

**UNDERSTANDING THE IMPLICATIONS OF INTELLECTUAL  
PROPERTY RIGHTS AND PLANT VARIETY PROTECTION ON  
DEVELOPMENT OF TRANSGENIC VARIETIES AND RELATED  
BIOLOGICAL MATERIALS**



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*ILSI workshop on Detection methods ---crops November 17<sup>th</sup> 2011*

## Technologies

DNA Markers  
Automation  
BAC & YAC libraries  
EST databases  
Reverse genetics  
DNA chips

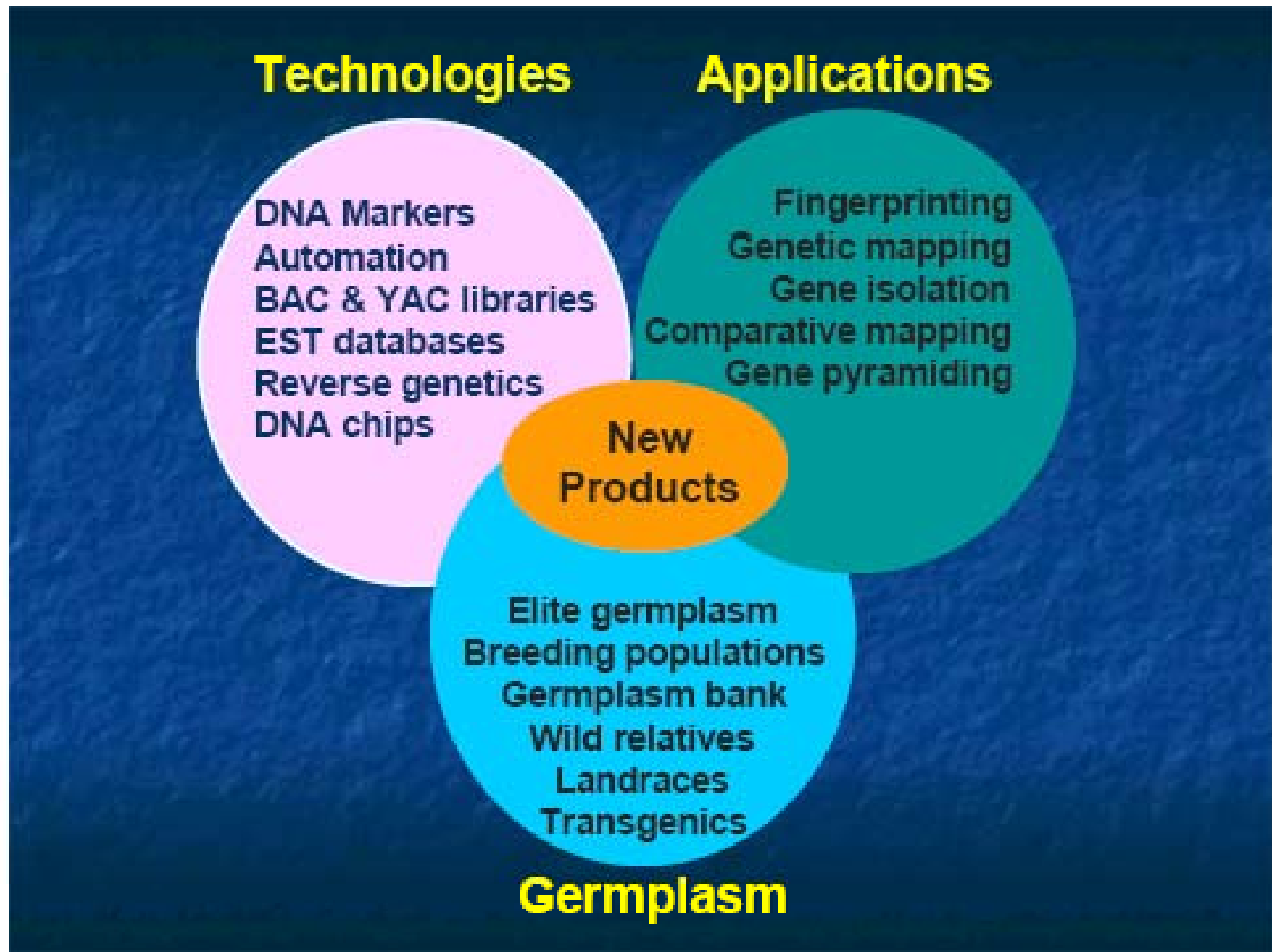
## Applications

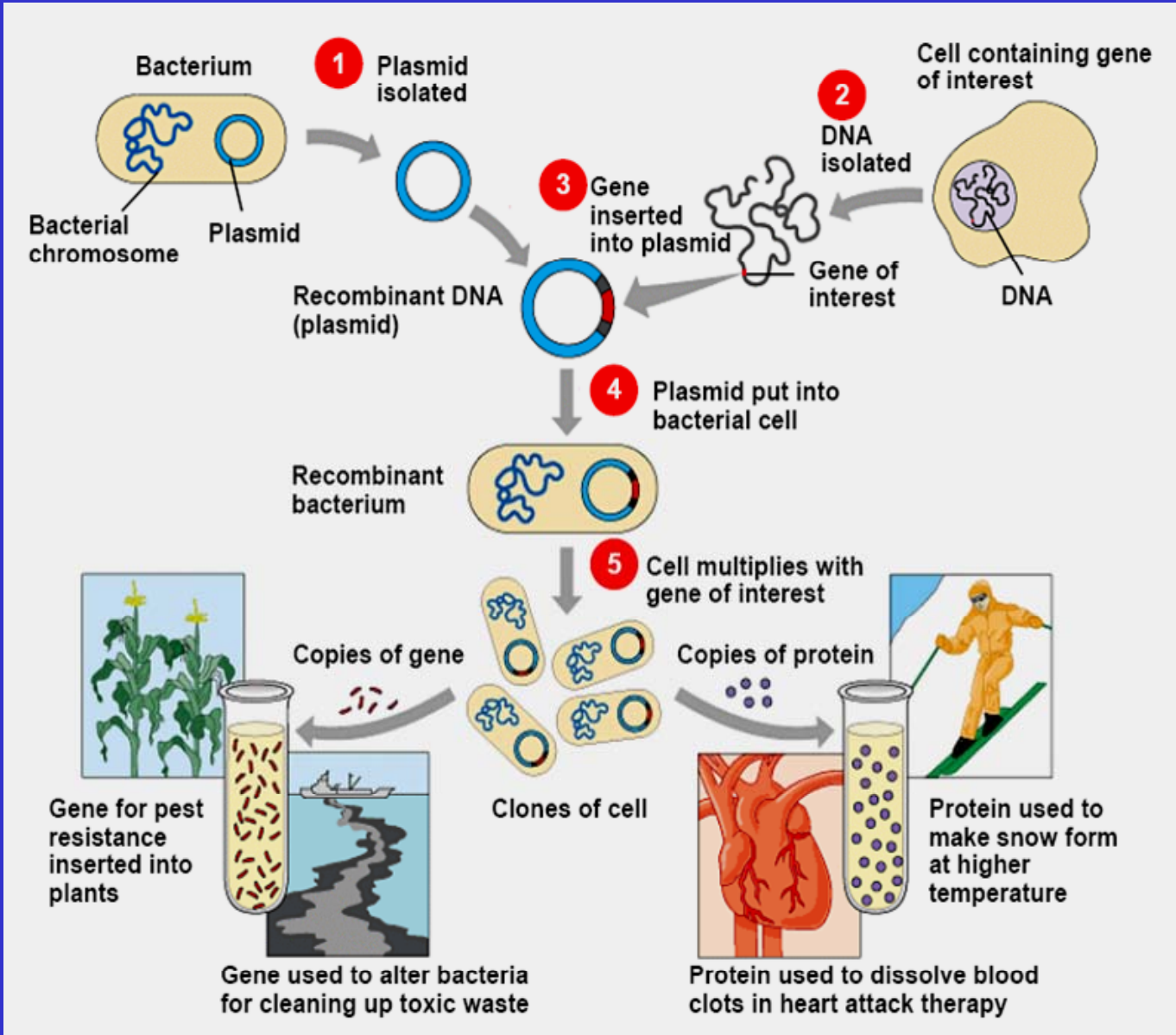
Fingerprinting  
Genetic mapping  
Gene isolation  
Comparative mapping  
Gene pyramiding

## New Products

Elite germplasm  
Breeding populations  
Germplasm bank  
Wild relatives  
Landraces  
Transgenics

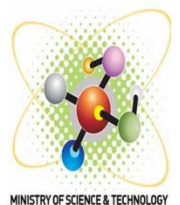
## Germplasm



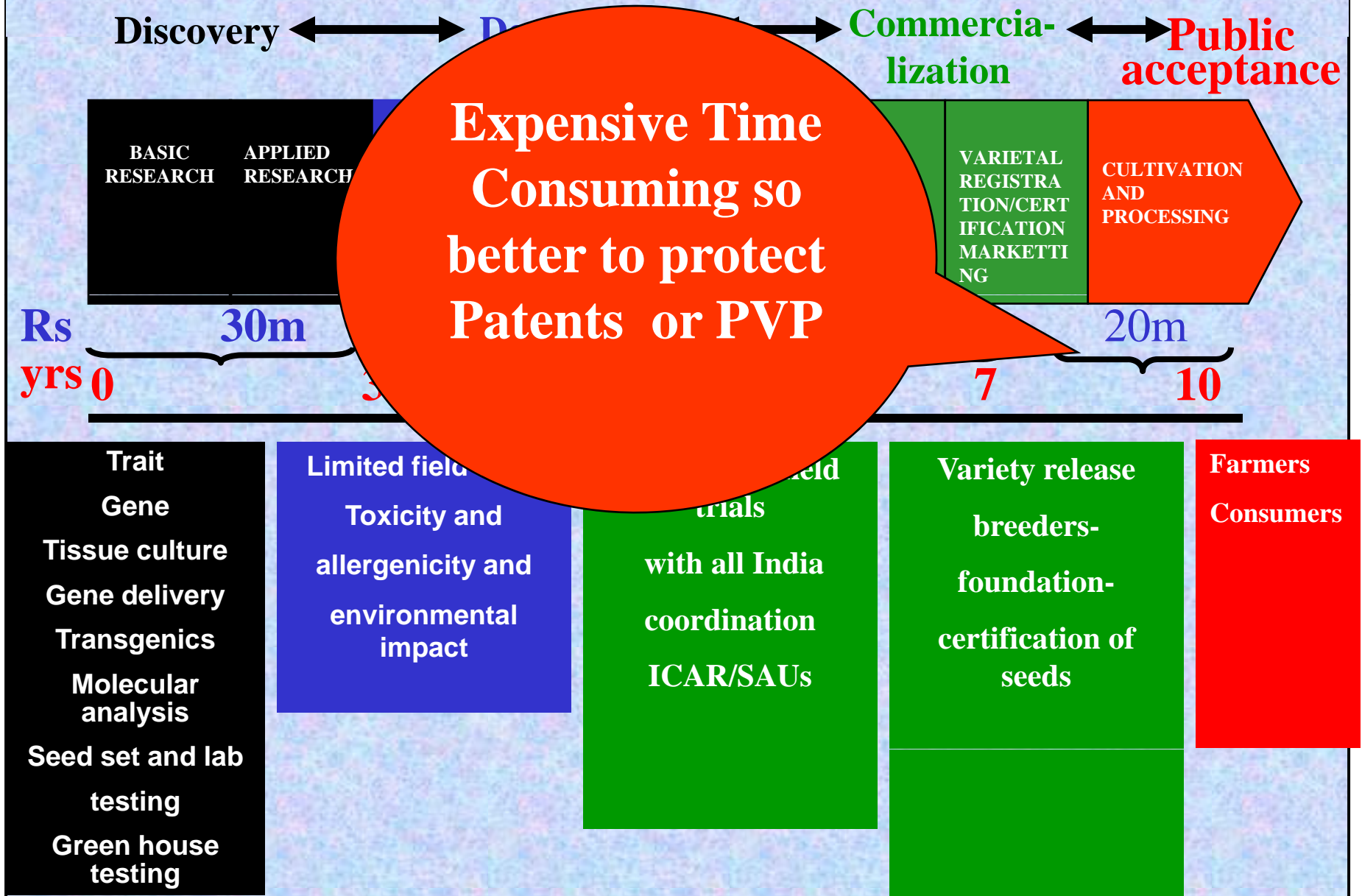


# Today Of Transgenic Research in India

<b>Crops 36</b>	<b>Traits 18</b>
<b>Research Institutions Companies engaged</b>	
<b>Universities</b>	<b>50</b>
<b>Research Institutions</b>	<b>45</b>
<b>Companies</b>	<b>140</b>
<b>Total</b>	<b>235</b>



# Stages in Research Development and Commercialization of Transgenics



# Stages in Research Development and Commercialization of Transgenics

Discovery ↔ Development ↔ Commercialization ↔ Public acceptance

Biosafety



EPA Act/rule

Industry Act

Patent Act

Destructive Insects & Pests Act/PQ order

Insecticides Act, 1968

PVP &FR

Seed Act and rules

PFA/food safety Acts

Consumer Act

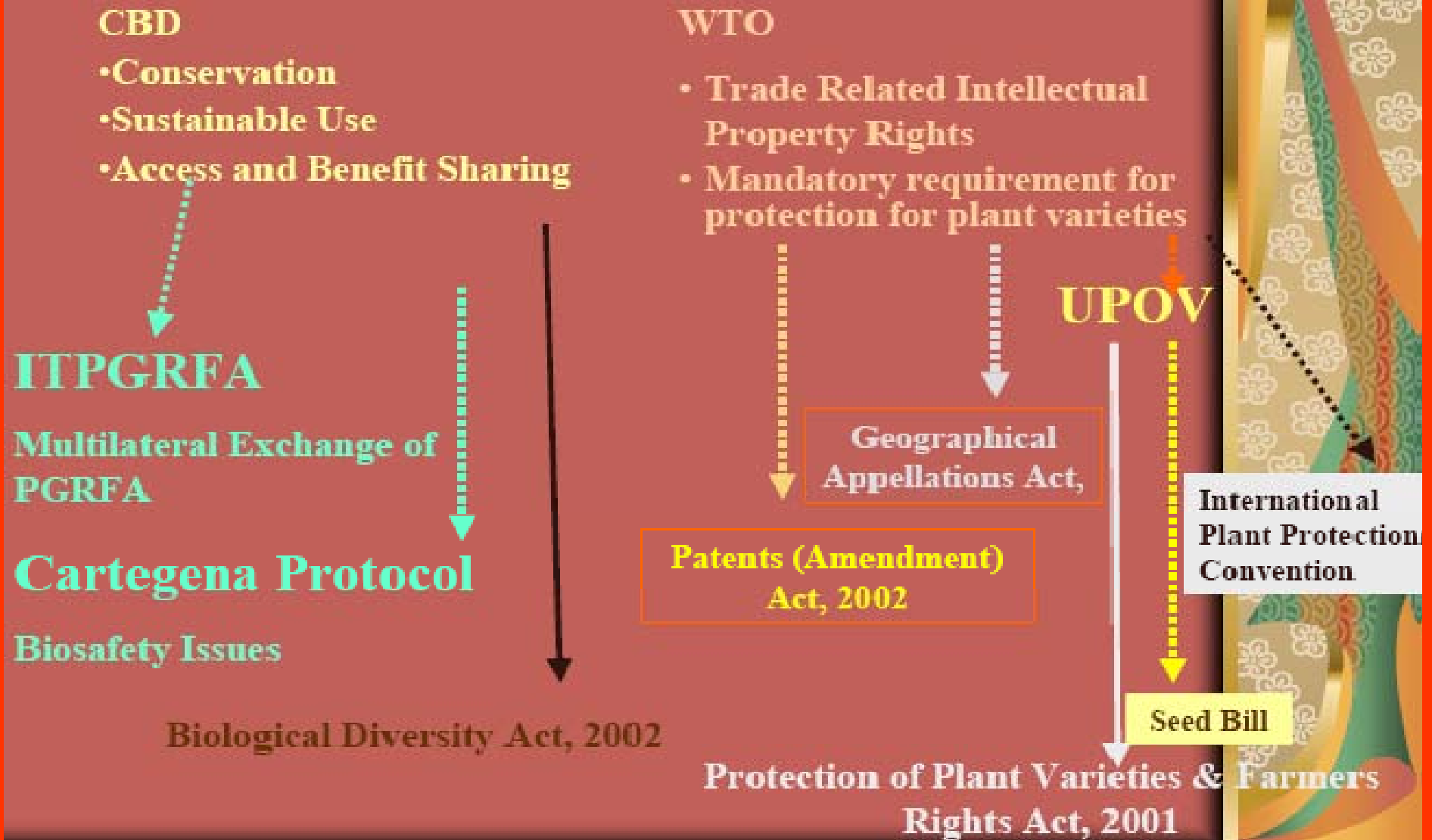
Liability & redress  
Labeling



## **Acts Linked to GM technology ,plant varieties and seeds**

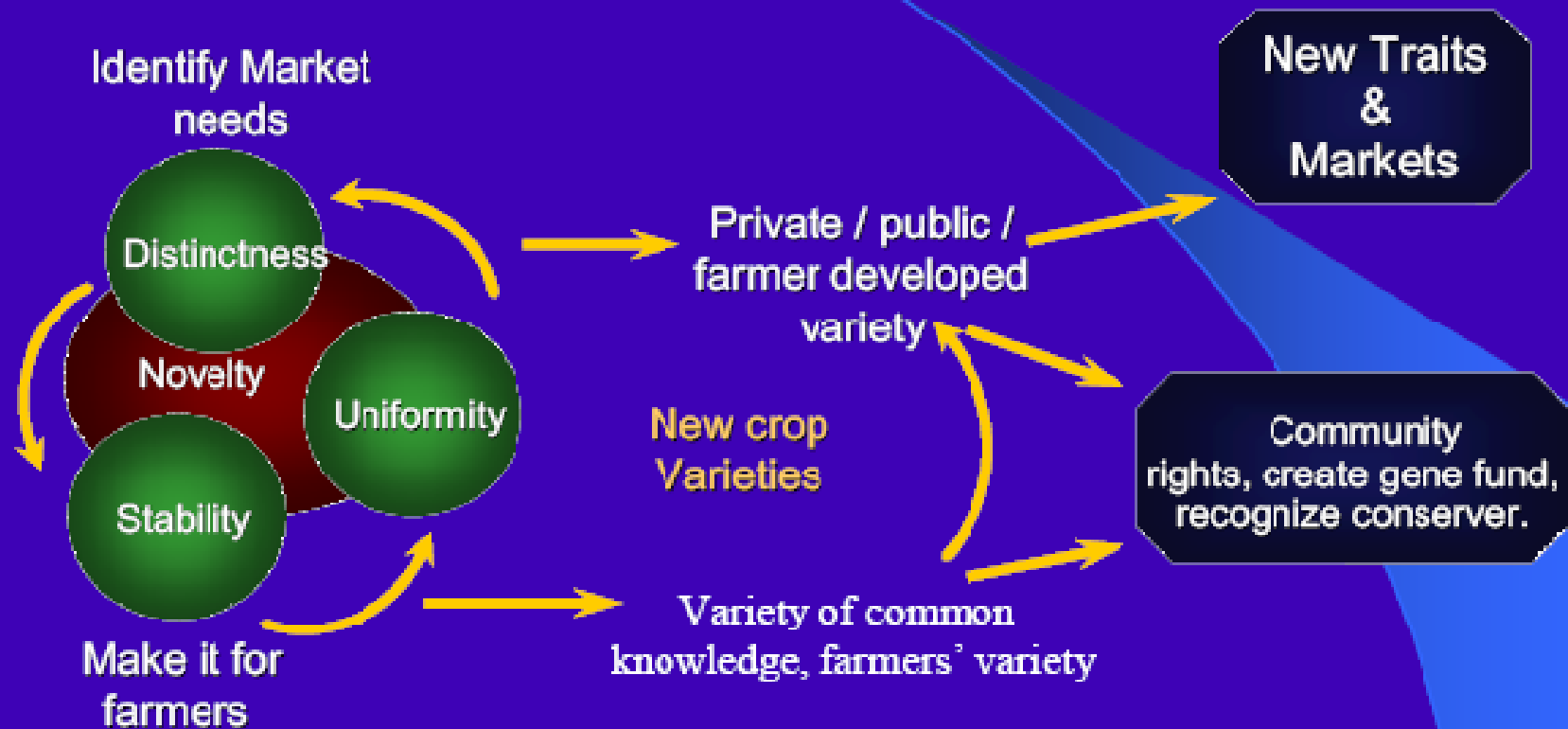
- The Patent Act for some aspects of GM technology, genes and molecules.**
- The Environment Protection Act. GEAC clearance for transgenic.**
- The Biodiversity Act for bio-prospecting natural resources**
- The Seed Act. Seed purity, health, import export, labeling and marketing.**
- The Protection of Plant varieties and Farmers' Rights Act.**

# Developments that influence plant breeding.





# Plant variety registration



# Intellectual Property Protection: Bt Maize: an Example

- **Gene ownership**
  - Cry1F
  - PAT marker gene
- **Enabling technologies**
  - Micro projectile bombardment
  - Herbicide selection
  - Backcrossing
  - Production of fertile transgenic
- **Enhanced expression**
  - Chimeric genes
  - using viral promoters
  - Enhanced expression
  - Enhanced transcription efficiency
  - Selective Gene expression
- **Elite maize inbreds and hybrids**

## What transgenic can be registered?

- Extant variety
- New Variety
- Essentially Derived Variety

## What can be an EDV?

- ✓ **Back cross derivative**
- ✓ **Deletion / Addition lines**
- ✓ **Chimera / extra nuclear variations**
- ✓ **Point mutation**
- ✓ **Ploidy changes**
- ✓ **A gene insertion.**
- ✓ **Somaclonal variation**
- ✓ **Predominantly derived from the initial parent**
- ✓ **Shared parentage (?)**

## **EDV will have five categories**

- Transgenic**
- Mutant**
- Tissue culture derived**
- Back cross derivatives**
- Others (Ploidy change)**

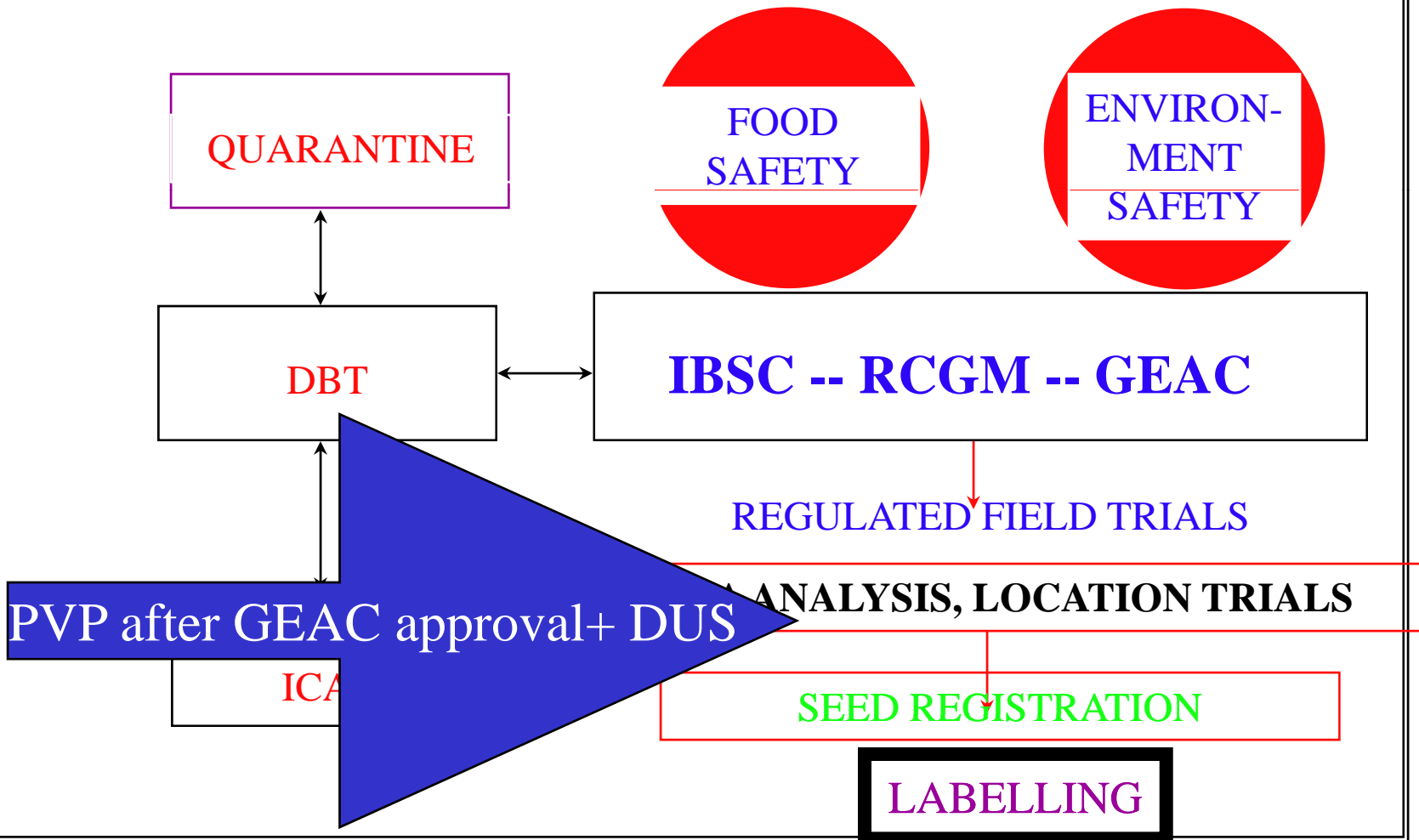
## **What is needed for registration**

- ✓ Section 18 of the Act. Genetic material/ parental are lawfully acquired.**
- ✓ Geographic location in India from where the material is acquired.**
- ✓ Sworn affidavit that the variety does not contain any gene sequence involving terminator technology.**
- ✓ As contained in section 19, seeds of such variety along with parental lines confirming to the standards.... Will be submitted. .**

- **For Transgenic Varieties a copy of GEAC approval will be required.**
- **Approval for bio-safety clearance from Ministry of Environment and permission for commercial seed production will be required.**
- **If required, special test in the laboratories will be conducted for establishing the distinctiveness of the EDV. The varieties developed through biotechnological research requires complicated screening techniques to established its distinctiveness over other variety putting pressure for establishment of high profile and well advanced laboratories**
- **No variety shall be registered if it contains any technology including GERT and Terminator Technology which is injurious to the plant health.**
- **The special test shall be conducted only, when DUS tests fails to establish the requirements of distinctiveness.**

# SYSTEM OF TRANSGENICS RELEASE and Link with PVP

## Current proposal as EDV





# ISSUES

**For Discussion**

# Challenge 1

One gene in so many hybrids/ varieties /  
genera

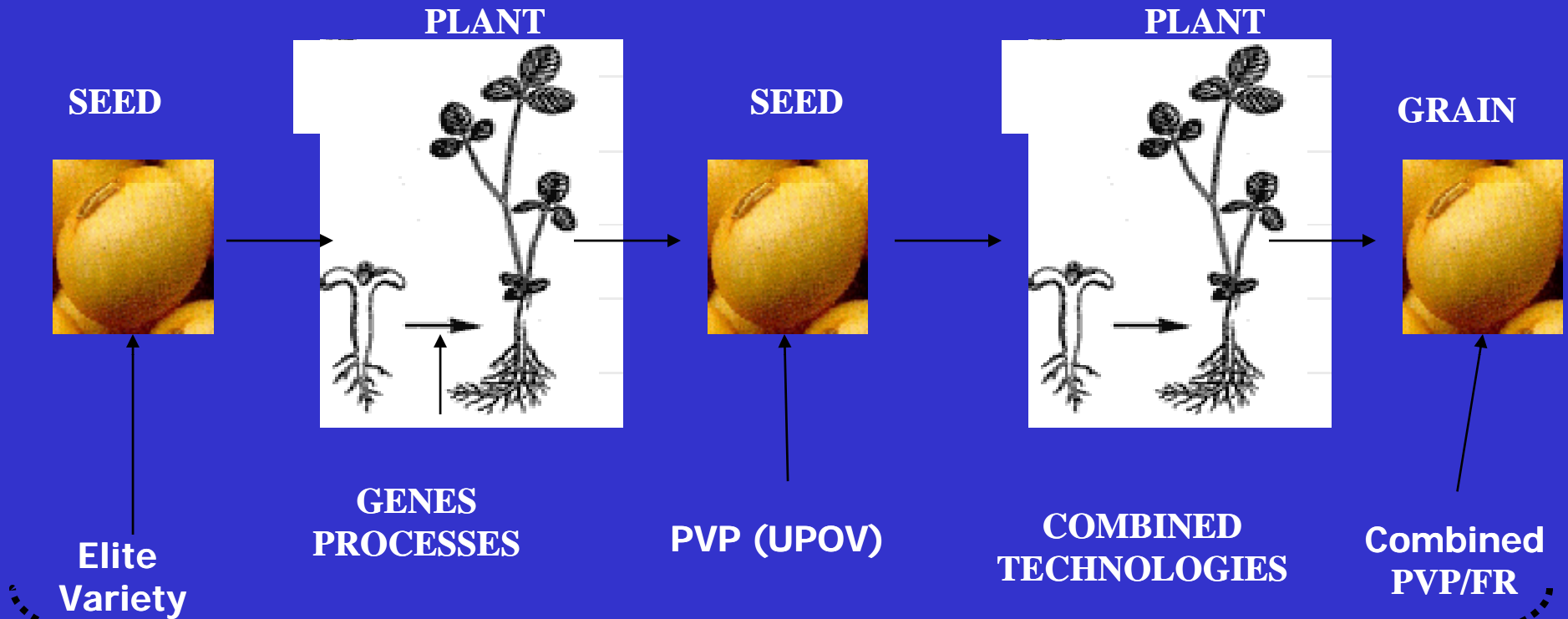
What is different and distinctive

Gene or germplasm

We may end up in protecting all commercially important  
varieties/hybrids just by back cross breeding

Costs of PVP/EDV may add to seed cost borne by farmer

# Challenge 2 can its be PV or EDV

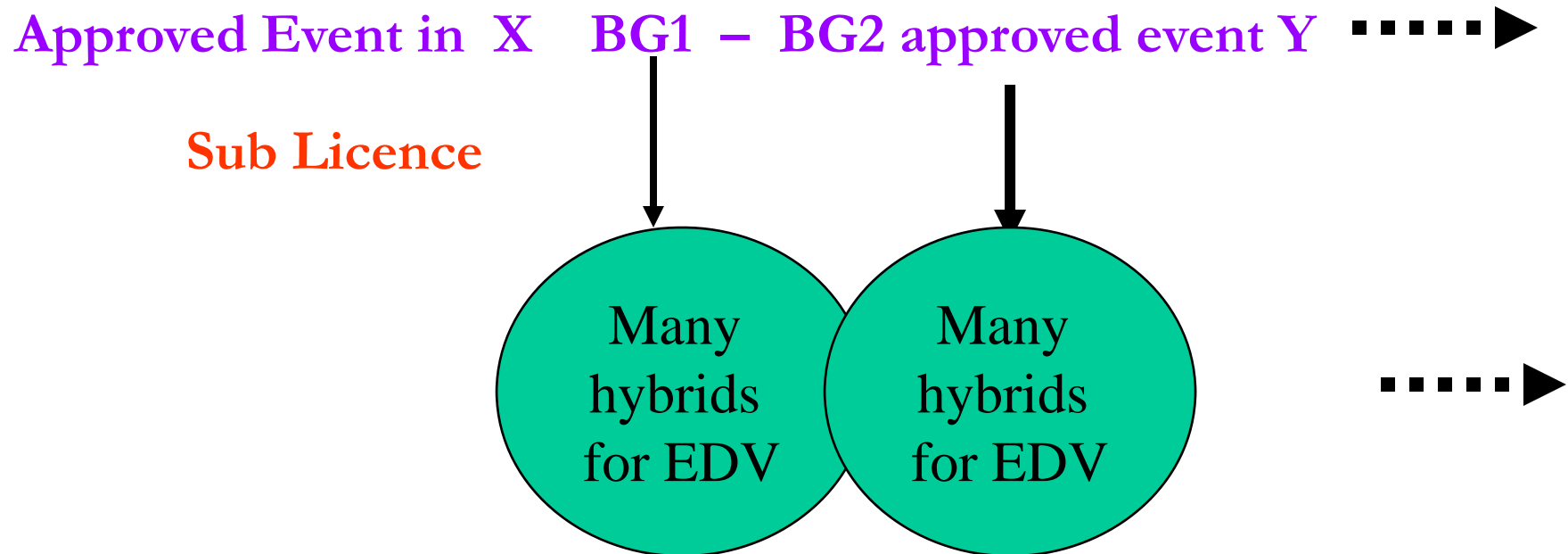


The varieties developed through genetic engineering technique are also used in conventional plant breeding raising implications for the ownership of varieties for such a research for example pyramiding genes ( derived non transgenic)

# Challenge 3 : Add gene for new EDV in already registered EDV

some countries require bio-safety analysis for each new transgenic variety event if the variety is based on previously approved event since such testing, sufficient funds is required, to meet the cost of the testing.

In India approved event based new trasgenic simple approval process



## Challenge 4 : **Dilemma of scientists**

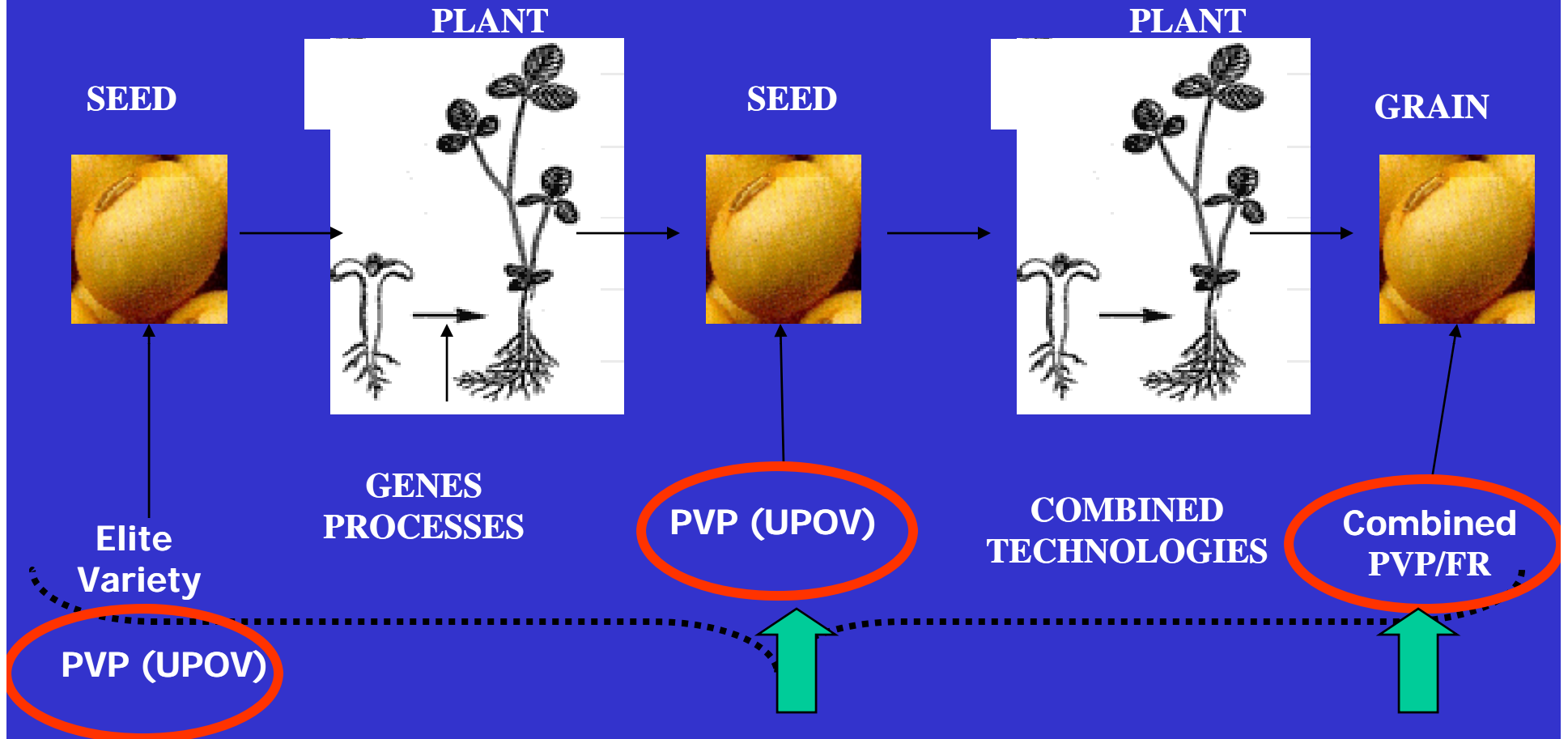
- For Transgenic Varieties a copy of GEAC approval will be required.
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**Here comes**

**Dilemma of scientists**

**who develops a breeding transgenic line with proof of concept not essentially commercial so does not have GEAC approval**

# Challenge 4

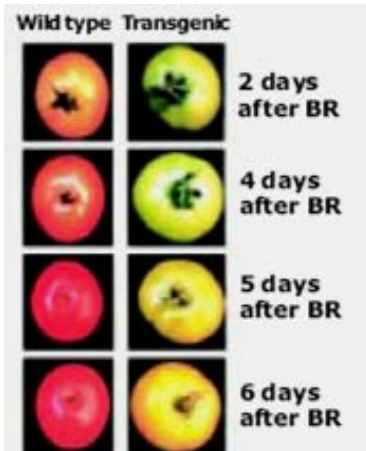


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# Agriculture



## Insect resistance



Delay ripening of fruits



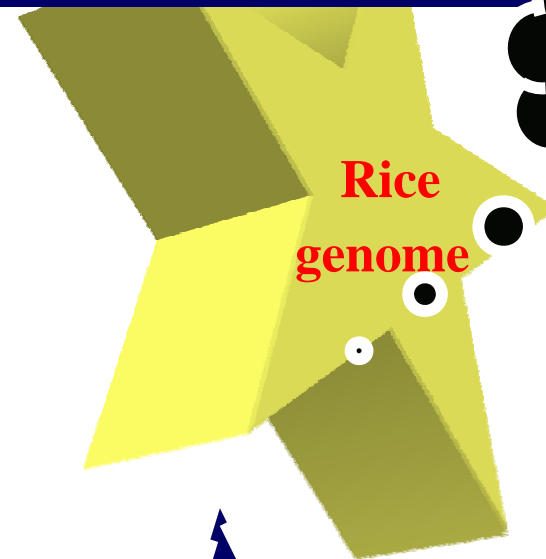
Golden Rice with Provitamin A for malnutrition

# Challenge 5: Types of collaborations- IPR

complexity



**Close**



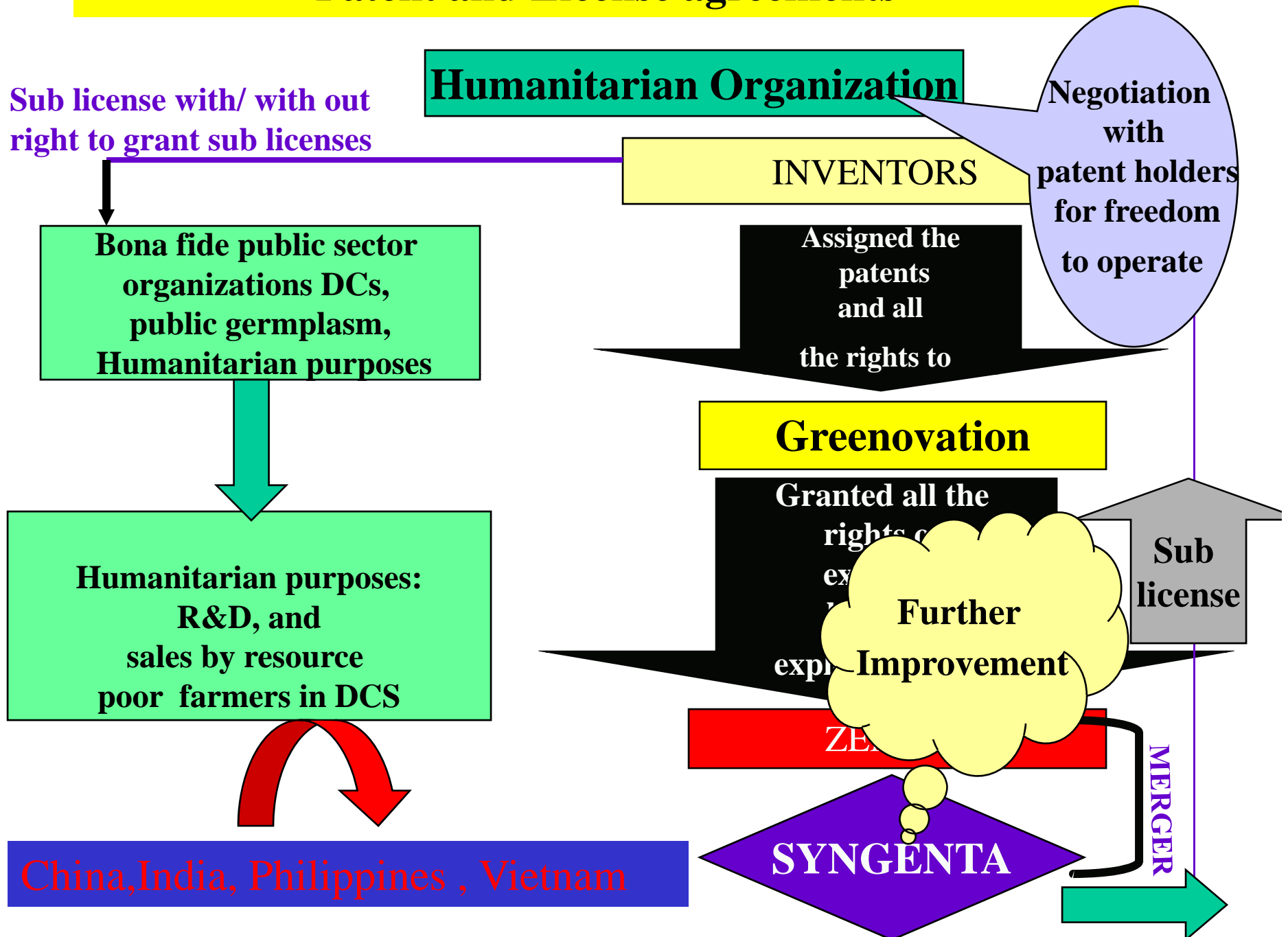
**Shared parallel**



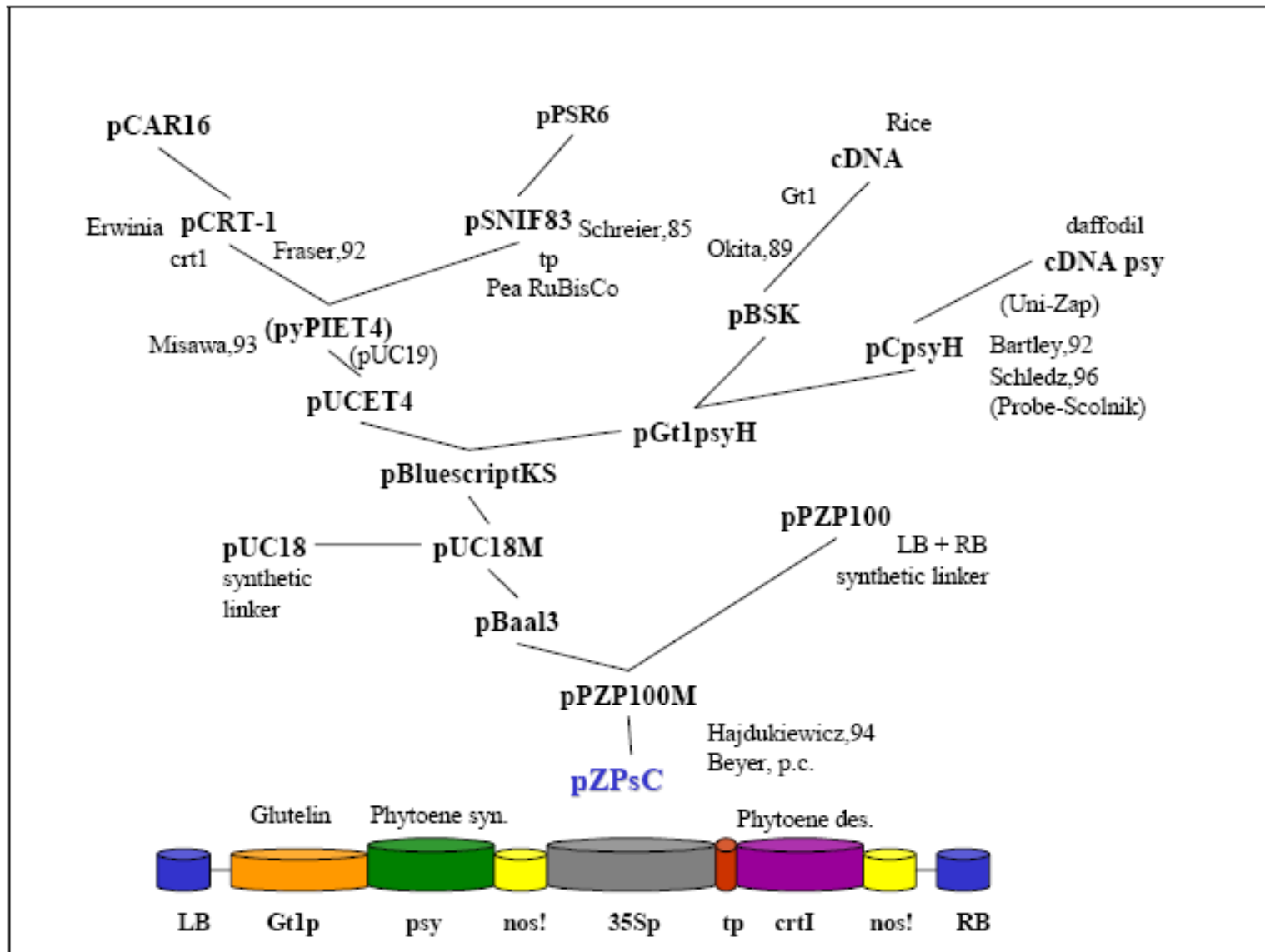
**Loose**



# Patent and License agreements



Flow chart of Tangible Property Transfers for one of the three constructs  
 (source: Kryder, Kowalski and Krattiger, 2000)



## Challenge 6: Harmonizing with patent Act

### Intellectual Property Protection: Bt Maize: an Example

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# Rice Transformation patents in the top ten Rice-producing countries

United States	44
Japan	21
China	11
South Korea	10
Brazil	10
Vietnam	9
Indonesia	6
<b>India</b>	<b>5</b>
Philippines	1

Freedom / Licence from all patents should be pre-requisite for PVP application to harmonize with Patent act

No patents taken in other major rice producing countries

**Dilemma : Section 18 of the Act. Genetic material/ parental are lawfully acquired**

## **Technology transfer mechanisms in agricultural biotechnologies**

### **Commercial**

**Purchase of technology ( seed variety/planting material)**

**Licensing with royalty payments of tools /Product/ process(eg;seeds, diagnostic kits, mapping techniques)**

**Trade secrets ( inbred, parental lines )**

**Joint ventures, Collaborative research, Bio-processing agreements**

**Material transfer agreements**

### **NON commercial Training and technical cooperation**

**☞ Collaborative Research**

**☞ Material transfer agreements**

**☞ Technology” donations”**

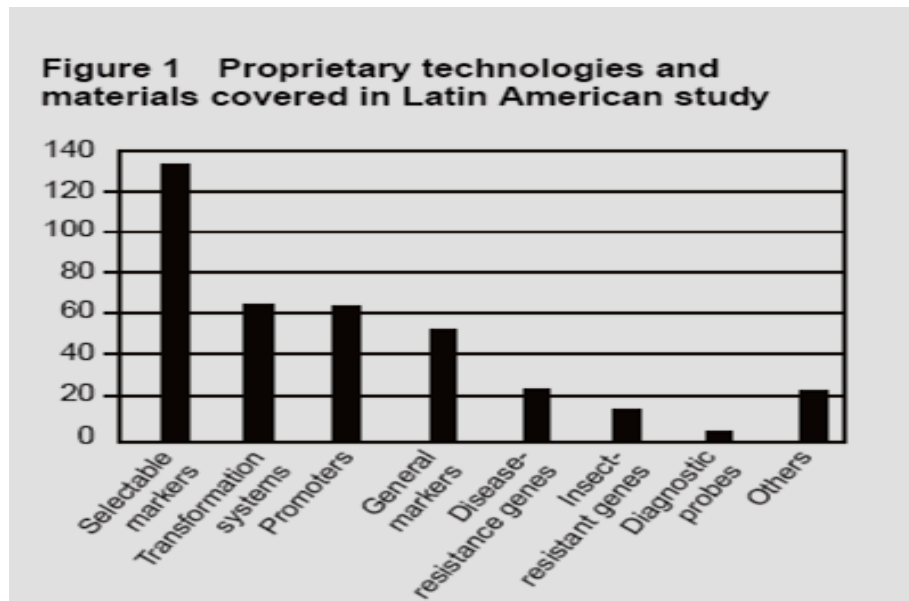
**☞ Seed exchange among farmers**

**Dilemma : Section 18 of the Act. Genetic material/ parental are lawfully acquired**

**NARO study.** In 1998, ISNAR conducted a survey among NAROs in Brazil, Chile, Colombia, Costa Rica, and Mexico and India .

**Lacked formal written agreements or information was not available (35 percent).**

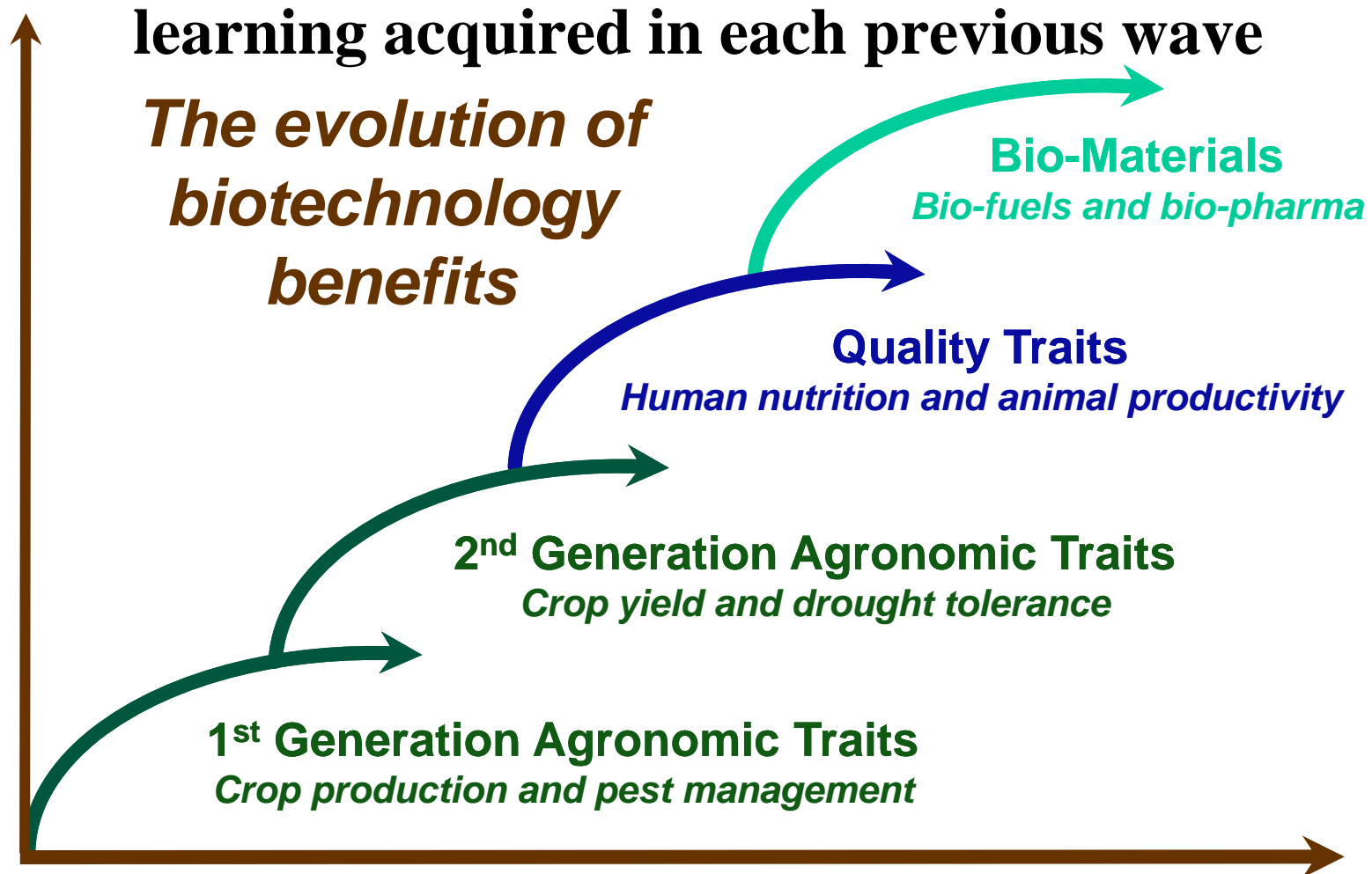
**MTAs accounted for 25 percent of acquisitions, being the most common means,**



Does It mean an MTA for R&D or commercialization .are there standards

# Future Challenges

The technology is progressing rapidly, building upon the



## Food & Nutrition

### Taste

#### Sensory quality:

Improved taste, texture and appearance (proteins, lipids, carbohydrates)

### Nutrition

#### Micronutrients

Bio-availability and preservation of vitamins & minerals: Iron, Folic Acid, Vitamins A, C, E

#### Fiber content

#### Protein

Quantity, composition and quality  
Amino acids methionine, lysine, tryptophan

#### Vegetable oils

Nutritional quality, cooking stability, shelf life

- Low saturated fats
- High oleic acid
- Increased stearate
- Increased laurate
- Essential fatty acids (PUFA balance)

#### Carbohydrates / Starch

Resistant starch – slowly digested to improve colonic health, generation of short chain FA, slow energy release for diabetics and athletes  
Increased starch potatoes (reduce oil absorption during processing)  
Fructan producing sugar beets (sweetness equal to sucrose without the calories)

#### Probiotics

Gastro intestinal health: colonic microflora Lactobacillus and Bifidobacterium stimulate mucosal immune system, increase resistance to food borne illness & chronic disease

#### Phytochemicals

Disease prevention (cardiovascular, cancer, diabetes, obesity, osteoporosis, arthritis)  
Bioactive peptides  
Isoflavones  
Phytosterols  
Anti-oxidants: flavanol, lycopene, tocopherol

### Shelf life

Controlled plant ripening and post harvest shelf life  
Enhanced package goods shelf life eg Bread  
Reduce browning from bruising, polyphenol oxidase

### Allergens and Safety

Reduced allergens: Glycoalkaloids, trypsin inhibitors, cyanogenic glycosides, proteins  
Reduced Mycotoxin: Fumonisin, Aflatoxin  
Detection methods for pathogens, toxins

## Bio-Processing

### Food Enzymes

#### Raw material conversion:

Enzymes in food production with higher purity & specificity: chymosin, lactase, alpha-amylase, amyloglucosidase, aceto lactate carboxylase, xylanase, lipase, mnicullases, cyclomaltodextrin glycosyltransferase.

Conversion of plant or animal raw material substrates into foods (e.g. cheese, bread, beer).

Bacteriocin preservatives / peptide antimicrobials (e.g. Nisin)

### Food Processing

#### Improved processing

Increased yield, quality, consistency  
Optimized cost  
Reduced food loss / waste

#### Improved food ingredients

Organic acids: Lactic, citric, gluconic, propionic  
Amino acids: lysine, methionine, tocopherol  
Vitamins  
Gums  
Sucrose  
Non nutritive and semi-nutritive sweeteners  
Processed starch products e.g. maltodextrins, oligosaccharides, sugars, high fructose corn syrups for health  
Carbohydrates such as arabinogalactans and inulins for prebiotic improved colonic microflora.  
Pectin processing yield and cooking properties

### Industrial Processing

#### Bio-energy production

Ethanol  
Lubricants  
Liquid Wax

#### Waste water treatment

#### Bio-catalysts

#### Detergent proteases

#### Bio-polymers

#### Specialty Chemicals

#### Fibers

Modified lignin from pulp  
Silk  
Cotton

## Medicine

### Therapeutics

#### New Drugs

Influenza vaccine  
AIDS treatment  
Blood pressure  
Heart disease  
Cancer  
Multiple sclerosis  
Psoriasis

#### Manufacture complex proteins

Abundant, cost effective production of therapeutic proteins with improved safety and specificity. Eg Hirudin

#### Efficient drug delivery vehicle

Edible vaccines for the management of:

- Dental caries
- Gastroenteritis virus
- Hepatitis B
- Measles
- Genital herpes
- Rotavirus
- Enterogenic Escherichia coli
- Norwalk virus
- Pseudomonas,
- Staphylococcus
- non Hodgkin's B-cell lymphoma
- Insulin-dependent diabetes mellitus (IDDM), an auto immune disease

### Drug Discovery

#### Bio-active molecules

Mode of action  
Novel chemistry

#### Natural products

Identification and synthesis of phytochemicals from plants with medicinal and cosmetic properties.

### Diagnostics

#### Nutri-genomics

#### Personal nutrition screening

#### Allergen sensitivity testing, prevention and treatment



# Crop Production

## Crop Yield

### Output: grain and biomass

Photosynthesis, enzymatic regulation, plant structure, flowering, ripening, sprouting

### Grain quality

Composition specifications and grade

### Selective breeding

Reducing the time it takes to develop improved crops

### Abiotic stress tolerance:

Increase the ability of crops to grow in a geography by increasing tolerance to:

- Moisture and Drought
- Heat and Cold
- Saline
- Heavy Metals Al, Se, Mn and Ozone

## Pest Management

### Disease resistance

Fungus: verticillium, fusarium, sclerotinia, grey mould, botrytis, powdery mildew, black sigatoka

Bacteria: bacterial blight

Virus: BYDV, mosaics, leaf curl, spotted wilt, ring spot, feathery mottle, necrotic yellow vein viruses

### Insect & Nematode resistance

Foliar, Root, Fruit, Grain

Sucking, Chewing, Piercing

### Herbicide tolerance

More environmentally benign e.g. Glyphosate,

Alternate mode of action e.g. IML, SU, Glufosinate

### Bio-pesticides

## Environment

### Decrease pesticides

Substitute chemicals for gene traits

### Improve production practices

Reduced soil erosion, Improved ground and surface water, Less fuel, Less land

### Reduce fertilizer dependence

Improved plant extraction, transport and utilization decreases demand for synthetic fertilizers (Nitrogen, Phosphorus, Potash)

### Increase plant biodiversity

Expand crop gene pool and reduce risk of crop failures. 80,000 species of edible plants, cultivate 300, 12 are food staples.

# Animal Production

## Livestock Performance

### Feed to gain improvements:

High density, more completely balanced feed resulting in more meat per ton of feed

- Protein quantity and quality
- Oil (caloric energy)
- Amino acids
- Fatty acids
- Starch
- Carbohydrate
- Vitamin and mineral composition
- Antioxidants
- Improved performance of growth factors and hormones to increase food yield

### Feed digestibility

Derive greater nutritional value from feed

Ruminant animals (corn silage lignin)

Increase oligosaccharides to reduce non-digestible compounds in soybeans (stachyose, galactose, raffinose)

Reducing phytate content for increased bioavailability of amino acids, chelation of mineral ions for less P & N waste

### Carcass quality

Meat composition: efficient delivery of micro / macro nutrients in human diet

Meat texture, appearance, taste

Protein, Oil and Amino Acids

Vitamin and mineral composition

Antioxidants

## Animal Health

### Animal fertility and genetics

### Plant based animal vaccines

Gastroenteritis virus

### Pathogen resistance

Reduced infestations from infectious disease that are human health risks eg Salmonella

## Aquaculture

### Sustainable production

Salomon

Talapia

Trout

Flounder

Catfish

Shrimp

## **other arguments.....**

**Gazette notification is for a species for registration.**

**In intergeneric crosses female parent species is taken as basis for DUS.**

**Should novelty then be a character available within a species or genera or can be anything?**

**Should distinctness be as a consequence of the given species gene pool or can be due to genes from across the genetic barrier.**

**The promoter, expression system and the trait of value are all from outside the notified genome. So what is registered ?**

## **Trans Gene escape.....?**

**Can it be pleaded as innocent infringement.**

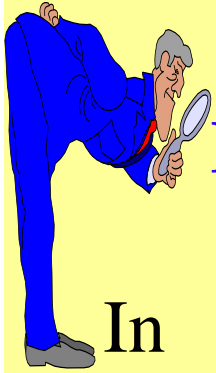
**Or can neighbor challenge for compensation for reasons of contamination.**

**Who owns the guilt, the adjacent farmer or the technology supplier.**

**What does section 39 (2) expected performance under a given condition mean.**

## Burden of Proof and Cost of Law

- The transgenic infringement etc are to be defended by innocent small players and the related tendencies are of concern to all.
- At times of need DNA finger printing may have to be resorted to. So small players are to generate costly molecular data to defend themselves in the eyes of law.
- The cost of the law incurred by plant breeders will add to seed cost which will be passed on to the farmers



## Private character of biotechnology A CONCERN

In **1979** there were **7000** public and private seed institutions. Not even one company occupied significant percentage of global commercial seed market. **Today 10** companies control in excess of **1/3** of global commercial seed market.

- In the **late 1970s**, there were **65** companies that were inventing and marketing **crop chemicals**-- herbicides, insecticides, nematocides and so on . Now we're down to **nine** companies that make up about **91** percent of the global market.

## **My personal views**

- **Transgenic research is expensive so protection of some sort is essential to recover costs through technology fees etc – biosafety and PVP processes should be cost effective**
- **Adding a gene or two does not mean creation new germplasm- there EDV for transgenic is preferred option than PV- in such case applicants may file a PV for Original Line and EDV for transgenic line**
- **Back crossed based applications for EDV from approved event may glut the markets with EDVs in different backgrounds ( hybrids/ genera) although gene is same –EDV for transgenic may be given only if applicant is established original breeder/ owner.**

## **My personal views.....**

- **Pyramiding is continuous process –an EDV over another EDV would be carefully thought of for registration**
- **Biosafety regulations should also consider breeding lines of proof of concept to help technologist supplying such lines for backcrossing in commercial lines –PVP can follow to solve scientist dilemma – this would accelerate technology development and transfer**
- **Clearance certificates or Freedom to Operate from all patents related to gene technologies employed is should be prerequisite for PVP to harmonize with Patent act.**

## **My personal views.....**

- **Community Rights as per CBD should be settled in case of land races or farmer varieties used for transgenic development**
- **Capacity building for executing MTAs/ agreements and evolving standard formats checklists would help**
- **Regular dialogue is necessary to address future developments transgenic research and its relation to biosafety and PVP/FR and Patent Act/ Biodiversity issues**





*Thanks for this opportunity*