# National & International Regulatory Framework

Technical Session II

Regulatory Frame Work Of GM Crops: National And International Framework

**Workshop On Safety Assessment OfGM Food**

**14-15 October, 2015**

**Hotel The Claridges, New Delhi**

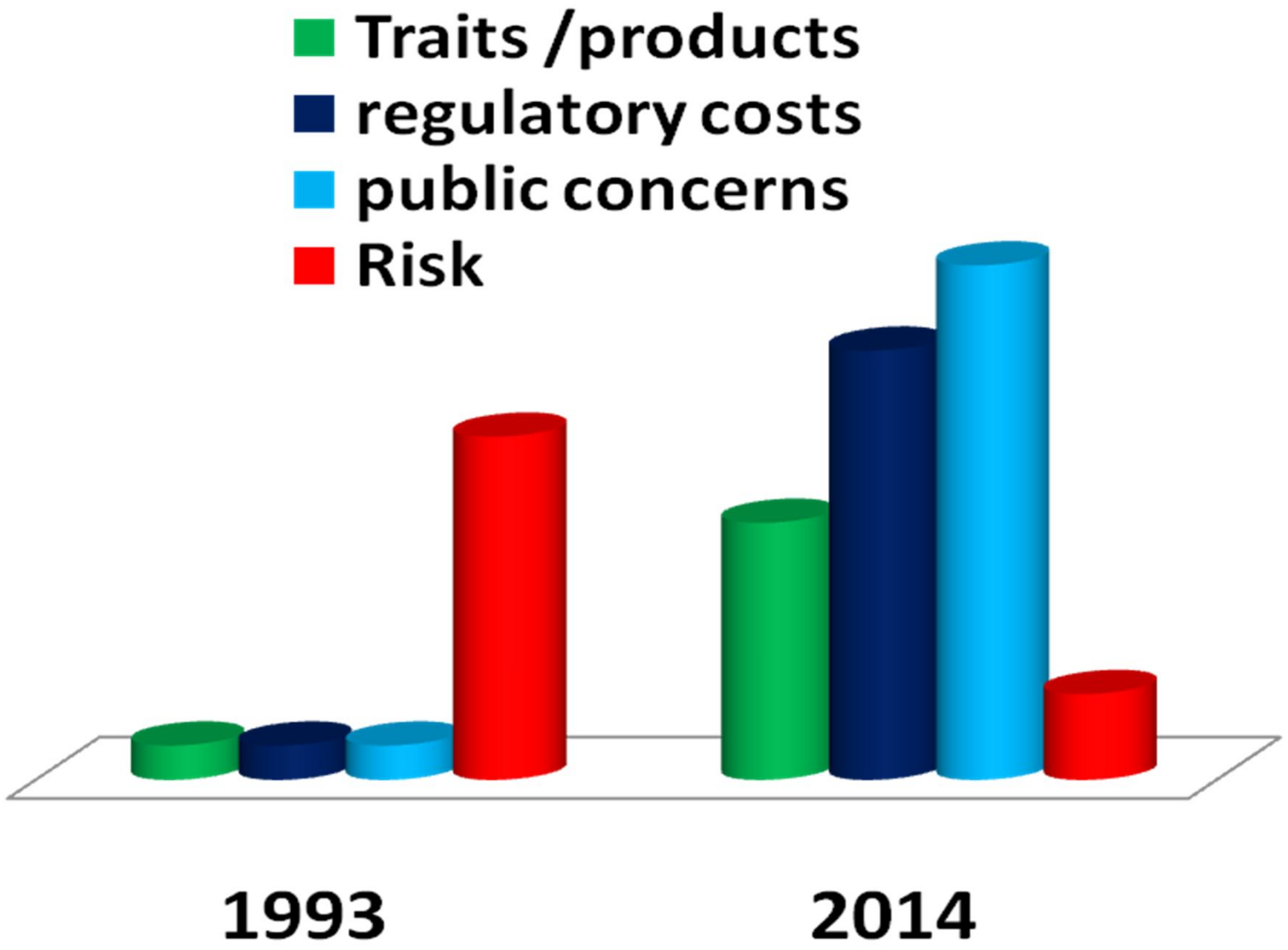




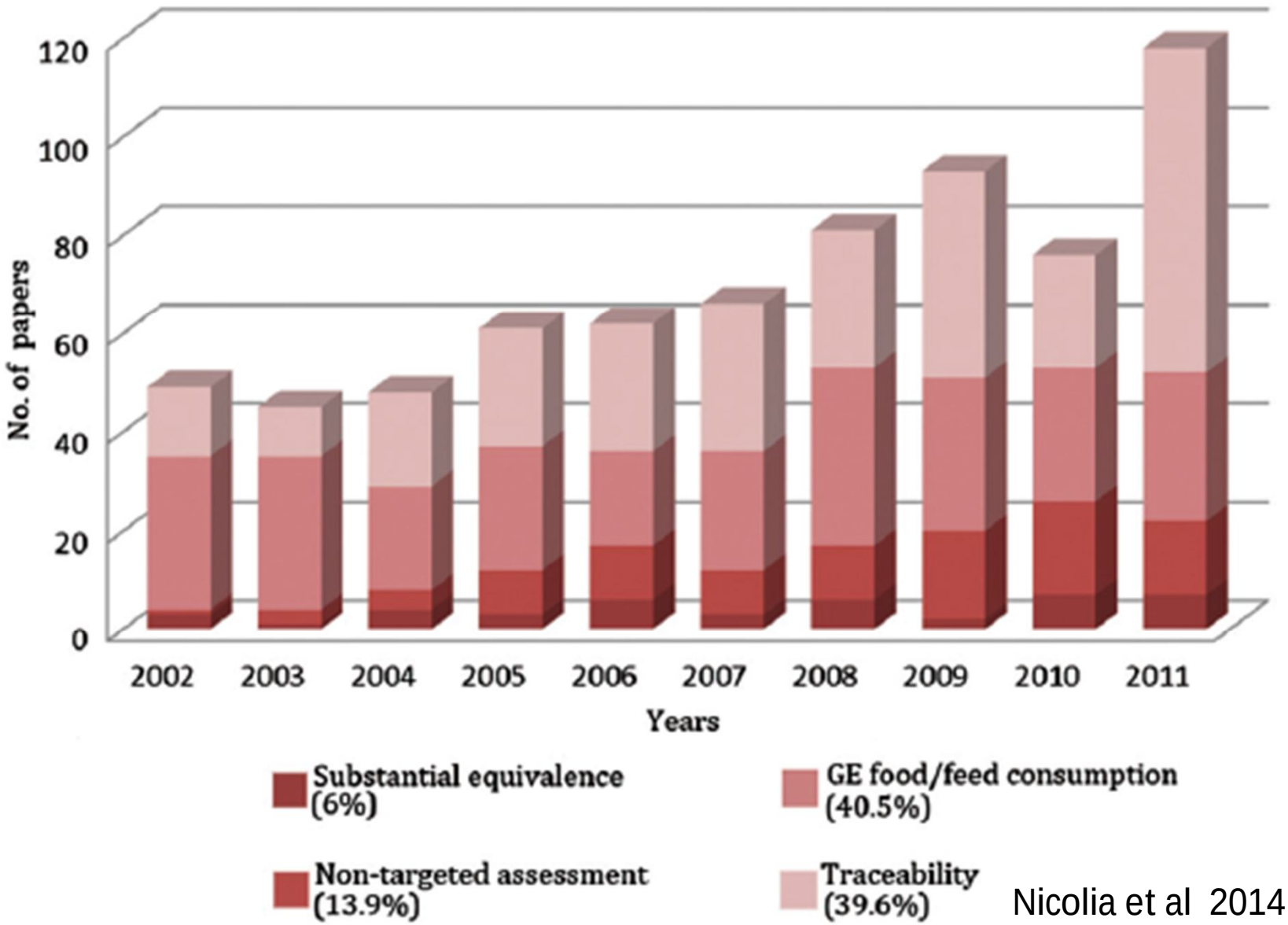


# Today's Topics

- Introduction
- International efforts in food safety
- Principles of GM food safety
- Current methods
- Laws Governing GM food safety in various countries
- Definitions of GMO in various countries and implications
- Indian Regulatory Frame Work
- Future requirements


Traits /products
regulatory costs
public concerns
Risk
1993
2014

# Publications out of 1783 total on GE food and Feed




Nicolia et al 2014

## Food Safety Systems—Institutions

- **OECD: Organization for Economic Cooperation and Development**
  - Promotes policies for highest sustainable economic development in member states
  - Establishes guidelines for chemical testing, toxic chemicals, pesticides, and biotechnology

- **Food and Agriculture Organization (FAO) of the United Nations**
  - Leads international efforts to ensure sufficient nutrition for all

- **World Health Organization (WHO) of the United Nations**
  - Provides scientific advice on matters related to food safety through its Food Safety Department

- **International Life Sciences Institute (ILSI)**
  - understanding of scientific issues relating to nutrition, food safety, toxicology, risk assessment, and the environment by bringing together scientists

# FAO/WHO Codex Alimentarius Commission

## Founded in 1963 by a joint initiative of the FAO and the WHO, the Codex Alimentarius Commission

- Formulates and harmonizes food standards and ensures global implementation
- Develops food standards, guidelines, and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme
- Generates guidelines to protect the health of consumers and ensures fair trade practices in food trade, and
- Promotes coordination of all food standards work undertaken by international governmental and non-governmental organizations

The Codex Alimentarius Commission established an Intergovernmental Task Force on Foods Derived from Biotechnology in 1999 to evaluate the health and nutritional implications of such foods.

The task force performs all of the functions listed above in relation to safety assessment of foods derived from genetically engineered organism based on the input of independent scientific expert consultations.







# The Evolution of Food Safety Systems

The Codex Alimentarius Commission has issued (since 1963)

- 237 Food Standards for commodities
- 41 codes/ Hygiene or technological practice
- 25 guidelines for Contaminants
- 185 evaluations of pesticides
- 1,005 Evaluations of food additives
- 54 evaluations of veterinary drugs
- 3,504 Documents / Limits pesticide residues

So far 5 expert consultation reports regarding safety of foods derived from genetically engineered organisms (including microorganisms, plants and animals) have also been issued.







*What is there that is not poison?*

All things are poison and nothing is without poison.

Solely the dose determines that a thing is not a poison.

Paracelcius (1493-1541)

# Toxicity Testing Methods

Many of the regulatory requirements for chemicals such as food additives and pesticides were first established during the 70s. These led to the development of a battery of tests to assess the safety of chemicals in foods

Most often, the results from three approaches are combined

1. Structure/function relationship – toxicity/allergenicity
2. In vitro assays – enzymes, receptors, cell lines
3. In vivo animal studies

**In order to monitor the performance of the product and the side effects, post-market surveillance can also be incorporated for certain products.**

4. Post-market monitoring

- Early warning
- Facilitates product recall
- Absence of adverse health effects
- Determining consumption patterns – implications and applications relevant to food toxicology to help determine estimated daily intake (EDI)

# Safety Assessments of Foods

## Food toxicology is unique

- Complex–1000s of macromolecules, micronutrients, anti-nutrients

- Ever-changing properties – Environment – Genetic rearrangement occurring in the plant

- For processed foods – Additives and chemicals migrating from the package

- Common food items – Presume their safety based on familiarity and history of use
  - –Neurotoxic glycoalkaloids present in potatoes

- Therefore, it is stateed that – *Safety can not be proved absolutely*



- Safety assessment seeks a level of *reasonable certainty that harm will not occur* (as long as they are free of contaminants)

**The milestones in the international consensus on the safety assessment of biotechnology-derived foods include the following:**

- ILSI Europe Concise Monograph Series Genetic Modification Technology and Food Consumer Health and Safety (Robinson 2001),
- EU-sponsored Research on Safety of Genetically Modified Organisms. "GMO Research in EU 2001 Perspective." Report of a Workshop held by External Advisory Groups of the "Quality of Life and Management of Living Resources" Program, European Union,
- New Zealand Royal Commission on Genetic Modification (NZRC 2001),
- FAO/WHO Guidelines for Codex Alimentarius Committee, developed by Task Force for Foods Derived from Biotechnology Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology (FAO/WHO 2002, 2003), and
- ILSI Crop composition database (www.cropcomposition.org) (ILSI 2003 to present).

# Safety Assessment of Foods Derived from GE Crops

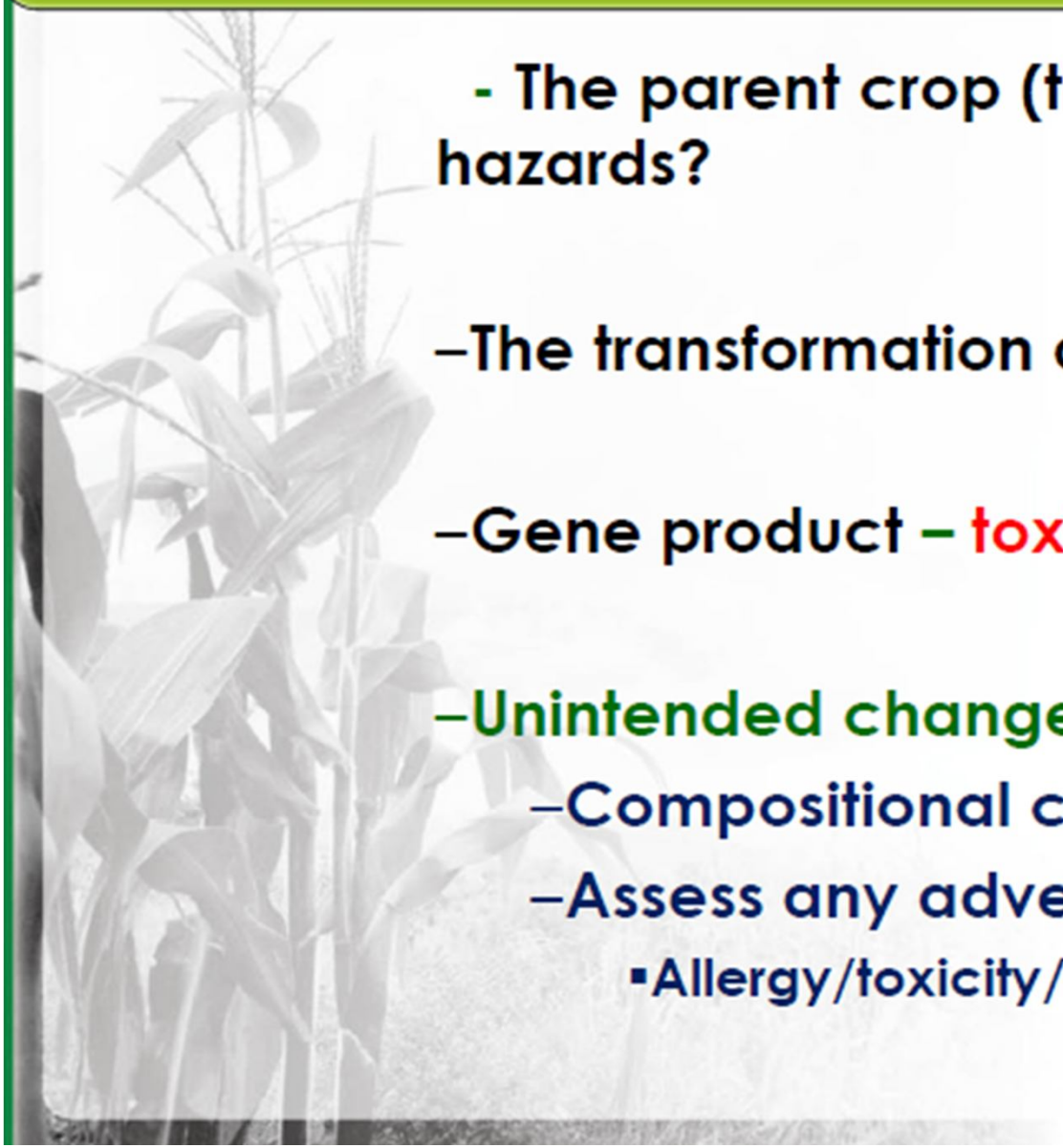
- Presumption of safety = Comparators Usually the traditionally bred parent crop

- Comparative assessment = Substantial Equivalence (FAO/WHO, 1991)

  - Agronomical and morphological characteristics
  - Chemical composition
    - Macro and micronutrients
    - Key toxins and anti-nutrients

**Are there any significant changes?**
**Do they pose a hazard to human health?**

# Hazard Identification & Characterization of GE Crops



- The parent crop (the comparator) – hazards?

–The transformation and inserted DNA

–Gene product – toxic/allergenic?

–Unintended changes

–Compositional changes

–Assess any adverse impact

▪Allergy/toxicity/nutritional alterations

# Test Methods to Assess the Safety of Foods Derived from GE Crops

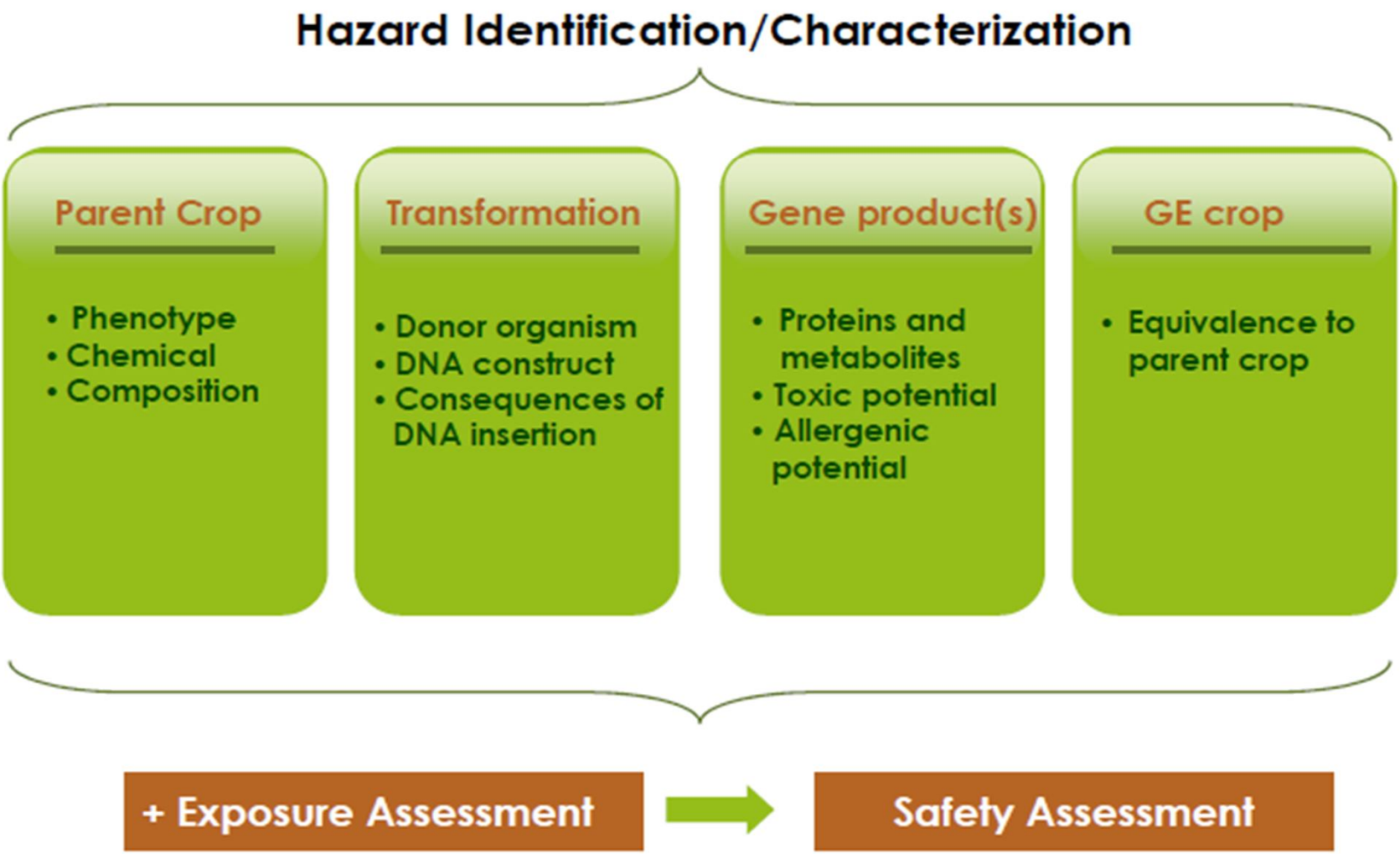
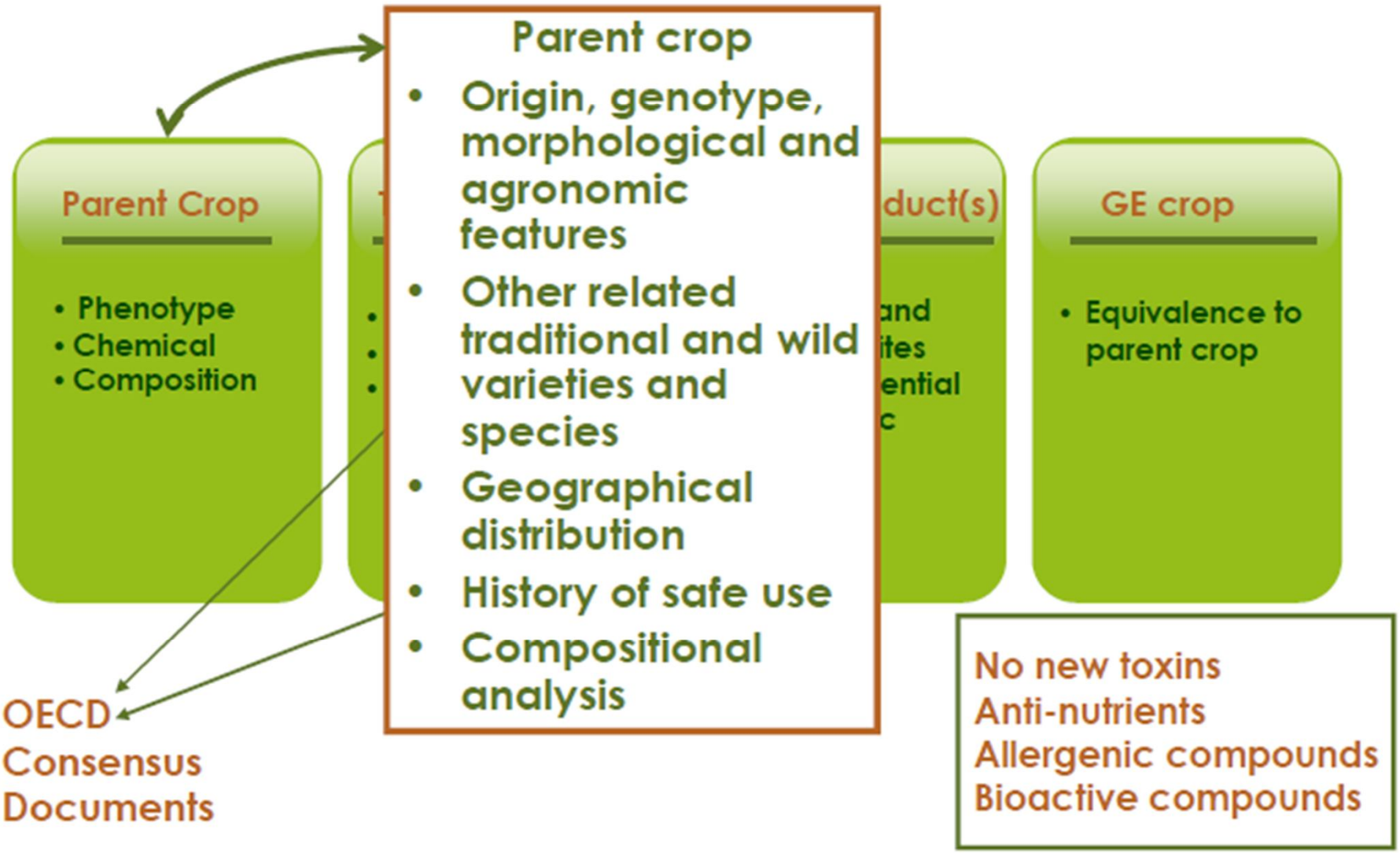



Figure modified from König et al, 2004

# Step 1 — Parent Crop

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# Step 2 — Donor Organism and Transformation

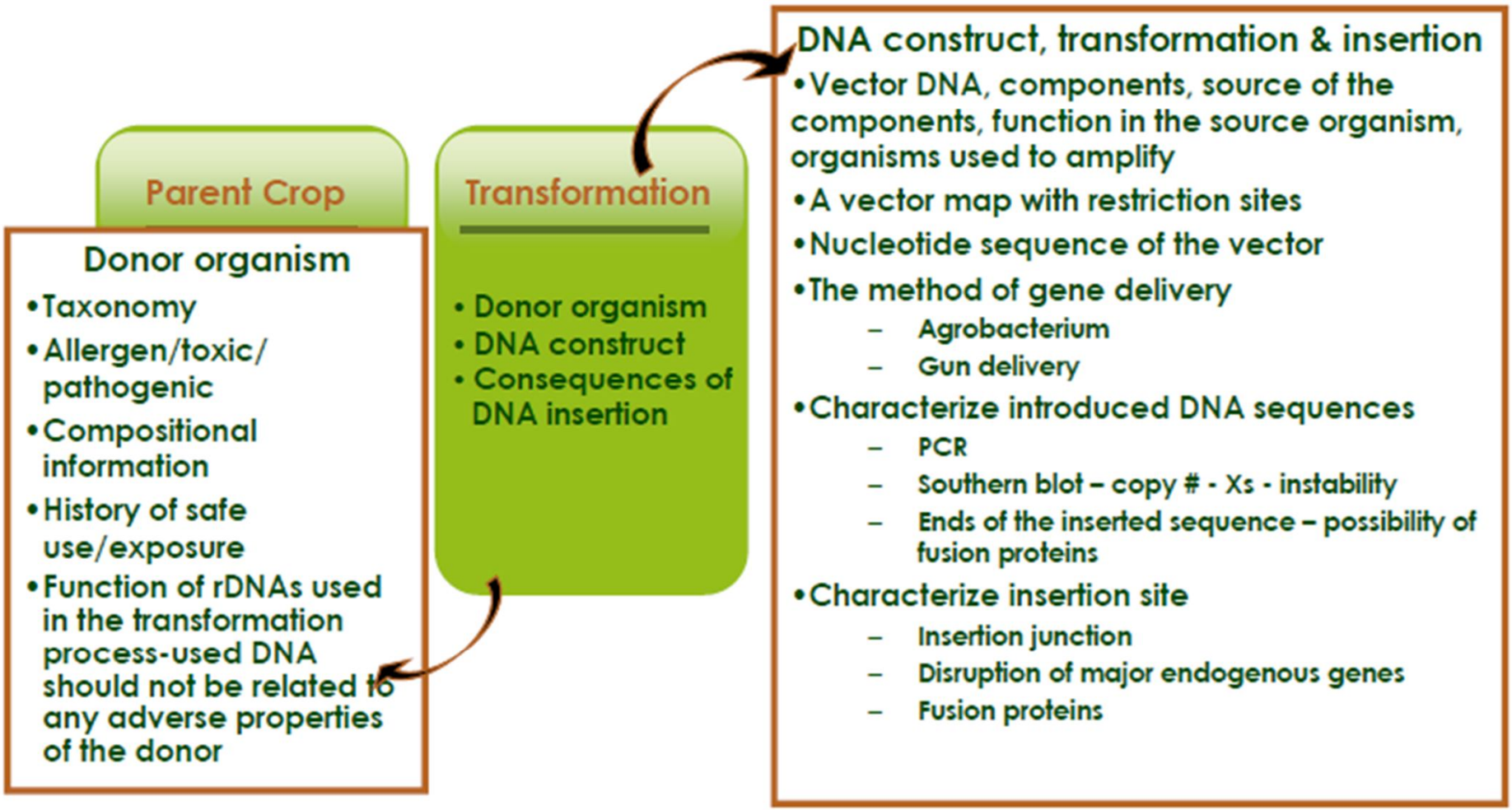


Figure modified from König et al, 2004

# Step 3 — Gene Products

**Recombinant proteins/metabolites**

- Protein-safety concern?
- Previous exposure/novel protein
- Structure, sequence, biochemical properties
  - Equivalent to the version produced in the source
    - MW
    - Aa sequence
    - Post-translational modification
    - Immuno-equivalance
- Mode of action
- Toxicity
- Allergenicity
  - Is the source an allergen/is the protein allergen?
  - Does the recombinant protein induce de novo sensitization?
  - Cross-reactivity with IgE induced by known allergens
  - FAO/WHO(2001), Codex Alimentarius (2003)

**Gene product(s)**

- Proteins and metabolites
- Toxic potential
- Allergenic potential

**GE crop**

- Equivalence to parent crop

Figure modified from König et al, 2004

# Step 4 — GM Crop

Finally the GE crop itself is subjected to tests to ensure that it is as s nal counterpart.

**GE crop**

- **Phenotypic and agronomic features**
  - Alterations: metabolic perturbations/pleitropic effects due to the modification
- **Compositional analysis**
  - Macro- and micro-nutrients, endogenous toxins and anti-nutrients
  - From different geographies
  - Helps design the animal diet

Parent Crop

- Phenotype
- Chemical
- Composition

duct(s)

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GE crop

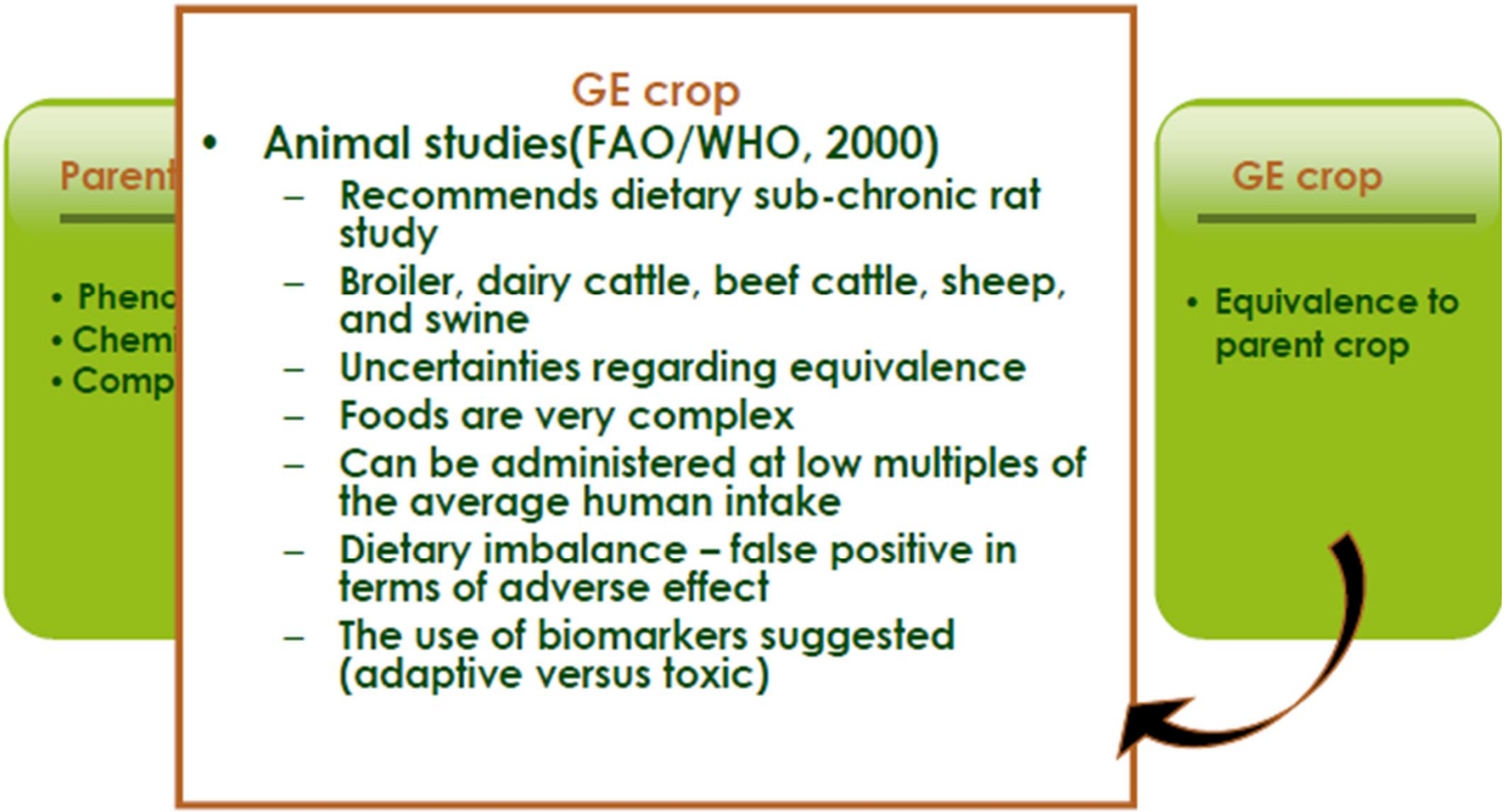
- Equivalence to parent crop

# Step 4 — GE Crop

An example:

- Roundup Ready soybeans
  - Soybeans naturally contain certain levels of anti-nutrients; trypsin inhibitor, lectins and isoflavones
  - Protein, oil, fiber, carbohydrates, moisture content, amino acid and fat composition in seeds and toasted soybean meal compared with conventional counterparts
  - Trypsin inhibitor levels were 11-26% higher in GE soybeans in defatted non-toasted soybean meal (not consumed-starting material)
  - In defatted, toasted soy meal trypsin inhibitor values were not different than the comparator
  - Feeding studies in rats, chickens, catfish, dairy cattle confirmed no nutritional value differences

# Step 4 —GE Crop



## Assessment of the health impact of GM plant diets in long-term and multigenerational animal feeding trials: A literature review……

- 12 long-term studies (of more than 90 days, up to 2 years in duration) and 12 multigenerational studies (from 2 to 5 generations)
- 90-day studies on GM feed for which long-term or multigenerational study data are available.
- Many parameters have been examined using biochemical analyses, histological examination of specific organs, hematology and the detection of transgenic DNA.
- The statistical findings and methods have been considered from each study.
- Results from all the 24 studies do not suggest any health hazards and, in general, there were no statistically significant differences within parameters observed.
- However, some small differences were observed, though these fell within the normal variation range of the considered parameter and thus had no biological or toxicological significance.
- Seven with Bt Maize on chicken, cattle , goats sheep and one Rice on monkey

Chelsea Snell et. al (2012) Assessment of the health impact of GM plant diets in long-term and multigenerational animal feeding trials: A literature review. Food and Chemical Toxicology 50 (2012) 1134–1148

# Test Methods to Assess the Safety of Foods Derived from GE Crops

As risk is correlated with levels and frequency of exposure to a certain hazard, safety assessment of food derived from GE crops can be completed with exposure assessment

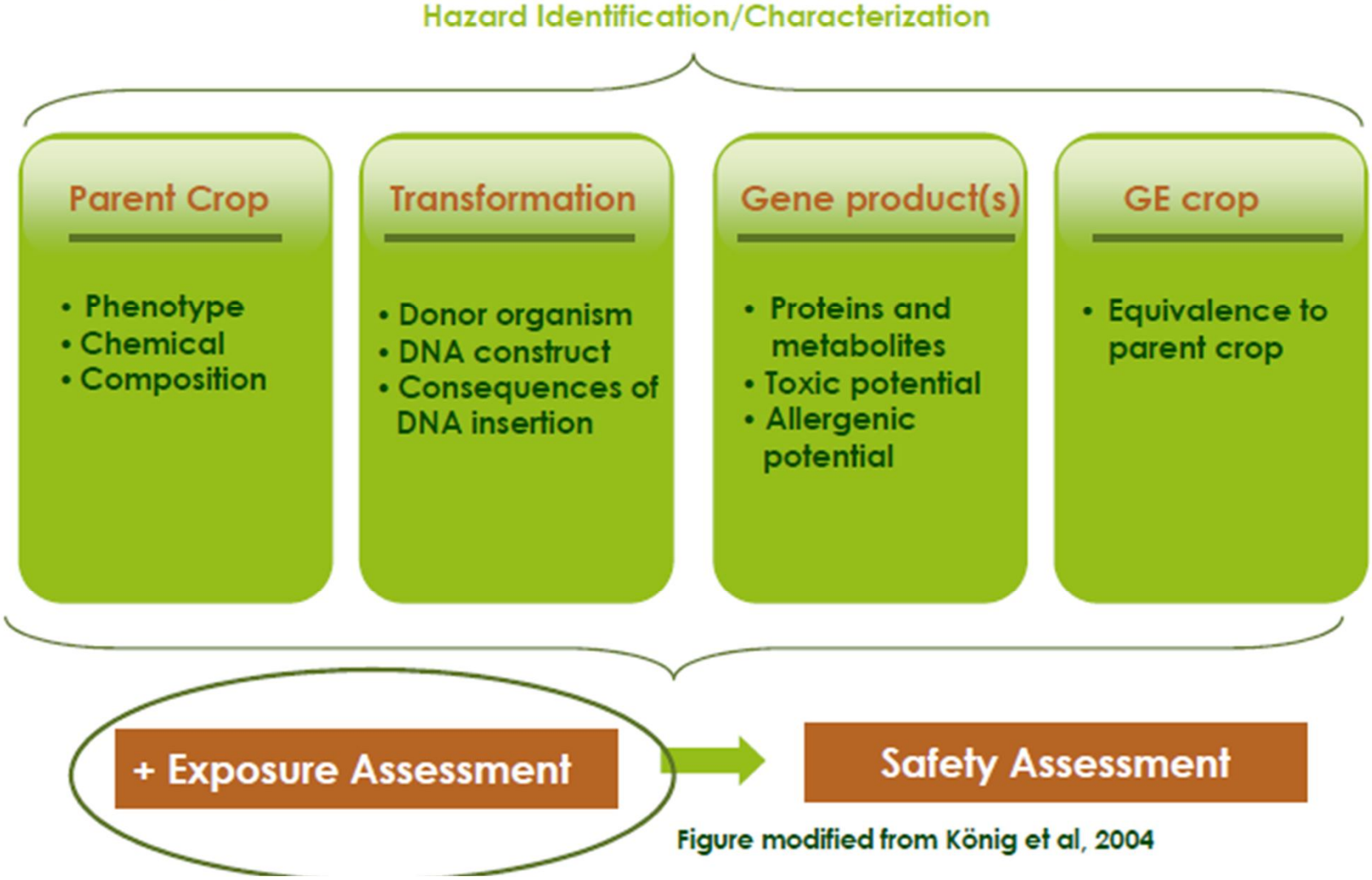



Figure modified from König et al, 2004

# Exposure Assessment

- Food supply information
- Household expenditure
- Food consumption surveys
- Import statistics

- Recombinant proteins in transgenic plants: 0.01-0.1% of total protein content (Betz et al, 2000)
- Estimated daily intake (EDI) for humans: 0.017 0.07mg/kg/day (König et al, 2004)
- NOAEL with acute toxicity tests >100 mg/kg/day (Chassy et al, 2002)

**Even if people consumed ~1,400X that of the EDI, there would not be a safety concern.**

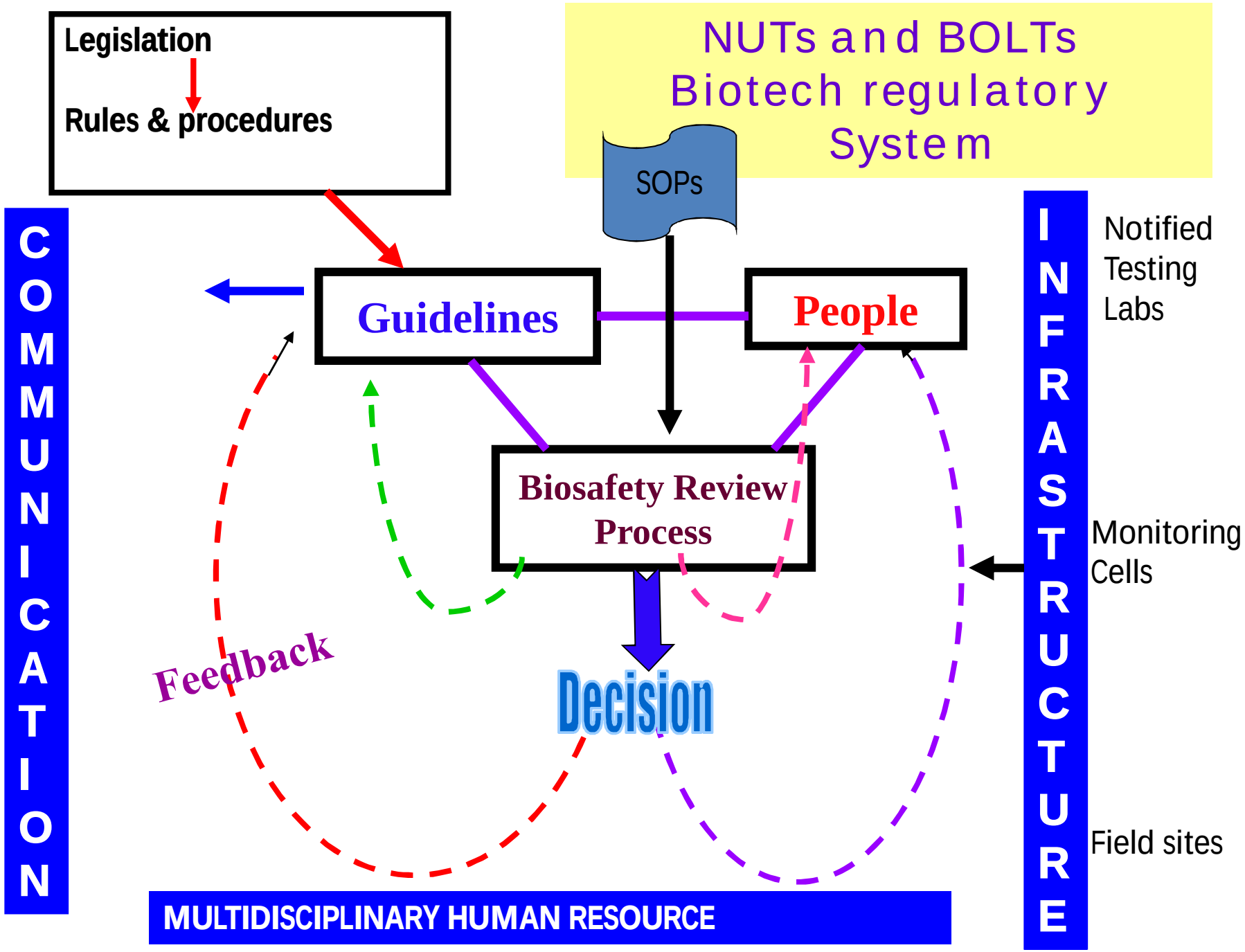
# Some facts of Gene products

| Protein studied | NOEL | Stable to digestion | Stable to processing? |
|---|---|---|---|
| Cry1Ab | >4000 | No (30s) | No |
| Cry1Ac | >5000 | No(30s) | No |
| Cry 2Aa | >4011 | No(30s) | No |
| Cry 3A | >1450 | No(30s) | No |
| Cry 3Bb | >3780 | No(30s) | No |
| Cry 9C | >3760 | +/- No(30s) | Partial |
| NPTII | >5000 | No | No |
| CP4EPSPS | >572 | No | N.A |
| GUS | >100 | No | N.A |

# Exposure Assessment

- GE seeds may be commingled with conventional ones
- Food ingredients derived from commodity crops are in many different products
- Food processing might alter ratios, may cause degradation

**Therefore, current exposure assessment approach does not take these degradation and overestimation into account to achieve the highest level of safety**


NUTs and BOLTs
Biotech regulatory System
Legislation
Rules & procedures
SOPs
Guidelines
People
Biosafety Review Process
Decision
Feedback
COMMUNICATION
INFRASTRUCTURE
Notified Testing Labs
Monitoring Cells
Field sites
MULTIDISCIPLINARY HUMAN RESOURCE

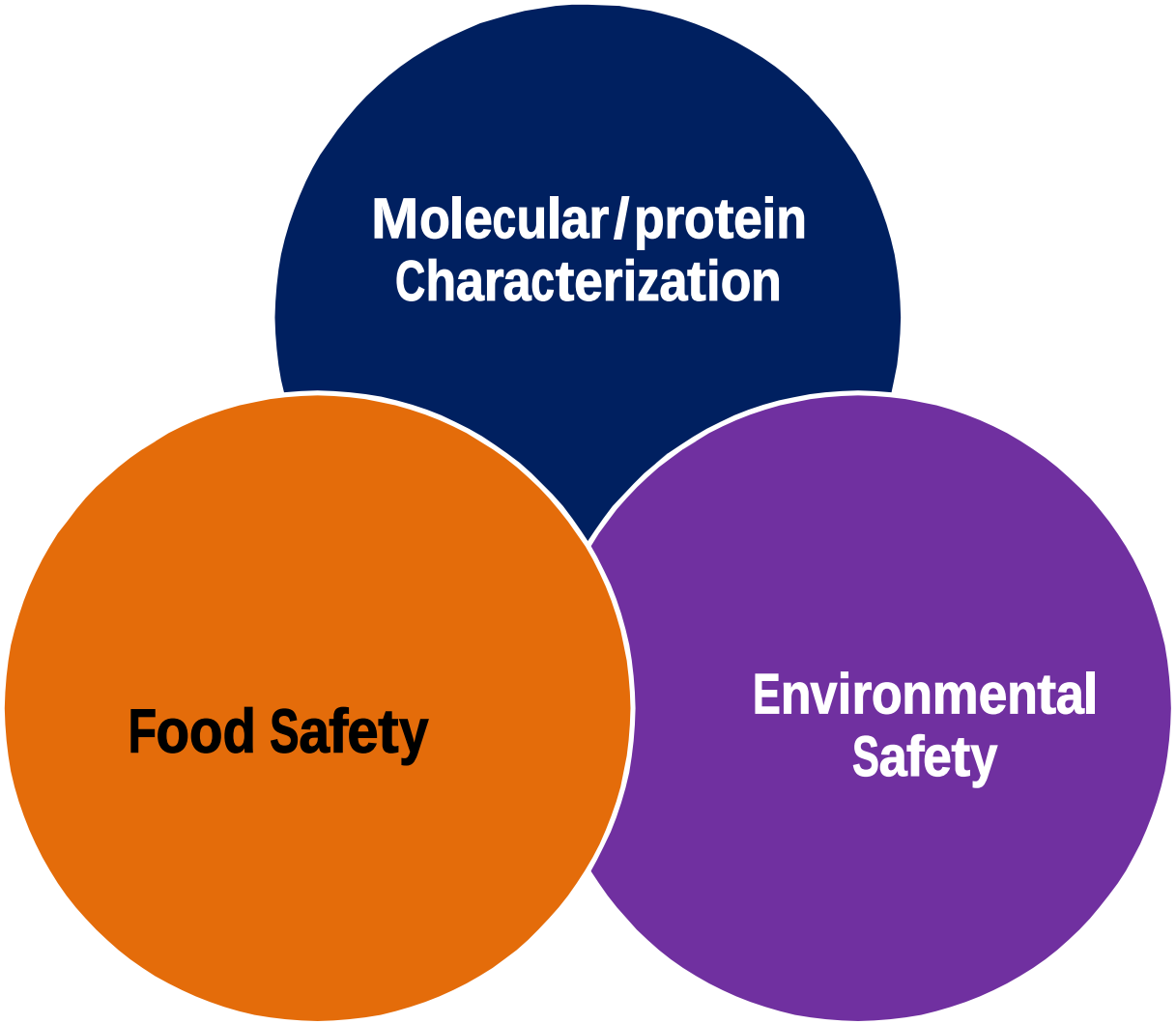
# Regulation of GM Crops


**The decision to regulate a plant is based on a variety of considerations**

- **Legal**
- **Social**
- **Scientific**

**Different jurisdictions will regulate differently based on their existing laws and regulations**

# Principles of scientific risk assessment




**Food and feed safety assessment** and the **environmental risk assessment** are **separate and distinct evaluations** and share some common elements of information through the **molecular characterization** of the GM organism and characterization of expressed, transgenic proteins

## Variable Agencies and laws governing GM crop regulation

| Country | Food safety | Environmental Safety |
|---|---|---|
| CANADA | Health Canada: Sole responsibility for evaluating the human health safety of all foods Authority is under the Food and Drugs Act and Regulations | Ministry of Environment |
| USA | Food and Drug Administration (Center for Food Safety and Applied Nutrition) | USDA – APHIS<br>Environmental Protection Agency |
| India | Environmental protection Act 1986<br>Ministry of Environment, Forests and Climate Change and Science And Technology | |

## Variable Agencies and laws governing GM crop regulation

| Country | Food safety | Environmental Safety |
|---|---|---|
| European Union | In 2012, the European Food Safety Authority (EFSA) which provides guidance under the framework of Regulation (EC) No 1829/2003 on GE food and feed. | Ministry of Environment of respective countries |
| Argentina | National Advisory Commission on Agricultural Biotechnology | National Service of Agri-food Health and Quality ( Food and feed) |
| Brazil | National Biosafety Technical Commission (CTNBio, part of the Ministry of Science, Technology and Innovation) | |

# Variable Agencies and laws governing GM crop regulation

| Country | Food safety | Environmental Safety |
|---|---|---|
| China | Regulatory oversight from laboratory to commercial use is within the Ministry of Agriculture (MoA) | |
| Australia | Australia- New Zealand Food Safety Authority | Office of Gene Technolgy Regulator. Gene technology Act 2000. Department of Health |
| South Africa | Ministry of Agriculture, Forest and Fisheries GMO Act, 1997 , Promulgated in 1999, Amended in 2006 and implemented in 2010 | |

## Establishment of regulatory oversight Different countries took *different regulatory approaches*:

- ***New gene technology laws vs. extending scope of existing laws***
- **Oversight by different authorities:**
  - **Ministry of Agriculture (or Fisheries)**
  - **Ministry of Environment**
  - **Ministry of Science**
  - **Multiple ministries**

- **Differences often a function of existing regulatory structures and legal enabling authorities, as well as different philosophies Some countries are members of Cartagena Protocol, some not**

- **Regulatory approach has affected the development of Plant Biotechnology**

## There are as many regulatory approaches as there are countries

- Little consistency between countries
- Much room for interpretation within countries
- Regulatory approach does not matter so long it is effective
- Science based and defensible
- Transparent
- Expeditious
- Credible to the public – who may be more concerned about non – scientific, value based issues

**Establishment of regulatory oversight Different countries took *different regulatory approaches*:**

- Differences between countries
  - Regulation endpoints based upon adverse effects or defined risks
  - Combined or separate environmental or food/feed safety reviews
  - Triggers- novelty, GE/GMO, combination
  - Adverse effects
  - Number of ministries involved in regulation (and in developing positions for international discussions)

# Variable definitions in laws across world would be determining future course of regulation of new technologies

| Country | Definition by Law of Land |
|---|---|
| CANADA | **Novel Foods**: Products that have never been used as a food; foods which result from a process that has not previously been used for food; or, foods that have been modified by genetic manipulation. |
| USA | USDA :<br>A "regulated article" must meet two requirements:Produced using genetic engineering (recombinant DNA techniques) **AND** Donor organism, recipient organism,vector, vector agent, is a plant pest **OR** Is an unclassified organism the Administrator determines is a plant pest or has reason to believe is a plant pest |

**Variable definitions in laws across world would be determining future course of regulation of new technologies**

| Country | Definition by Law of Land |
|---|---|
| **EUROPEAN UNION** | **GMO/GMM defined as *"an organism/micro-organism... in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination"***<br><br>**Annexes in Directive: Non-exhaustive list of techniques that lead to genetic modification; Techniques not considered to result in genetic modification (exhaustive list) AND Techniques excluded from the scope of the GMO legislation (exhaustive list)** |
| **ARGENTINA** | **Genetically Modified Plant Organism (GMPO) :** plant organism that has a ***combination of genetic material*** obtained through the application of modern biotechnology.<br><br>**Combination of genetic material :** A new DNA sequence that has been introduced into the plant genome and encodes for a new protein or some functional element. |

# Variable definitions in laws across world would be determining future course of regulation of new technologies

| Country | Definition by Law of Land |
|---|---|
| AUSTRALIA | *genetically modified organism* means:an organism that has been modified by gene technology; or an organism that has inherited particular traits ... that occurred in the initial organism because of gene technology; or anything declared by the regulations to be a GMO;<br>but does not include: a human being, if the human being is covered by paragraph (a) only because [of] somatic cell gene therapy; or an organism declared by the regulations not to be a GMO |
| INDIA | *Genetic engineering" means the technique by which heritable material, which does not usually occur or will not occur naturally in the organism or cell concerned, generated outside the organism or the cell is inserted into said cell or organism. It shall also mean the formation of new combinations of genetic material by incorporation of a cell into a host cell, where they occur naturally (self cloning) as well as modification of an organism or in a cell by deletion and removal of parts of the heritable material;* |

## Variable definitions in laws across world .....

| Country | Definition by Law of Land |
|---|---|
| OECD | rDNA (1986) safe development and use of rDNA organisms<br>➢Techniques used to produce organisms with novel genetic combinations<br>➢Represent an extension of conventional genetic procedures<br>➢Risks presented by organisms same in kind as those posed by any other organism.<br>➢Governed by same physical and biological laws. |
| Cartagena protocol | "modern biotechnology" means the application of *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid and direct injection of nucleic acid into cells or organelles, or fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection but does not include tissue culture of unmodified plant cells; animal cell culture of unmodified gametes; and natural processes such as conjugation, transduction, transformation; polyploidy induction; and mutation breeding; |

# Definition of rDNA

- No agreed upon definition in OECD texts.
- Reference country definitions
- Sometimes use “transgenic”
- GMOs
- LMOs
- GEOs.
  - Introduction of a trait.

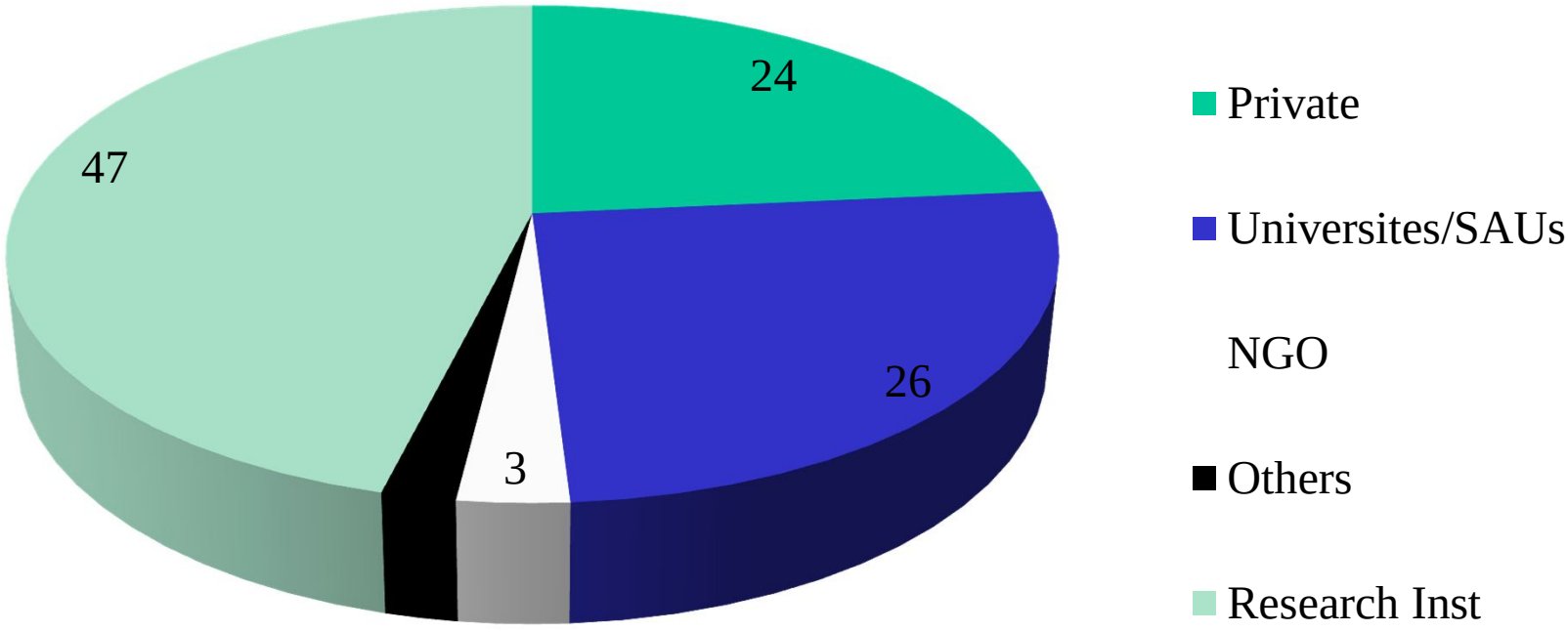
# Similarities between countries

- Risk assessment systems
  - Biology + trait + environment X interaction
  - Field Trials
  - Use of familiarity
  - Comparative
  - Step-by-step, case-by-case
  - Conditional approvals
  - Federal structure and local laws

# Summary of survey on GM research Activity 2014-2015

# Source MOEFCC

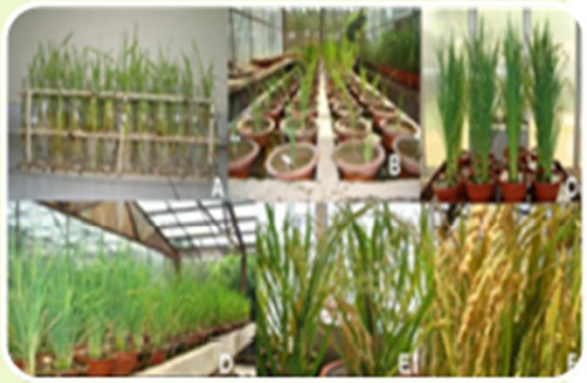
**243 Agencies**



# PUBLIC PERCEPTION AND RESPONSE

## Task force on Agricultural Biotechnology

## M/o Agriculture



2003-2005

**Need for New Authority**

**Priorities**

**Do 's do not's**

## Task force on biopharma

## M/o Environment & Forests

2004-2006

**Need for New Authority**

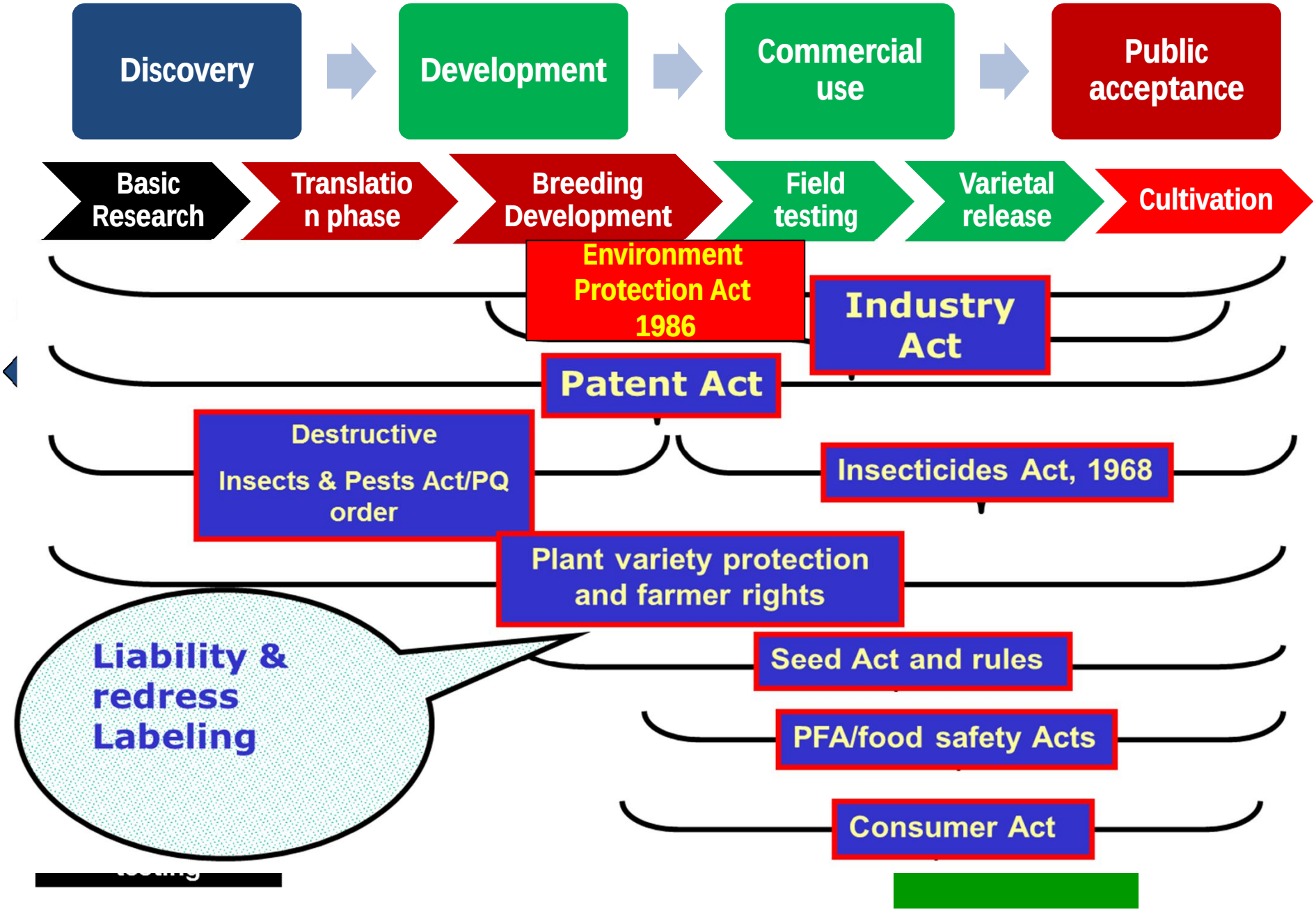
**Simplification of biopharma regulations**

## Expert Committee On Genetically Modified on food safety

2005-2006

**Harmonize food safety assessment with international systems**

# Complexity with Research Development and Commercialization of Transgenics



## Regulatory frame work - Scope

# ENVIRONMENT PROTECTION ACT 1986

## RULES FOR THE MANUFACTURE, USE/IMPORT/EXPORT AND STORAGE OF HAZARDOUS MICROORGANISMS/ GENETICALLY ENGINEERED ORGANISMS OR CELLS

**New Delhi, The 5th December, 1989**

## Applicable to:

- **The import, export, transport, manufacture, process, use or sale of GMOs and use of GMOs for research**
- **Authorization for production of genetically modified microorganisms, plants and animals**
- **Approval for deliberate or intentional release of GMOs into the open environment**
- **Approval for production, sale and import of foodstuff, ingredients in foodstuff including processing aid which may contain GMOs or cells**

# Regulatory frame work - Scope..... Statutory Bodies

| | | | |
|---|---|---|---|
| National Level | Genetic Engineering Appraisal Committee (GEAC) | Final Approval for environmental release | Ministry of Environment and Forests |
| National Level | Review Committee For Genetic Manipulation (RCGM) | Scientific risk assessment of plants, animals, biopharma, microbes and Guidelines | Ministry of S&T Department of Biotechnology |
| State Level | State Biotechnology Coordination Committee (SBCC) | Local monitoring and compliance | 29 State governments |
| Institute university/ company level | Institutional Biosafety Committee (IBSC) with Nominee of RCGM | R&D and Contained Experiments | Ministry of S&T Department of Biotechnology |

**Expertise in RCGM (about 36 members) including 6 inter-ministerial nominations**

**Mandate : Scientific Risk assessment of all recombinant products and recommendation to GEAC /DCGI etc**

**Core Characterization** : Molecular biologist; Microbiologists; Biochemist; Toxicologists; Bioinformatics; Biostatistics

**Animal Biotechnology** Physiologist; Pathologist; Nutritionist; Animal Breeder; Veterinary Scientist; Fisheries/ aquaculture scientist

**Plant Biotechnology**; Physiologist; Pathologists; Entomologist; Agronomist; Plant Breeder

**Human health Biotechnology**; Immunologist; Epidemiologist; Pharmacologist; Clinical Scientist

**Industrial and Environmental Biotechnology;** Ecologist; Environmental biologist; industrial microbiologist; Bioprocessing and Analytical Chemist

# Composition of GEAC

(i) **Chairman –** Additional / Special Secretary, MoEF

**Co-Chairman –** Representative of Department of Bio-technology

**Vice-Chairman –** Joint Secretary, MoEF

(ii) **Members:**

(iii) **Expert Members :** Representatives of concerned Agencies and Departments, namely, Ministry of Industrial Development, Department of Biotechnology and the Department of Atomic Energy. Director General-Indian Council of Agricultural Research, Director General – Indian Council of Medical Research, Director General – Council of Scientific and Industrial Research, Director General-Health Services, Plant Protection Adviser, Directorate of Plant Protection, Quarantine and Storage, Chairman, Central Pollution Control Board and AYUSH.

(iv) **Member Secretary :** An official of the Ministry of Environment, Forest and Climate Change.

(v) **Co-opt:** 13 Experts co-opted

## Regulatory frame work - Scope..... Guidelines

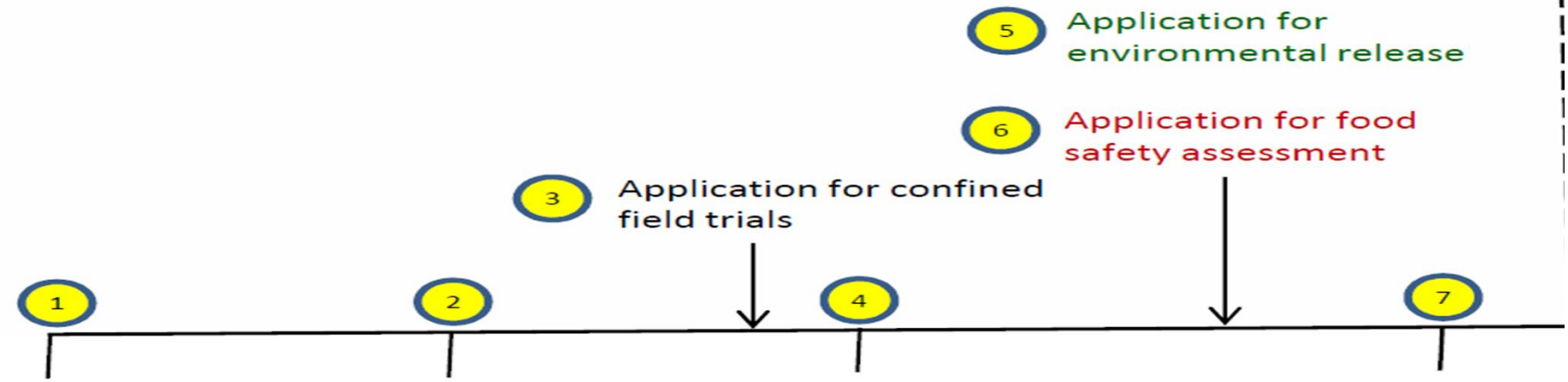
**The approach to formulation of new Guidelines or for review or revision of protocols, guidelines of safety assessment of GM crops in India at national level is:**

**to examine all the available peer reviewed research publications and documented experiences followed by wide ranging consultation at multiple level of stakeholders to arrive at consensus documents for wider adoption and harmonisation of practices at global level**

# CURRENT ROADMAP DEVELOPMENT PROCESS OF A GM CROP

**GE PLANT MATERIAL REGULATED UNDER RULES, 1989 & RELEVANT GUIDANCE IS IN PLACE**

- Guidelines for Research in Transgenic Plants, 1998
- Guidelines and Standard Operating Procedures (SOPs) for Confined Field Trials of Regulated Genetically Engineered (GE) Plants
- Guidelines for the Monitoring of Confined Field Trials of Regulated, GE Plants
- Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants
- Protocols for Food and Feed Safety Assessment of GE crops




**Laboratory research**
- Construct development
- Plant transformation
- Plant regeneration
- Tissue culture

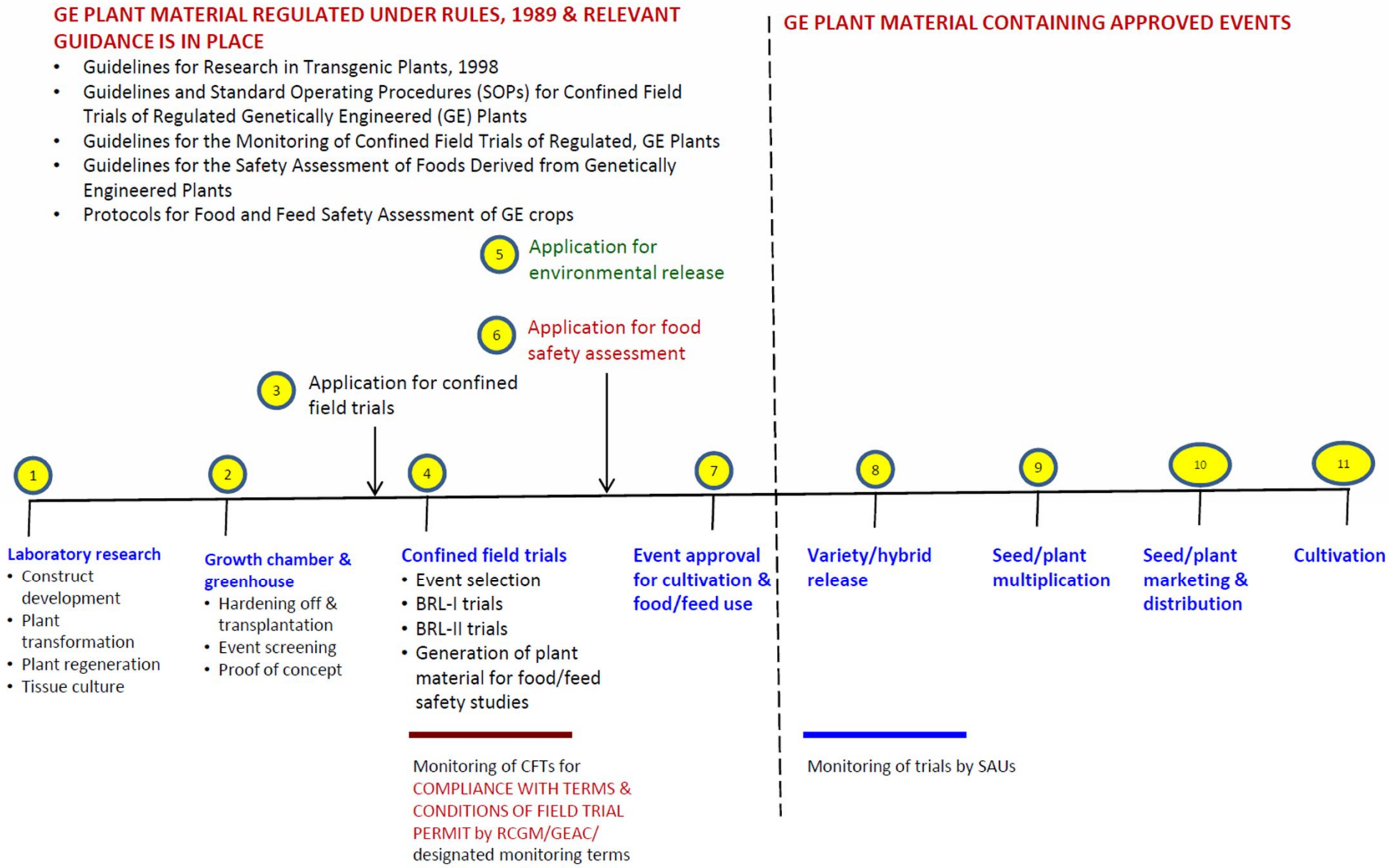
**Growth chamber & greenhouse**
- Hardening off & transplantation
- Event screening
- Proof of concept

**Confined field trials**
- Event selection
- BRL-I trials
- BRL-II trials
- Generation of plant material for food/feed safety studies

Monitoring of CFTs for COMPLIANCE WITH TERMS & CONDITIONS OF FIELD TRIAL PERMIT by RCGM/GEAC/ designated monitoring terms

**Event approval for cultivation & food/feed use**

# CURRENT ROADMAP DEVELOPMENT PROCESS OF A GM CROP

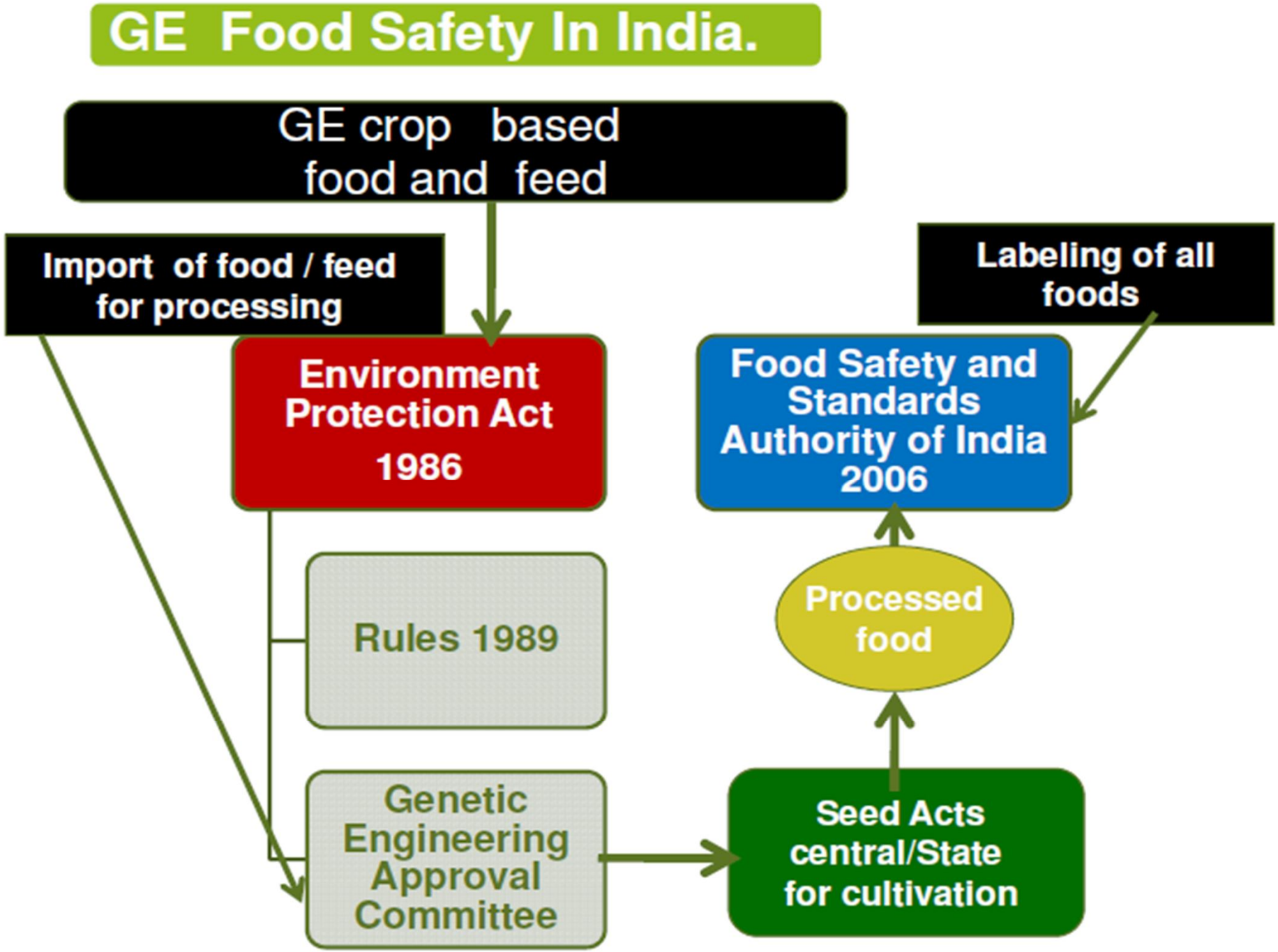


# Specific information and data requirements for the Food & Feed Safety and Environmental Risk Assessment of GE plants

- Description of the genetically engineered plant
- Biology of the non-transgenic host plant
- Donor organism information
- Molecular characterization
- Bio-informatic analysis: potential toxicity and allergenicity
- Expression of introduced protein(s)
- Compositional analysis
- Acute oral safety limit study
- Pepsin digestibility assay
- Protein thermal stability
- Sub-chronic feeding study in rodents (if required)
- Livestock feeding study (if required)
- Inheritance of introduced trait
- Stability of introduced trait
- Reproductive and survival biology
- Impact on non-target organisms

# GM Food Safety Evaluation

| Category of Information/Data Requirement | India | Argentina | Australia | Canada | Philippines | Japan | S. Africa | EU | USA |
|---|---|---|---|---|---|---|---|---|---|
| Host information | X | X | X | X | X | X | X | X | X |
| Donor information | X | X | X | X | X | X | X | X | X |
| Molecular characterization | X | X | X | X | X | X | X | X | X |
| Characterization of expressed protein | X | X | X | X | X | X | X | X | X |
| Nutritional composition | X | X | X | X | X | X | X | X | X |
| Potential toxicity of novel protein(s) | X | X | X | X | X | X | X | X | X |
| Potential allergenicity of novel protein(s) | X | X | X | X | X | X | X | X | X |


GE Food Safety In India.
GE crop based food and feed
Import of food / feed for processing
Labeling of all foods
Environment Protection Act 1986
Food Safety and Standards Authority of India 2006
Rules 1989
Processed food
Genetic Engineering Approval Committee
Seed Acts central/State for cultivation

## Now and In The Future

- FAO/WHO, 1991, 1996, 2000, 2001
- Codex Alimentarius Commission, 2003
- NAS, 1987
- NRC, 1989, OECD, 1993, 1996, 1998, 2002

## Conclusions

**Potential risks that foods derived from GE crops are not different than those of new varieties produced with conventional breeding**

- Substantial equivalence
- Case-by-case analysis tailored for the GE crop under question
- No adverse effects so far
- Future? – Advances in molecular biology, biochemistry, allergy science, nutrition, and toxicology

# In the future?

- Existing methodologies are considered sufficient for safety assessment of GE crops

- First generation of GE crops; herbicide tolerant or insect resistant

- Next generation of GE crops; more complex – nutritionally enhanced or resistant to abiotic stress

- New methodologies for safety assessment?
- Most likely

# Resources

http://www.who.int/foodsafety/biotech/en/

http://www.fao.org/UNFAO/about/index_en.html

http://www.cfsan.fda.gov/list.html

http://www.foodsafety.gov/~fsg/biotech.html

BIGMAP ( Biosafety Institute for Genetically Modified Agricultural Products) Iowa State University

Thanks

# Thanks