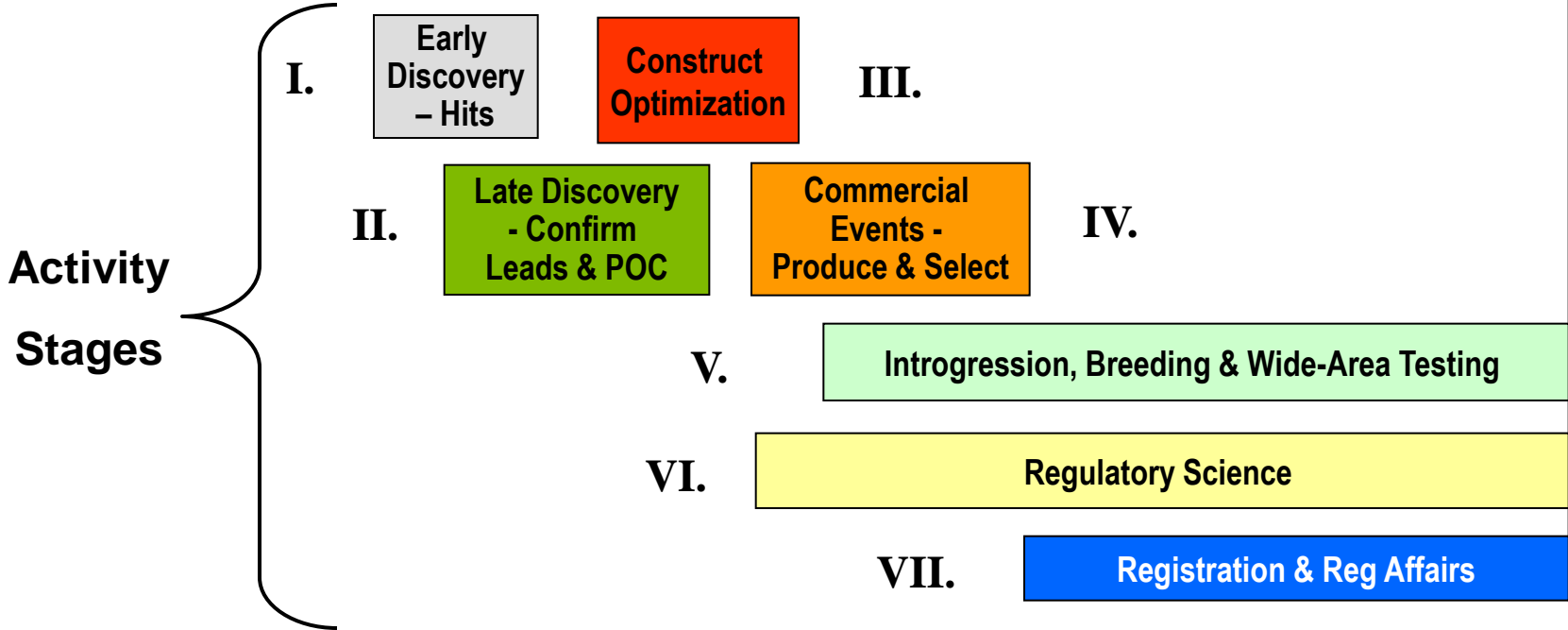
Crop Biotech Trait Introductions Since 1995

Planted area of biotech crops (million acres)



Activity Stages for Crop Biotech R&D

R&D Phases	Discovery			Proof of Concept		Early Development		Advanced Development		Pre-Launch					Launch
Years for R&D	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15

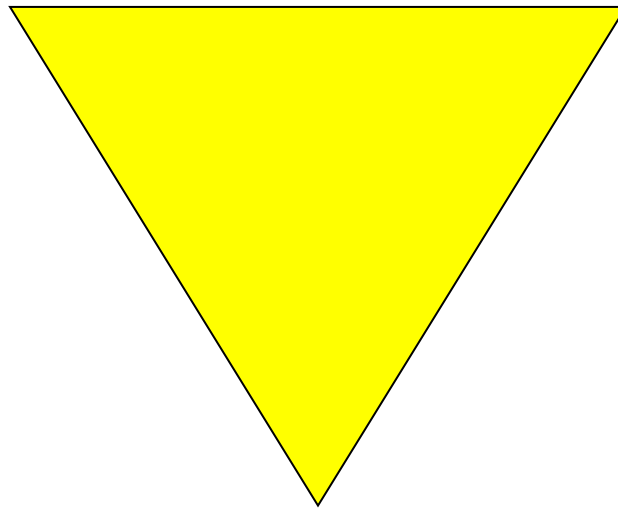


Regulatory Safety Evaluation for Biotech Crops

**Feed
Safety**



**Food
Safety**



**Environmental
Safety**



General Principles

- Substantial Equivalence
- Safety Assessment

Regulators conduct a peer-review on the science provided in the dossiers filed for GM crops



Substantial Equivalence

- Principle recognizes that it is not possible to demonstrate that any food is absolutely safe
- Originally proposed in 1991
 - Endorsed by International Scientific Organizations:
 - OECD
 - FAO/WHO
 - Codex Alimentarius Commission



Substantial Equivalence

- Foods from GM crops should be “as safe as” foods from non-GM crops
- Data are produced to determine if GM crops are similar to those with a history of safe use



Substantial Equivalence

— Multidisciplinary scientific efforts from:

- Agronomists
- Entomologists
- Bioinformaticists
- Allergologists
- Environmental fate
- Analytical chemists
- Molecular biologists
- Protein chemists
- Animal nutritionists
- Statisticians
- Toxicologists



Safety Assessment

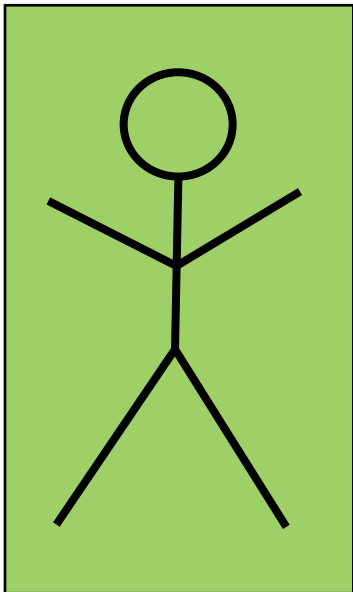
— Two Goals

- Assess the safety of intended changes
 - Frequently imparted by expression of transgenic proteins
 - Safety assessment of transgenic proteins
- Determine if unintended changes occurred during development of a GM crop that could result in adverse effects



New proteins may be expressed for GM traits

*in silico &
in vitro*



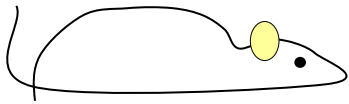
Database of

- all known protein allergens
- all known protein toxins

} *Search for potential
homology using
Codex (2003)
recommendations*

Protein digestibility (*time of potential exposure*)

- Simulated gastric fluid (SGF)
- Simulated intestinal fluid (SIF)

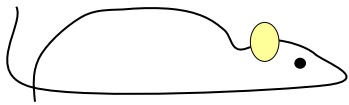


Confirm protein safety

- **Mouse acute oral toxicology study with purified protein**

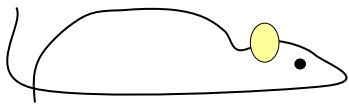
- **Health and diet of test animals is carefully controlled.**
- **Many decades of data from such studies provide the baseline**
- **Well-characterized & validated endpoints for organs and tissues.**





Confirm protein safety

- Mouse acute oral toxicology study with purified protein



Confirm the safety of grain composition

- 90-day rat feeding study



Environmental Safety Assessment

Case-by-Case Approach

- Different crops

Soy ⇔ canola ⇔ maize

- Different traits

Insect control ⇔ herbicide tolerance ⇔ drought

- Different receiving environments

Cultivating country ⇔ Importing country

Each Environmental Assessment is unique.



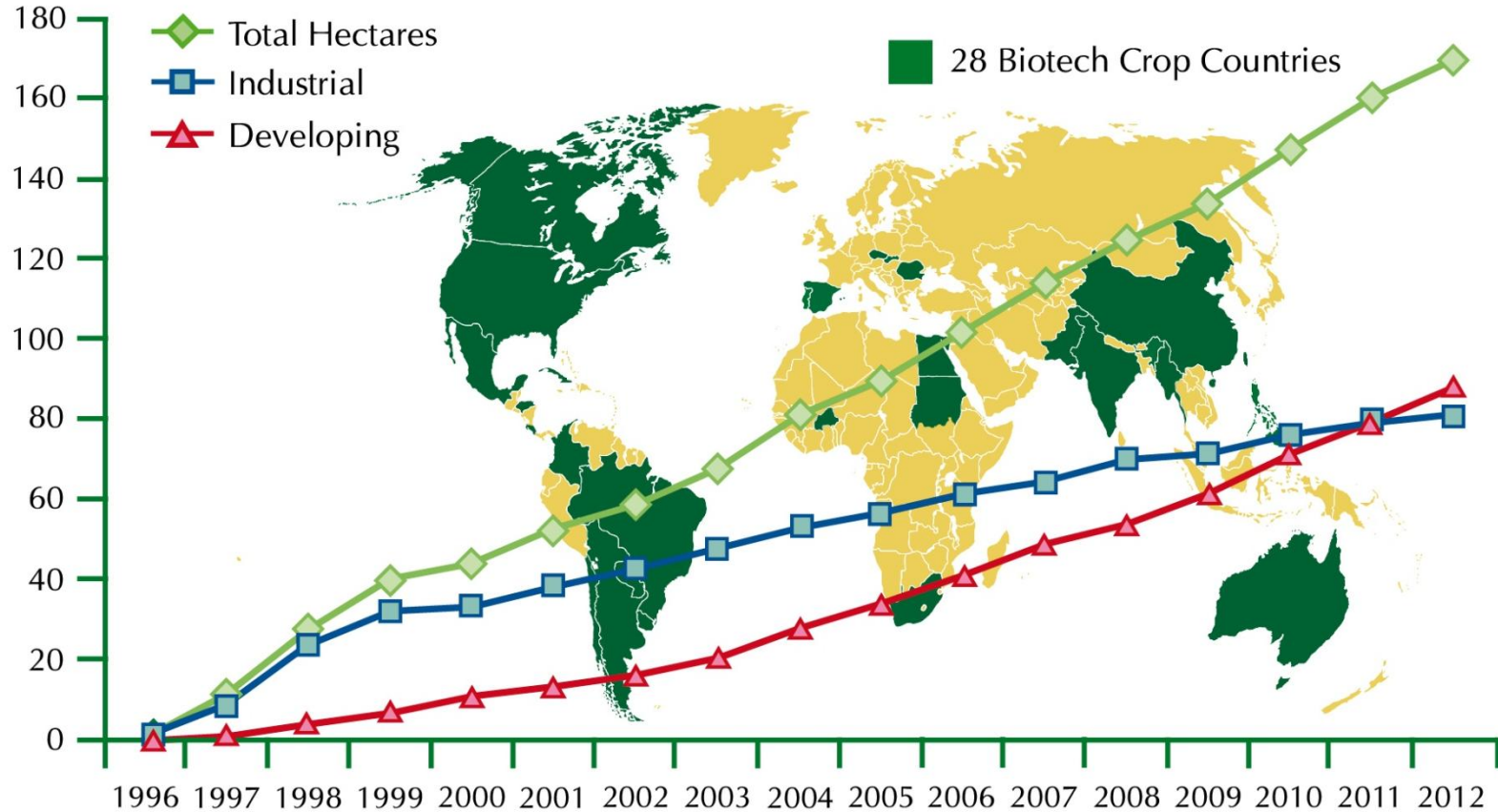
Conclusions

- Foods from GM crops undergo many scientific studies to demonstrate that they are substantially equivalent to those from non-GM crops
- Proteins expressed by GM crops undergo extensive analysis to demonstrate that they are not allergenic or toxic
- Environmental assessments are also conducted



Biotech Landscape: Global Adoption

GLOBAL AREA OF BIOTECH CROPS
Million Hectares (1996-2012)



Population & Income Drive the Demand for Corn & Soybean in the Last Decade

+13%

The growth in world **population** over the last 10 years

+29%

The growth in global **income** over the last 10 years

+18%

The growth in **meat consumption** (Beef +3%, Pork +18%, Chicken +35%) over the last decade

+10%

The growth in world **crude oil** consumption (OECD Countries -5%, Non-OECD Countries +35%) over the last decade

+23%

The 10-year growth in global **crop consumption** (Soybean+47%, Corn+37%, Wheat+13%, Rice+14%, Cotton+31%)

+9%

The growth in world **crop area** harvested over the last decade