

ICGEB Workshop on the "Biosafety of Genetically Engineered Crops, Colombo,
21- 25 May,2012

Private Sector Experience in GE crops Field trial in India

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Review of GE crops in India

- Bt cotton is first commercialized GE crop in India.
- Work on development of Bt cotton initiated in early 90s.
- Commercialization was done in 2002.
- Till 2010 all the Bt cotton hybrids were released by private companies, but in 2010 one Bt cotton variety released by Govt. Institute.
- Presently 4 events viz. BG I, BG II, GFM fusion & JK Cry1Ac are growing in India.
- 1st food crop Egg plant is ready for commercialization.
- Other important crops are Rice, Okra, Cauliflower & Maize.



REGULATORY FRAME WORK

- ✦ Ministry of Environment & Forests and Department of Biotechnology, Ministry of Science & Technology, Govt. of India are regulatory body.
- ✦ ICAR, Ministry of Agriculture & Cooperation and Ministry of Health care & Family welfare, Govt. of India are cooperating dept.

COMPETENT AUTHORITIES

■ Advisory function

- Recombinant DNA Advisory Committee(RDAC)

■ Regulatory function

- Institutional Biosafety Committee(IBSC)
- Review committee on Genetic Manipulation(RCGM)
- Genetic Engineering Appraisal Committee(GEAC)

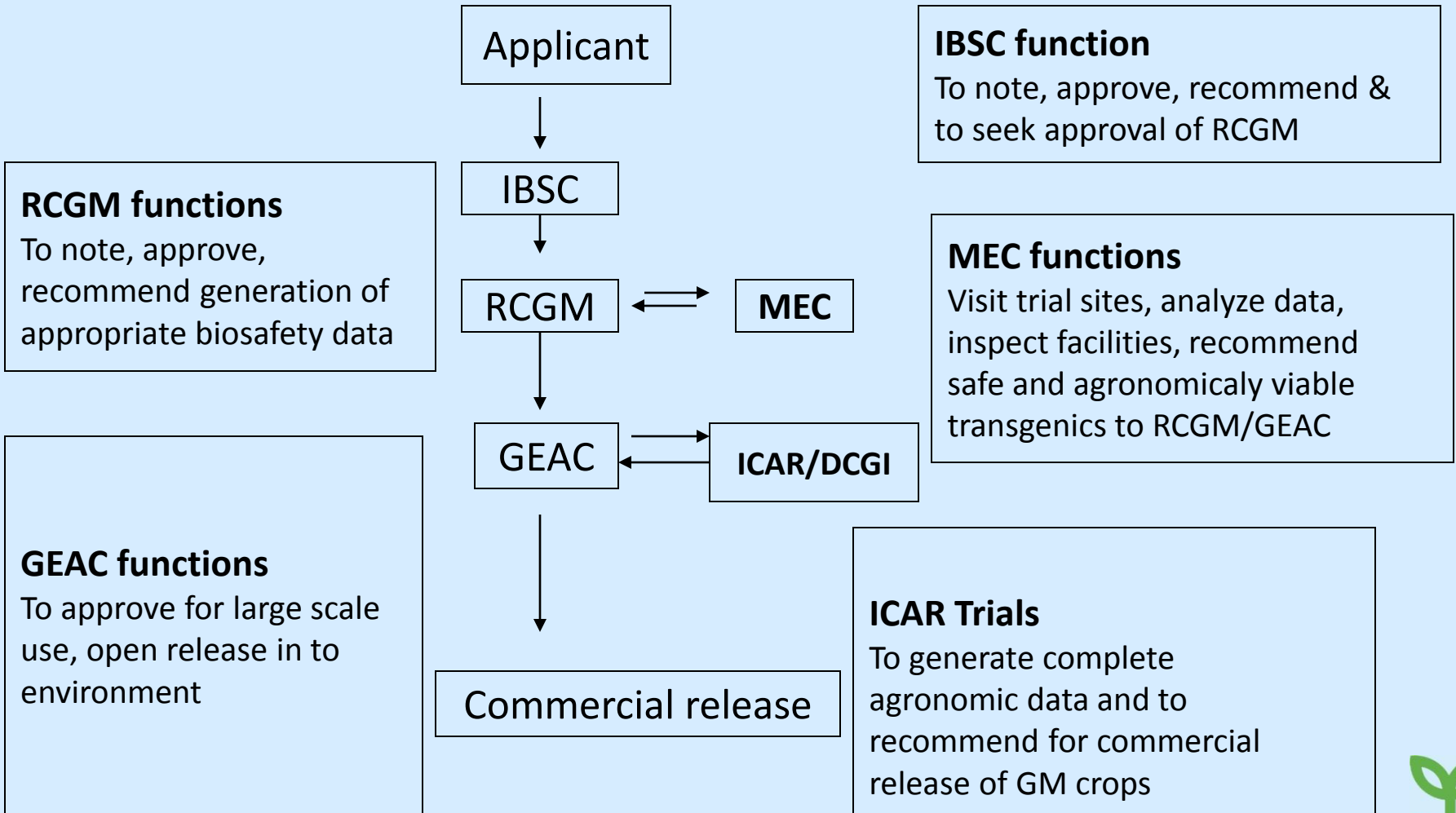
■ Monitoring function

- State Biosafety Coordination Committee(SBCC)
- District Level Committees(DLC)

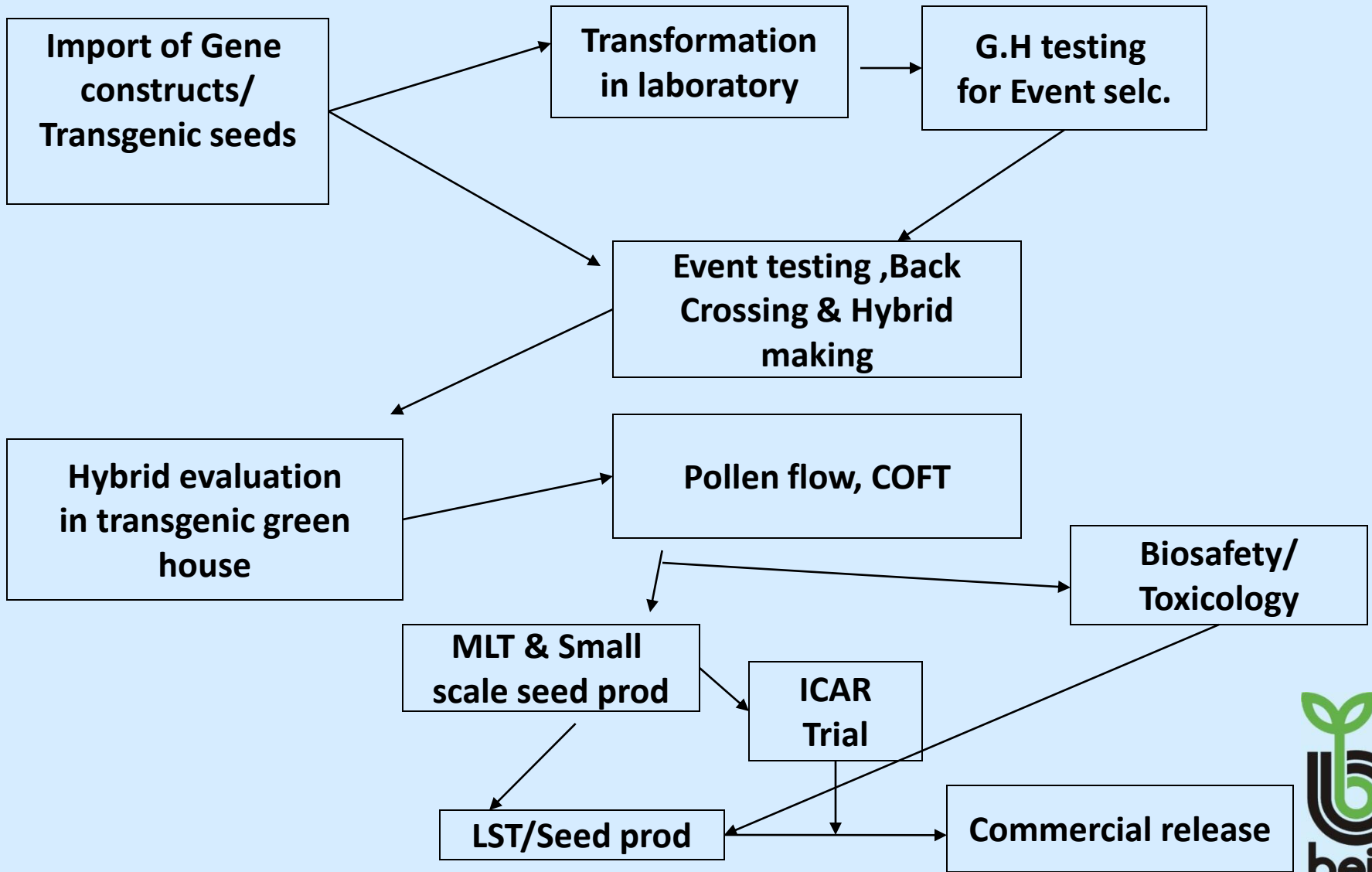
HYBRID BASED APPROVAL



HYBRID/VARIETY BASED APPROVAL SYSTEM



STEPS FOR GM CROP TRIAL



STEPS TOWARDS FIELD TRIAL

1. Introgression of gene and generation of events.
2. Molecular analysis, southern, segregation analysis etc of events.
3. Selection of best event in green house.
4. Back crossing in elite lines.
5. Hybrid making in the green house.
6. Evaluation of hybrids in the green house
7. Evaluation of selected hybrids as 'strip trial' in organization's own farm.
8. Application for Multi Location Trial for 2 years to the regulatory authority.
9. Application for Large Scale Trial to the regulatory authority.



SAFETY STUDIES

Bio-safety

- Skin irritation on rat & mouse.
- Feeding study in rat & mouse.
- Feeding studies of plant parts on Birds, Small animal, Large animal and fish.

Environment safety

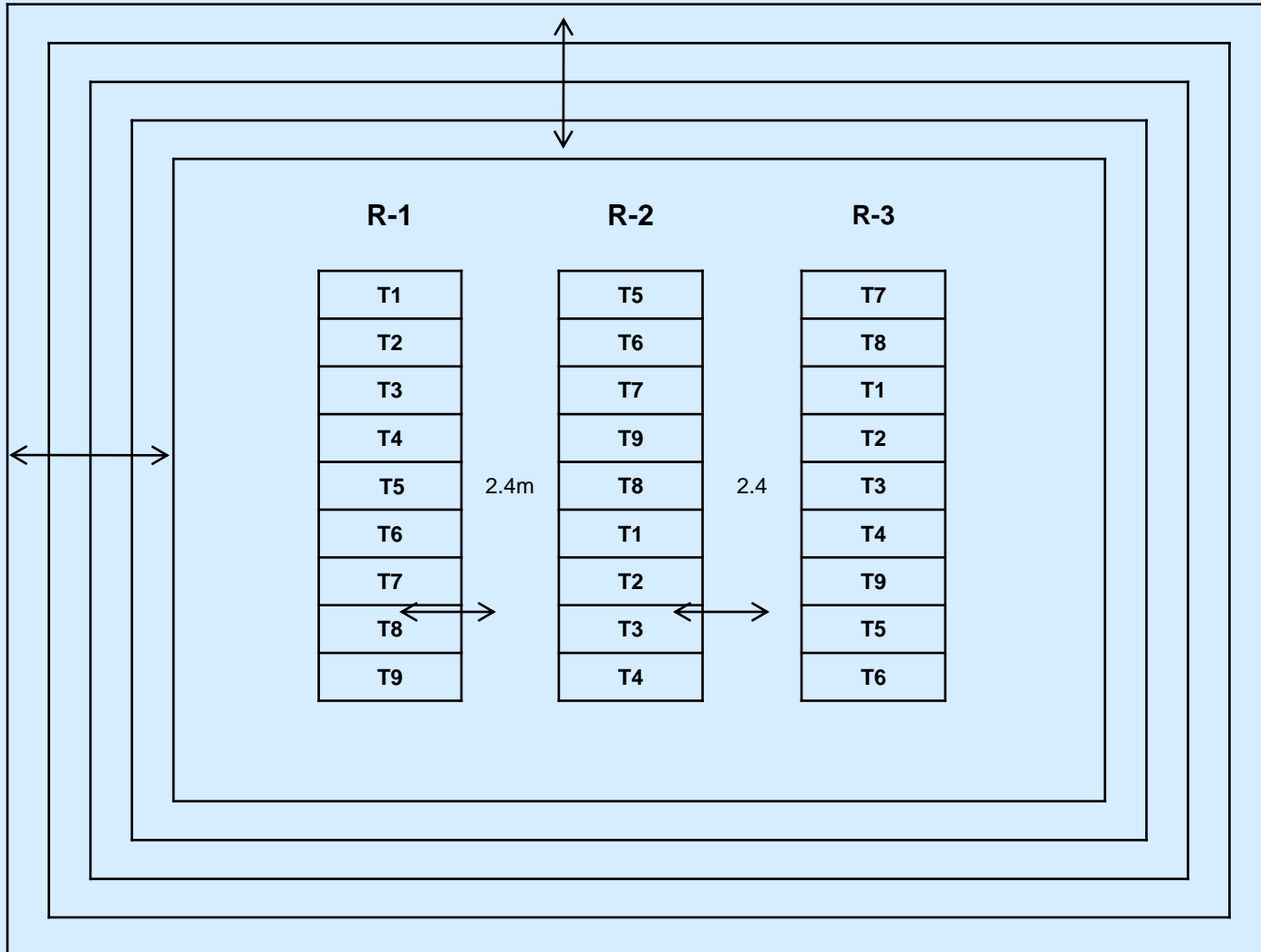
- Soil eco-system study.
- Pollen flow study.
- Weediness.

Food safety

- Compositional study.



TRIAL LAYOUT FOR CONFINED FIELD TRIAL



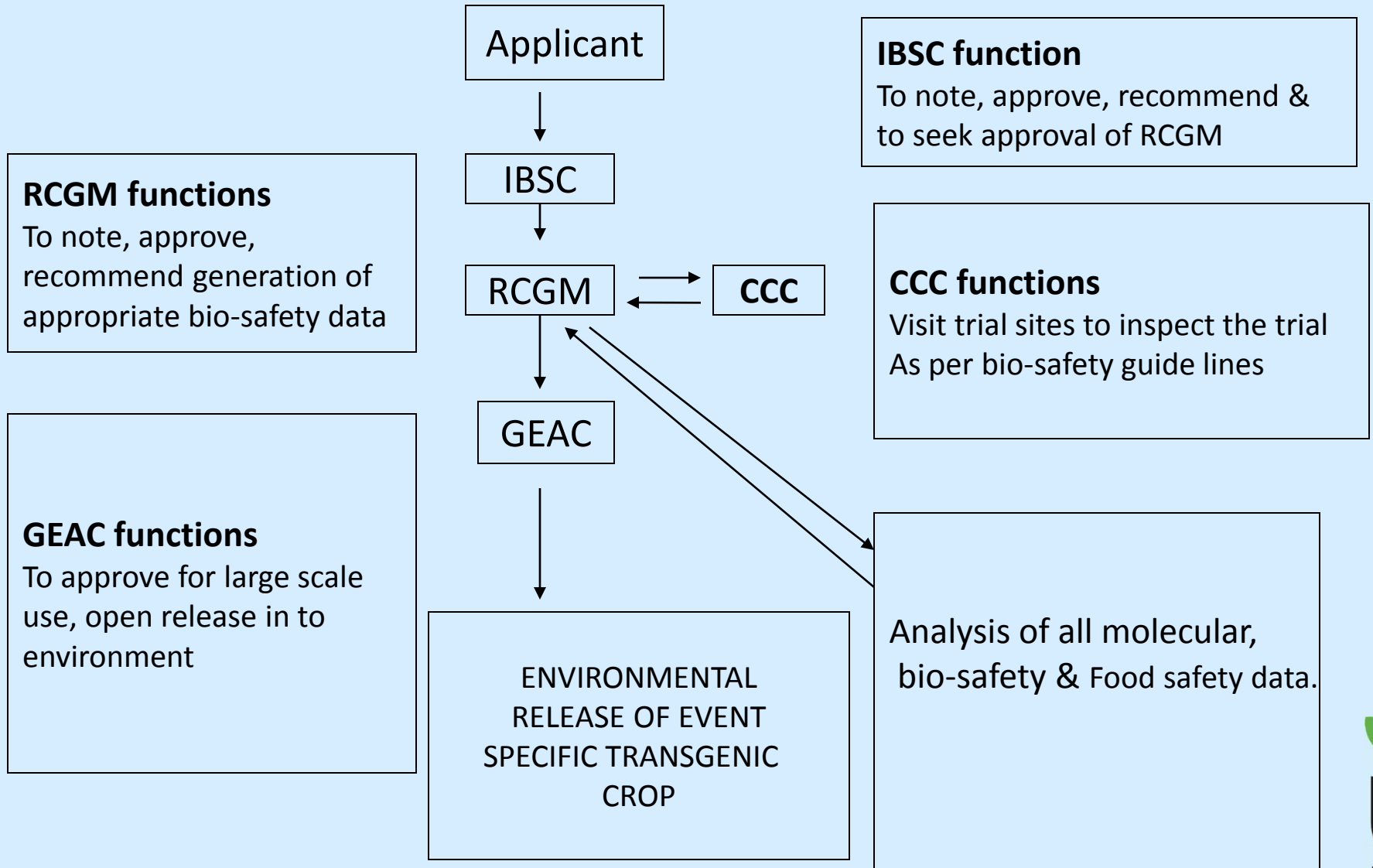
Bt COTTON FIELD TRIAL



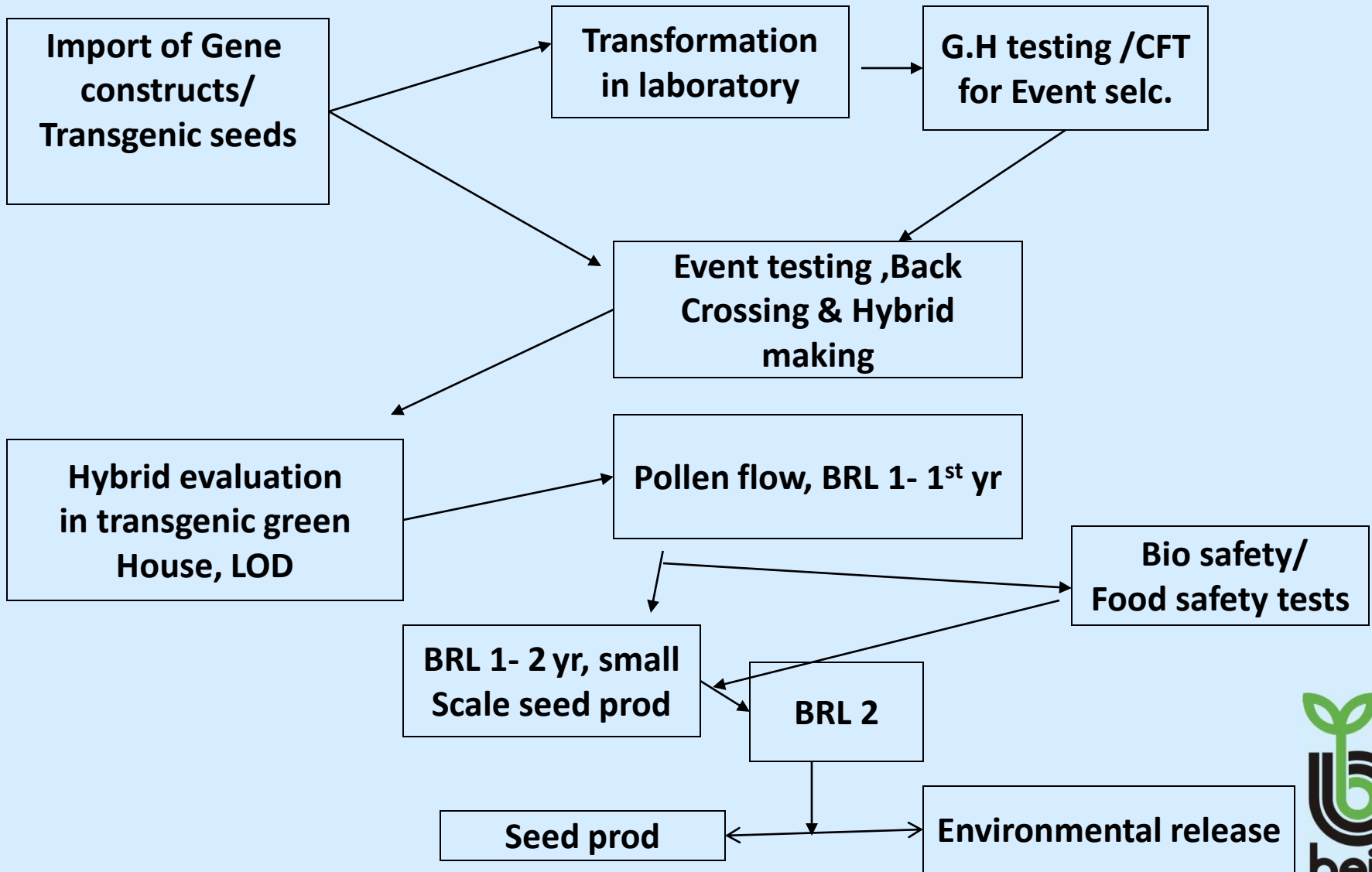
EVENT BASED APPROVAL



EVENT BASED APPROVAL SYSTEM



STEPS FOR GM CROP TRIAL- EVENT BASED



STEPS TOWARDS FIELD TRIAL

1. Introgression of gene and generation of events.
2. Molecular analysis, southern, segregation analysis etc of events.
3. Selection of best event either in green house or from the open field.
4. Back crossing/hybrid making in the green house.
5. Analysis of flanking sequence and development of LOD.
6. Evaluation of hybrids/var. in green house.
7. Application for BRL1 trial to the regulatory authority.
8. Application for BRL2 trial to the regulatory authority

SAFETY STUDIES TO BE CONDUCTED

Allergenicity & Toxicity with pure protein

- Pepsin Digestive Assay
- Thermo-stability
- Acute oral toxicity on rats & mice

Sub-chronic study

- Sub-chronic feeding studies of plant parts on rats

Environment safety

- Soil eco-system study
- Pollen flow/ behavior study

Food safety

- Compositional study

Other study

- Protein equivalence study



Bt Brinjal BRL-1 Trial Field



Bt Brinjal BRL-1 Trial Field



BEJO SHEETAL SEEDS PRIVATE LIMITED, JALNA
EXPERIMENTAL TRIAL SITE FOR BIOSAFETY RESEARCH LEVEL 1 (2ND YEAR)
OF Bt BRINJAL
LOCATION - GUNTUR (ANDHRA PRADESH)

No. of Treatments: 5
No. of Rows per plot: 8
No. of Replications: 4
No. of plants per row: 12
Space between row to row: 60 cm
Space between plant to plant: 60 cm
Space between Treatments: 2.4 m
Space between Replications: 2.4 m
No. of plants per Treatment: 96

Specifications on Entries:
T1 - JANAK BL, T2 - BSS 793 BL, T3 - JANAK NBL, T4 - BSS 793 NBL
T5 - LOCAL NBI CHECK (Kanak Durgal)

Trial In - Charge's Name: Dr. B. Mazumdar, Jalna Mobile: 09404036070
Local Trial In - Charge's Name: Mr. E. Venkateswari, Guntur Mobile: 09866979700
Contact Details: Bejo Sheetal Seeds Pvt. Ltd. Jalna (MS)
Permit No.: BT/BS/17/158/2005 - PID Dated 16.04.2010
Location address: S. No. 219, Bejo Sheetal Seeds Research Farm, Village-Gandhara, Tal. Sattenapalli, Dist-Guntur

Planting Date: 15.07.2010
Total area: 3854.16 Sq. m.
Distance: 40 Km from Guntur

GE CROP TRIAL

Hybrid/Variety Based

- No. of biosafety tests were more.
- Approval for each hybrid/var will require three years regulatory field trial.
- National /state trial result needed for commercial release.
- Agronomic data was important.

Event Based

- Specific biosafety tests.
- Test procedures more expensive & tedious.
- Approval of event will require 3-4 years.
- Field trial is more complicated.
- Once environmental release approved, no necessity for regulatory field trial for each hybrid having same event.



PRESENT SYSTEM OF RELEASE OF NEW Bt COTTON HYBRIDS

For already released events.

1. Testing of hybrids in organization's own field simultaneously in SAU/ICAR trial.
2. Generation of efficacy & protein data.
3. Generation of Agronomic data.
4. Submission of all data and SAU/ICAR report to the approving authority.
5. After examination of data & report authority will permit for commercial sale of new hybrids.



EXPERIENCE

- To arrange large quantity of pure protein.
- Production of lyophilized powder of leaves & fruits.
- To organize trial with proper isolation distance.
- To keep trial plot fallow for post harvest monitoring.
- Time requirement for trial completion and to initiate next trial is long.



- According to recent policy before initiation of field trial consent from state agriculture dept. is mandatory.
- Intervention of anti GE group.
- Technology overshadowed by politics.
- Over all silver line is there will be no necessary for regulated field trial for each hybrid having same 'event'.



THANK YOU