MANAGEMENT OF CONFINED FIELD TRIALS OF GENETICALLY ENGINEERED PLANTS

GUIDELINES AND STANDARD OPERATING PROCEEDURES

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The development of GM crops moves through different stages

- Lab
- Growth chamber or green house / contained facility
- Confined Field trials
- Full safety assessment
- Commercial release

What is the difference between "confined" and "contained" ?

- Contained means enclosed with in a container such as laboratory or greenhouse
- Confined means that genes and plant material are kept (confined) in a specific area
- Both are research experiments

What are Confined Field Trials (CFTs) ?

- Field experiments to evaluate the performance of GM plants.
- Performed under specified terms and conditions that confine the experimental material.
- Similar to field experiments done for conventional breeding, but they are confined and small.
- Essential for technology assessment and development

Why are Confined Field Trials Needed?

- Test the GM plants under real field conditions
- Test the value of the trait in local environment
- Breed biotech trait into local varieties
- Enable selection of superior lines for development
- Scale-up of production material, prior to commercial approval
- Generate safety data needed for subsequent risk assessment and approval
  - •Environment safety assessment.

Why confine ?

- Confined field trials minimize exposure
- Evaluate “harmful effects” if any with risk assessment.

When to start CFT

- Field trials for biosafety are important components of the process of approval of a genetically engineered (GE) crop for commercial cultivation.
- These trials **represent the first controlled introduction of GE crop into the environment** falling in between experiments in contained facilities and taken over for further evaluation.

Risk Mitigation in Field Tests Risk

- **For field trials of transgenic crops, risk mitigation measures reduce potential impact on the environment through:**
  - **Material confinement**
  - **Genetic confinement**
- **Measures for material and genetic confinement may vary according to**
  - ***the crop plant,**
  - ***the introduced trait**
  - ***the environment**

Guidelines for Conduct of Confined Field Trials

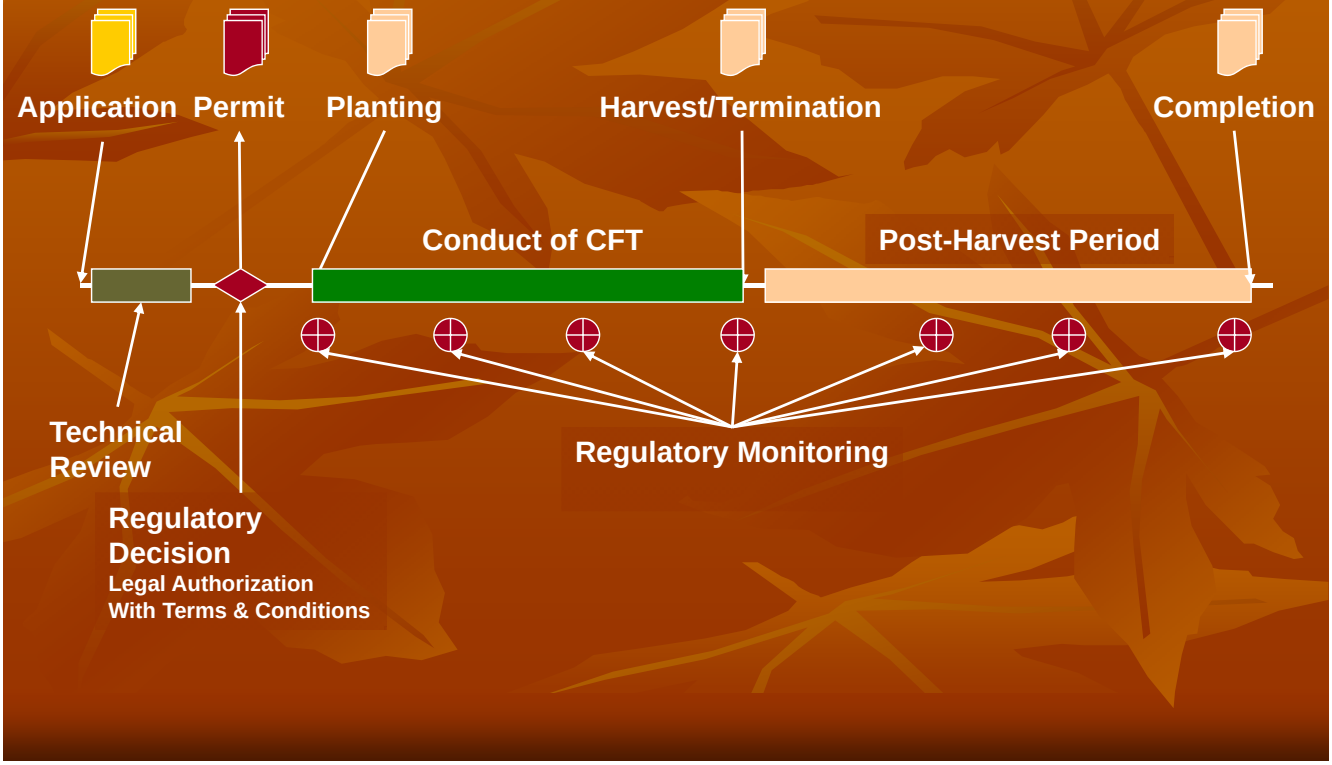
1. Guidelines for research in transgenic plants are existing to streamline the procedures for
   - safe conduct of confined field trials and
   - methodical evaluation and
   - provide instructions to applicants

2. Standard Operating Procedures have been prepared for conduct of field trials of regulated GE plants.

"3-Ps" of risk mitigation for field trials

- Prevent dissemination of new genes in experimental transgenic plant into and within the environment (*i.e.* prevent pollen-mediated gene flow).
- Prevent the persistence in the environment of the experimental transgenic plant and any progeny plants.
- Prevent the introduction of the experimental transgenic plant (or products) into the livestock feed and human food pathways.

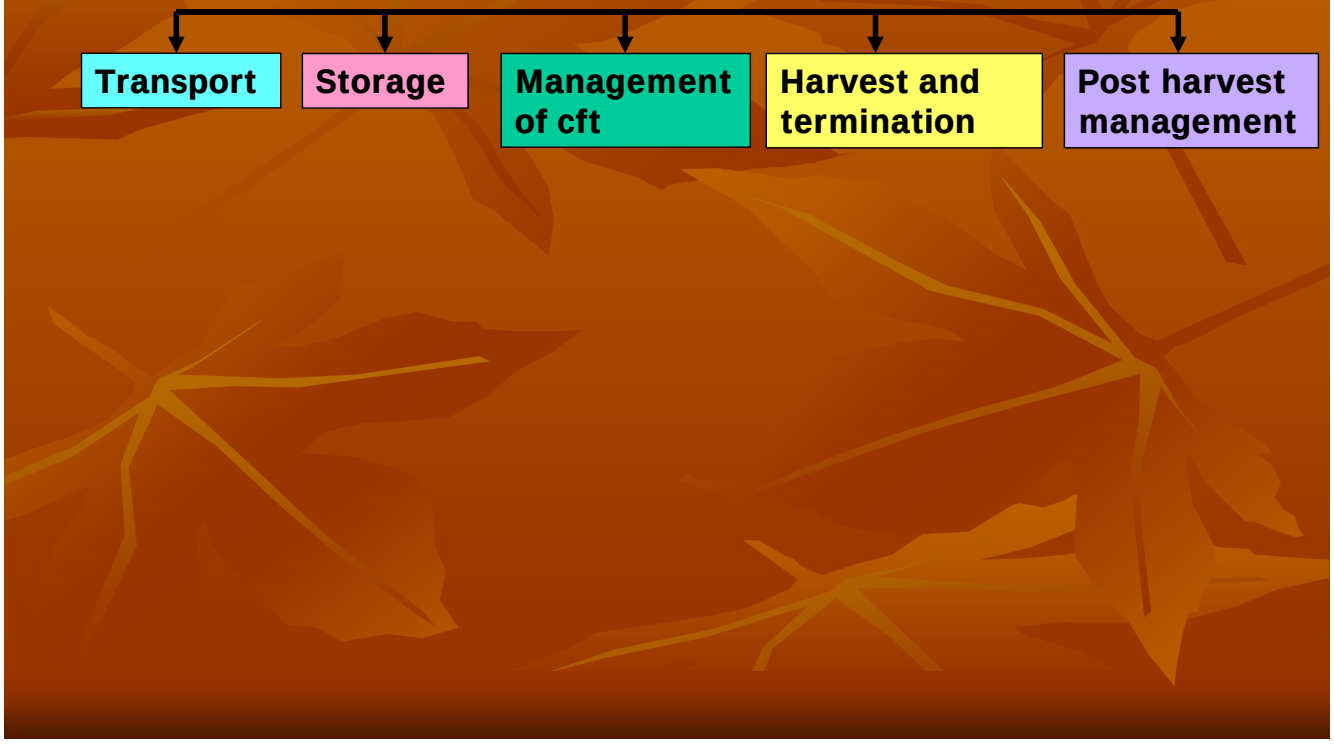
Confined field trial process

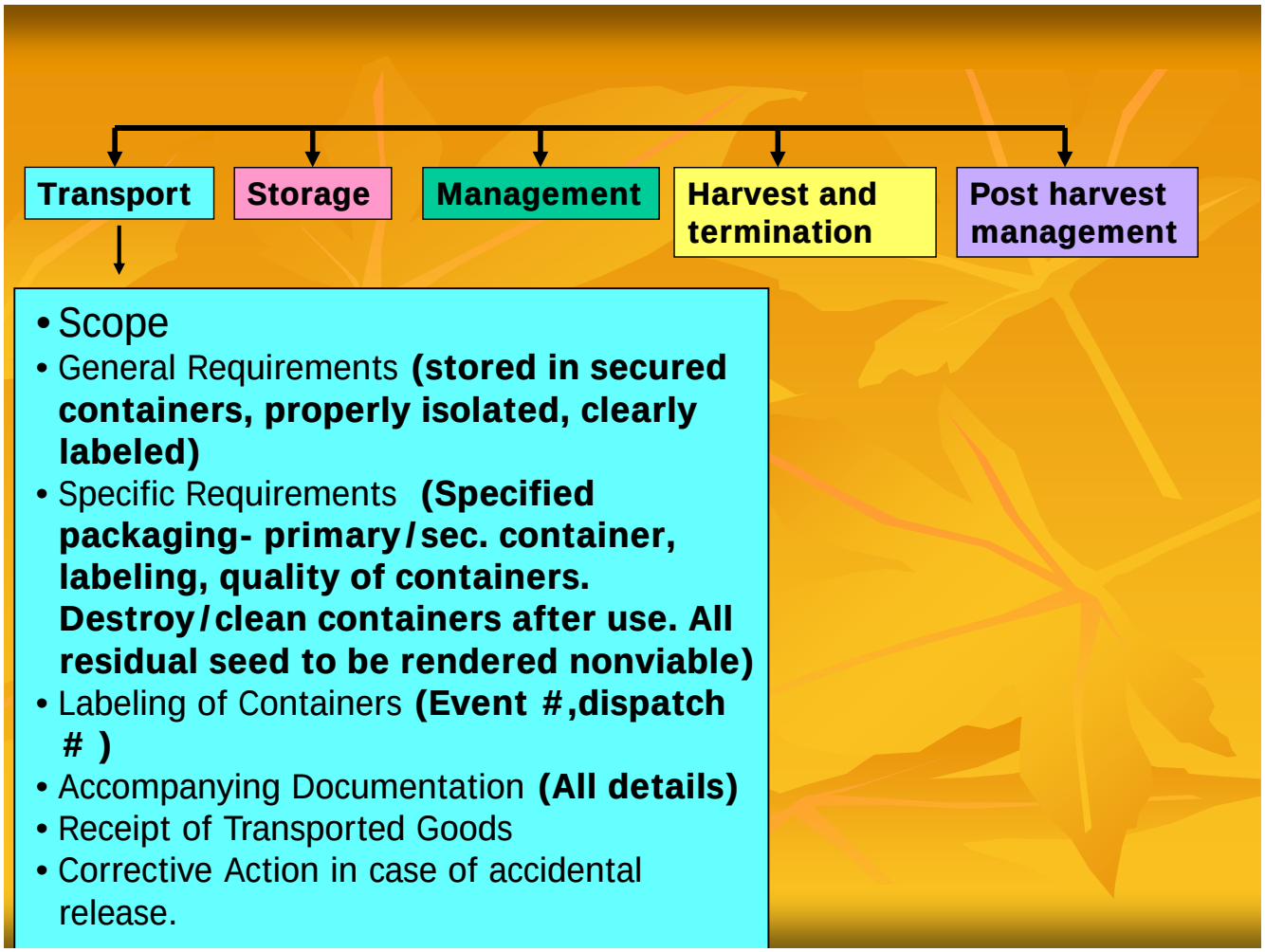


Standard Operating Procedures to conduct CFT

1. **SOPs have been prepared to provide guidance for the following aspects of conducting CFT of GE crops**
   - **Transport of GE material**
   - **Storage of GE material**
   - **Management of trial**
   - **Harvest and termination of trial**
   - **Post harvest management and land use restriction**
2. **Each SOP has a recording format for documentation.**

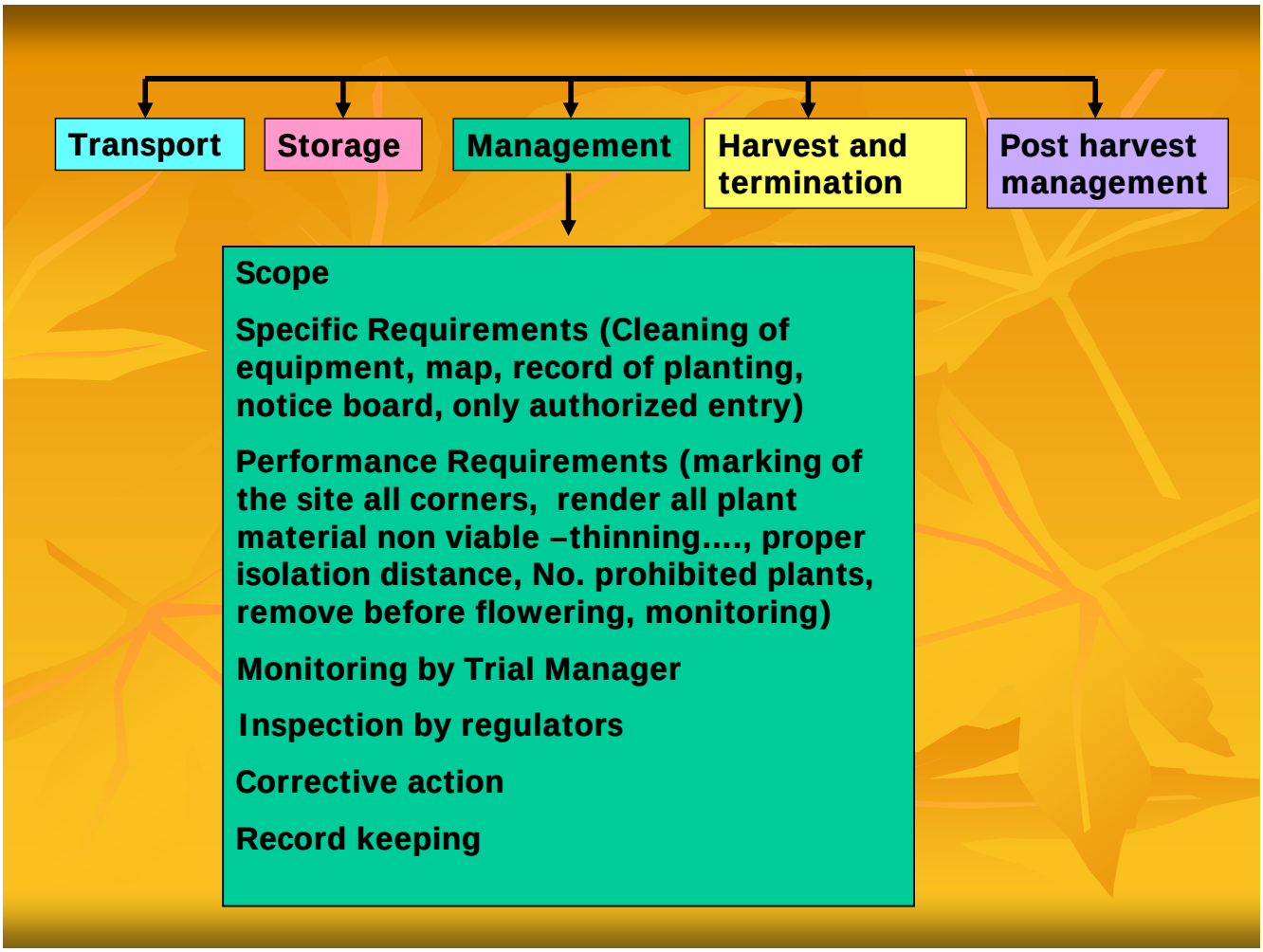
SOPs for Confined Field Trials of Regulated, GE Plants

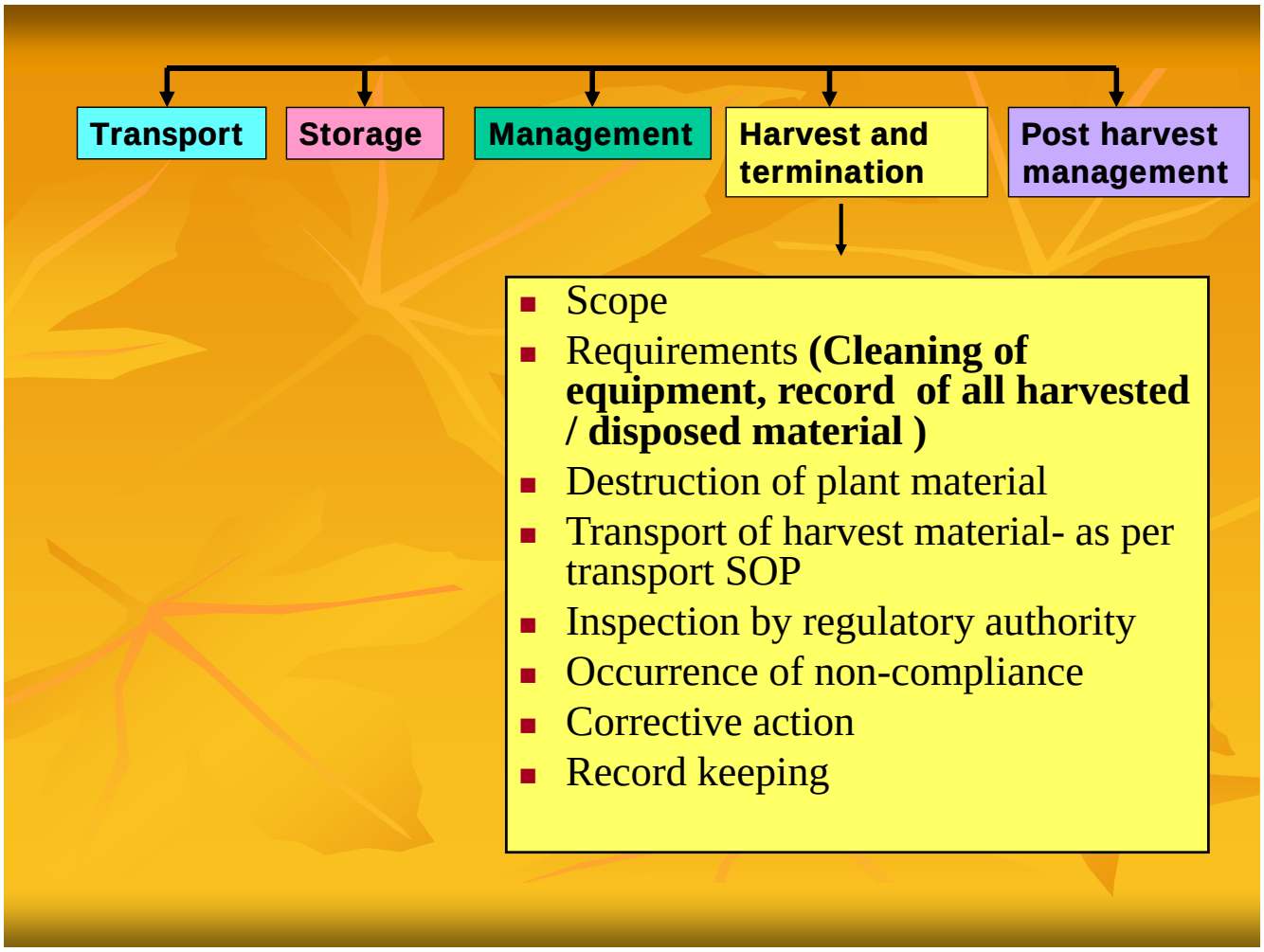


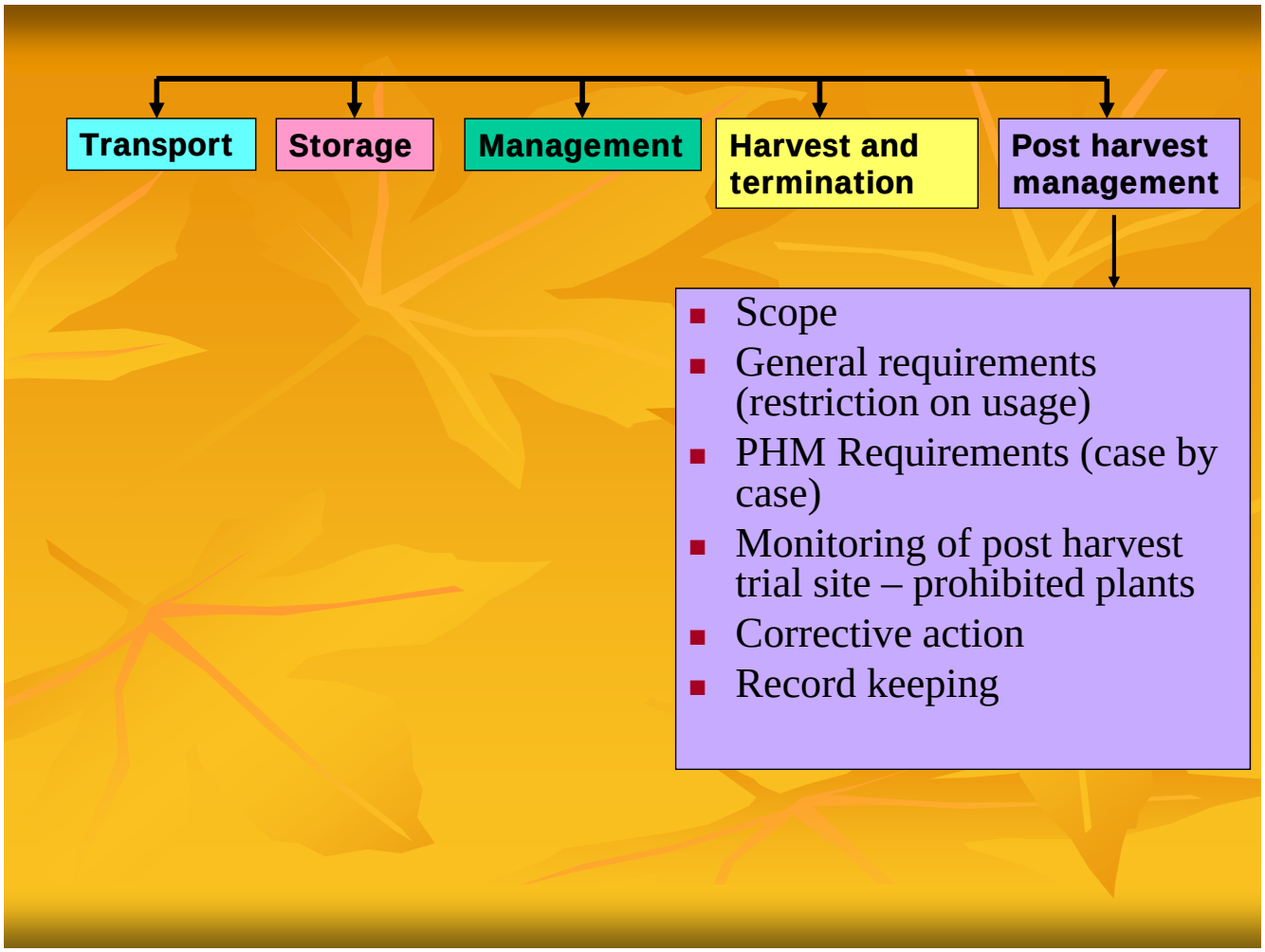


Transport | Storage | Management | Harvest and termination | Post harvest management

- Scope
- Specific Requirements (Suitability of storage area)
- Labeling of the Storage Area
- Inspection of the Storage Area
- Inspection by Regulatory Officials
- Occurrence of Non-Compliance
- Corrective Action in the Event of an Accidental Release
- Sample Storage Area Label




Transport
Storage
Management
Harvest and termination
Post harvest management
Scope
Requirements (Cleaning of equipment, record of all harvested / disposed material)
Destruction of plant material
Transport of harvest material- as per transport SOP
Inspection by regulatory authority
Occurrence of non-compliance
Corrective action
Record keeping


Transport
Storage
Management
Harvest and termination
Post harvest management
Scope
General requirements (restriction on usage)
PHM Requirements (case by case)
Monitoring of post harvest trial site – prohibited plants
Corrective action
Record keeping

Trial Site Map

- **Must provide sufficient detail to allow regulatory officials to locate each field trial site during the planting season**
- **Must provide details on the layout of the site and distances between the field trial site and surrounding features of permanent nature like poles etc**

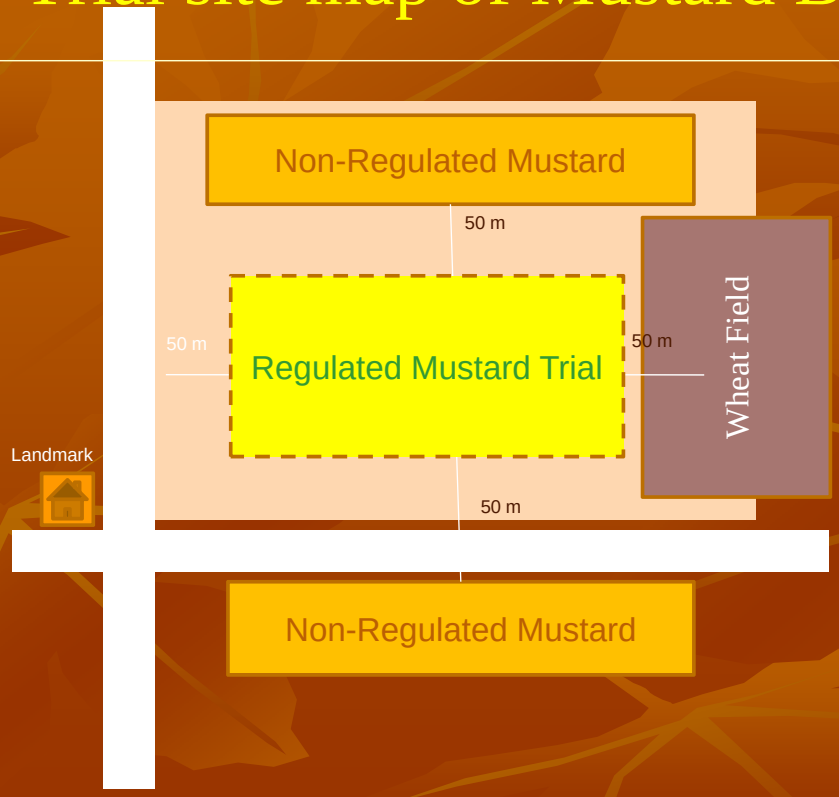
Items to be included in each Map of Field Trial site

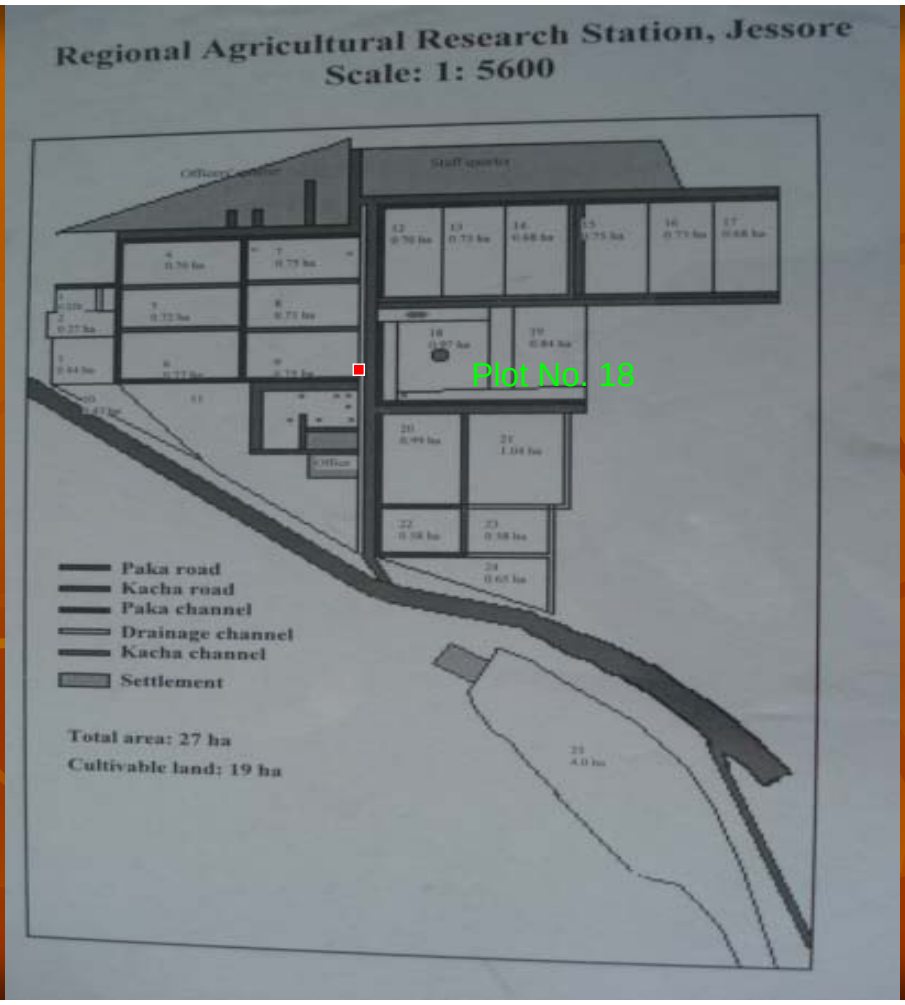
- **Trial In Charge name** and contact details.
- **Permit number** from the regulatory authority
- **Legal** or descriptive land **location**.(name of the village, taluka, district, state.)
- Accurate distances to **physical landmarks** or surrounding permnent landmarks such as telephone poles etc,
- **Total area planted** with the regulated material, including border rows when used.

Contd.

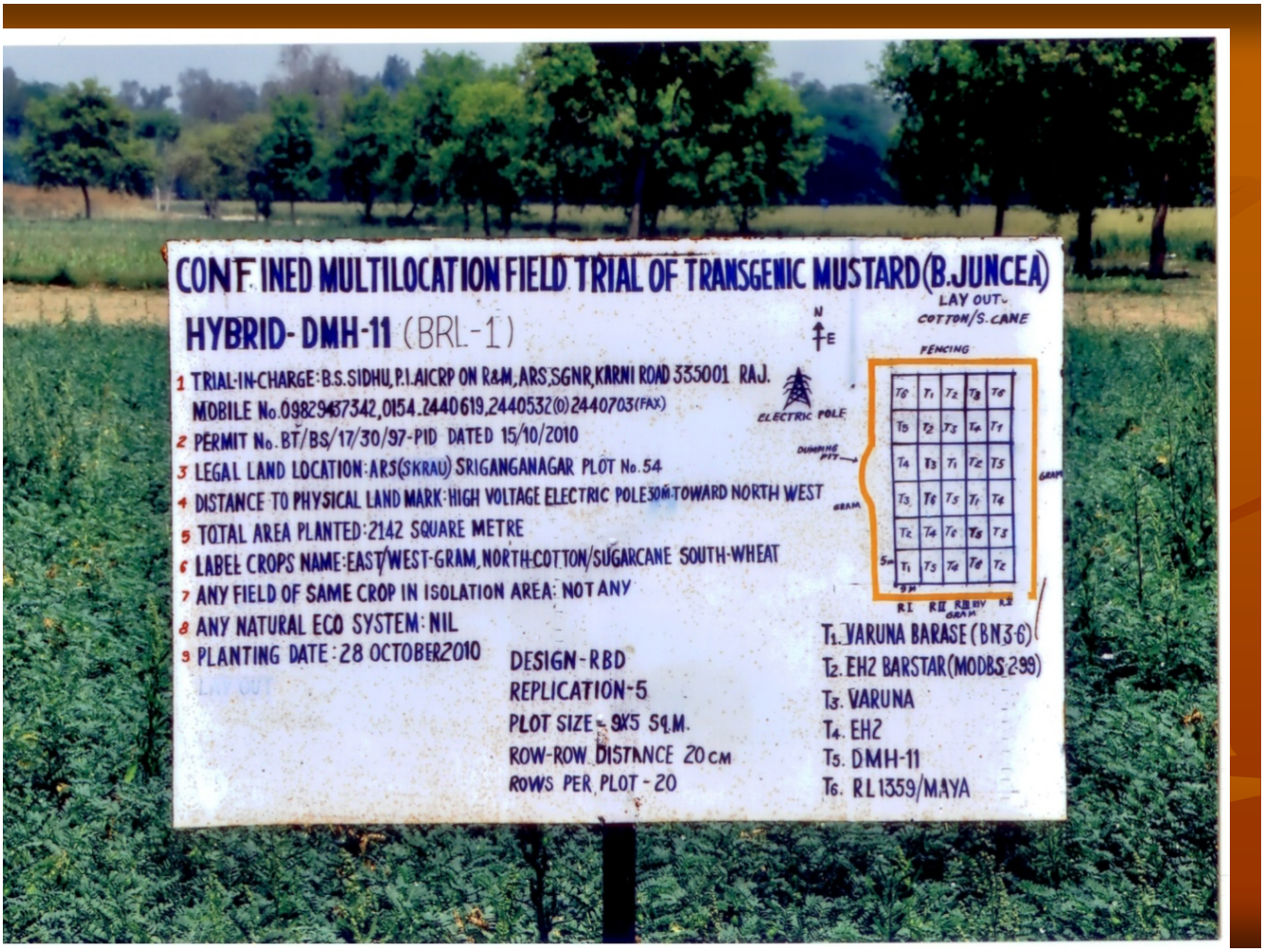
- **Label all fields** within the isolation area by the common name of the crop
- Indicate any fields of same/related crops that fall within, or border on, the isolation area
- Include any **natural ecosystems** adjacent to the trial site (natural habitats, waterways, garden, orchard, forests, wherever reasonable).
- **Planting date**
- **Compass directions**, with North at the top of the page

Trial site map of Mustard BRL I

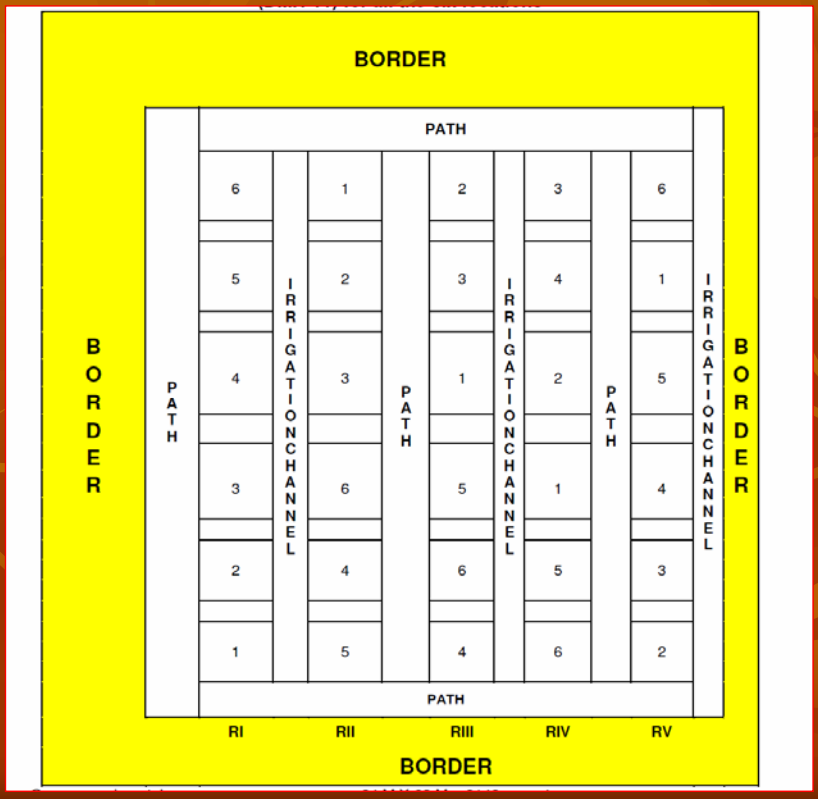




Display of sign boards at trial site.



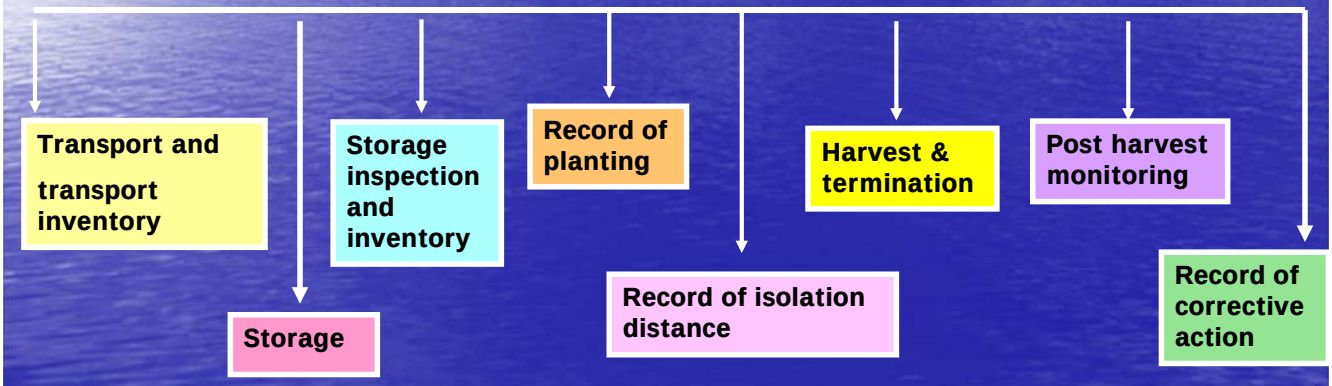
FIELD LAYOUT

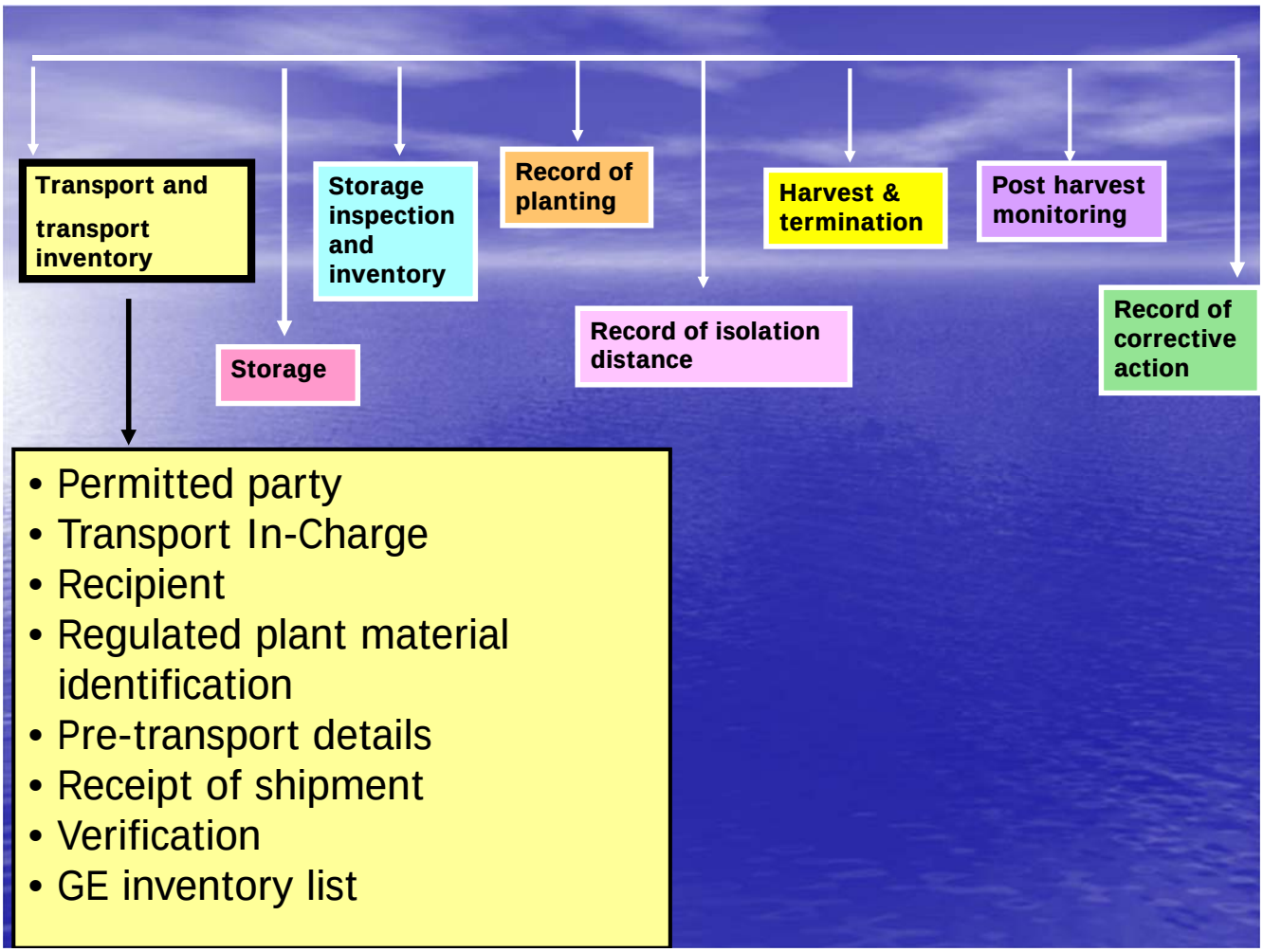


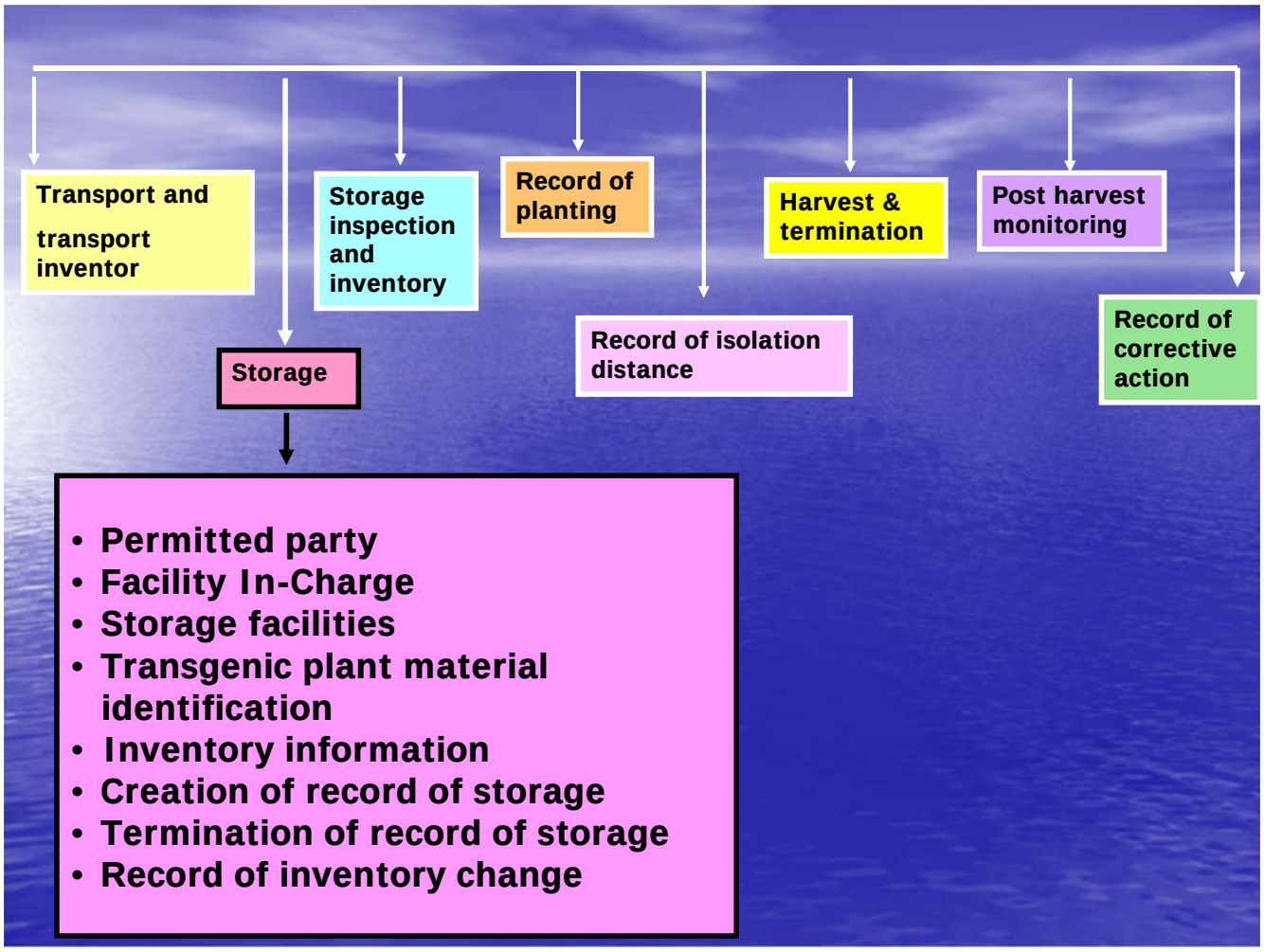
Recording Formats

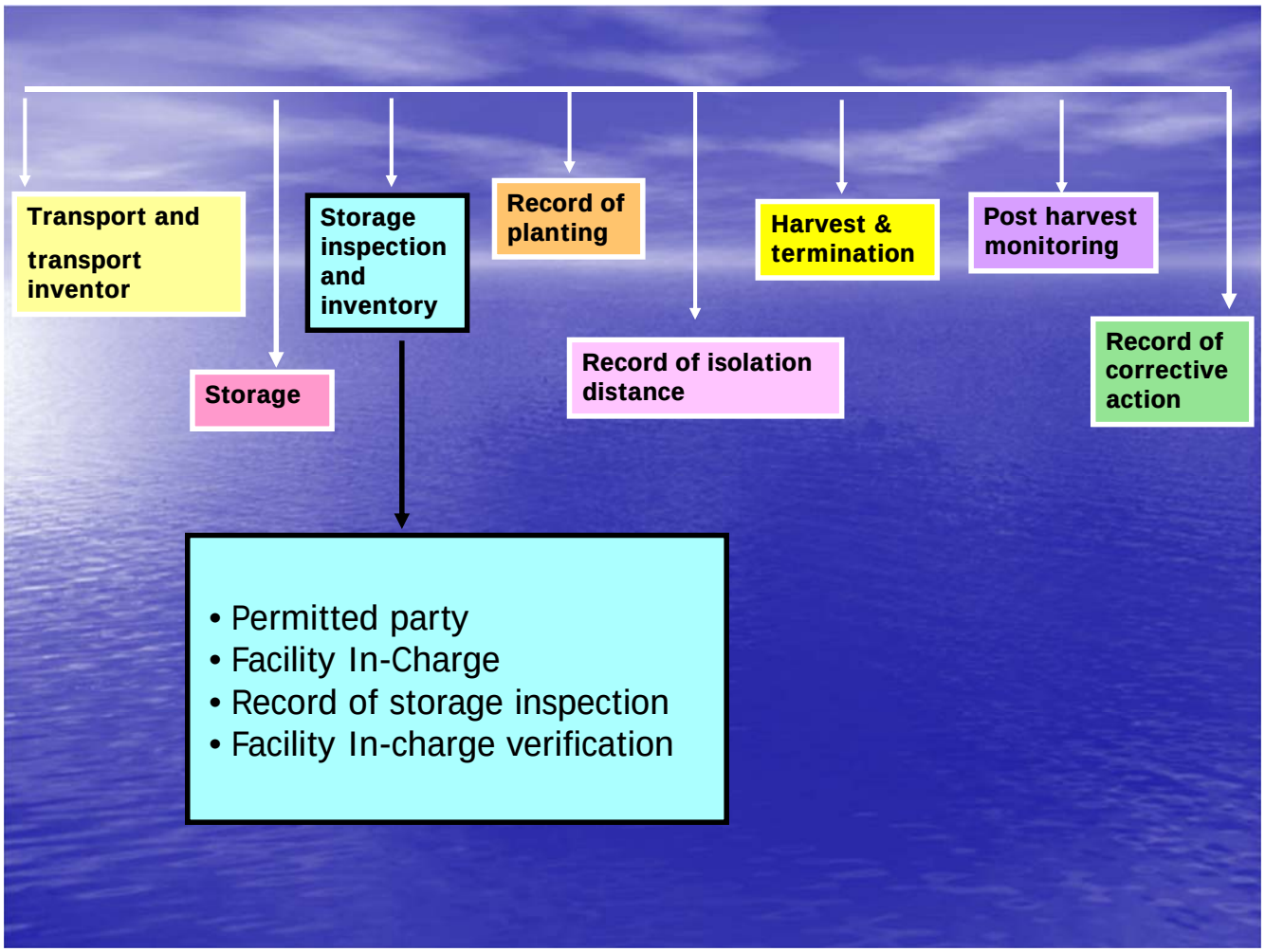
All the relevant records are to be filled as per the requirements indicated in each SOP.

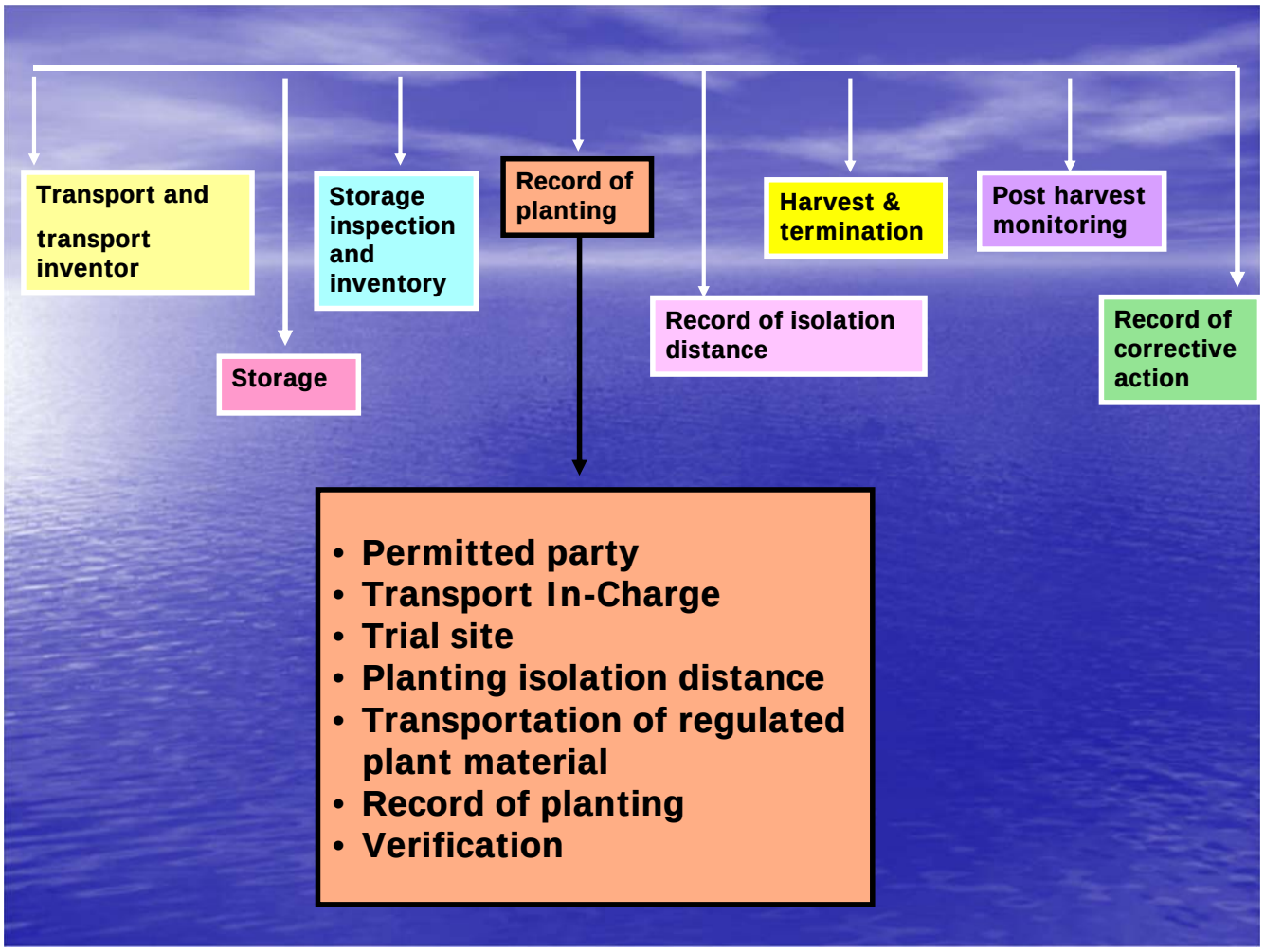
Following records in the formats are required to be maintained.

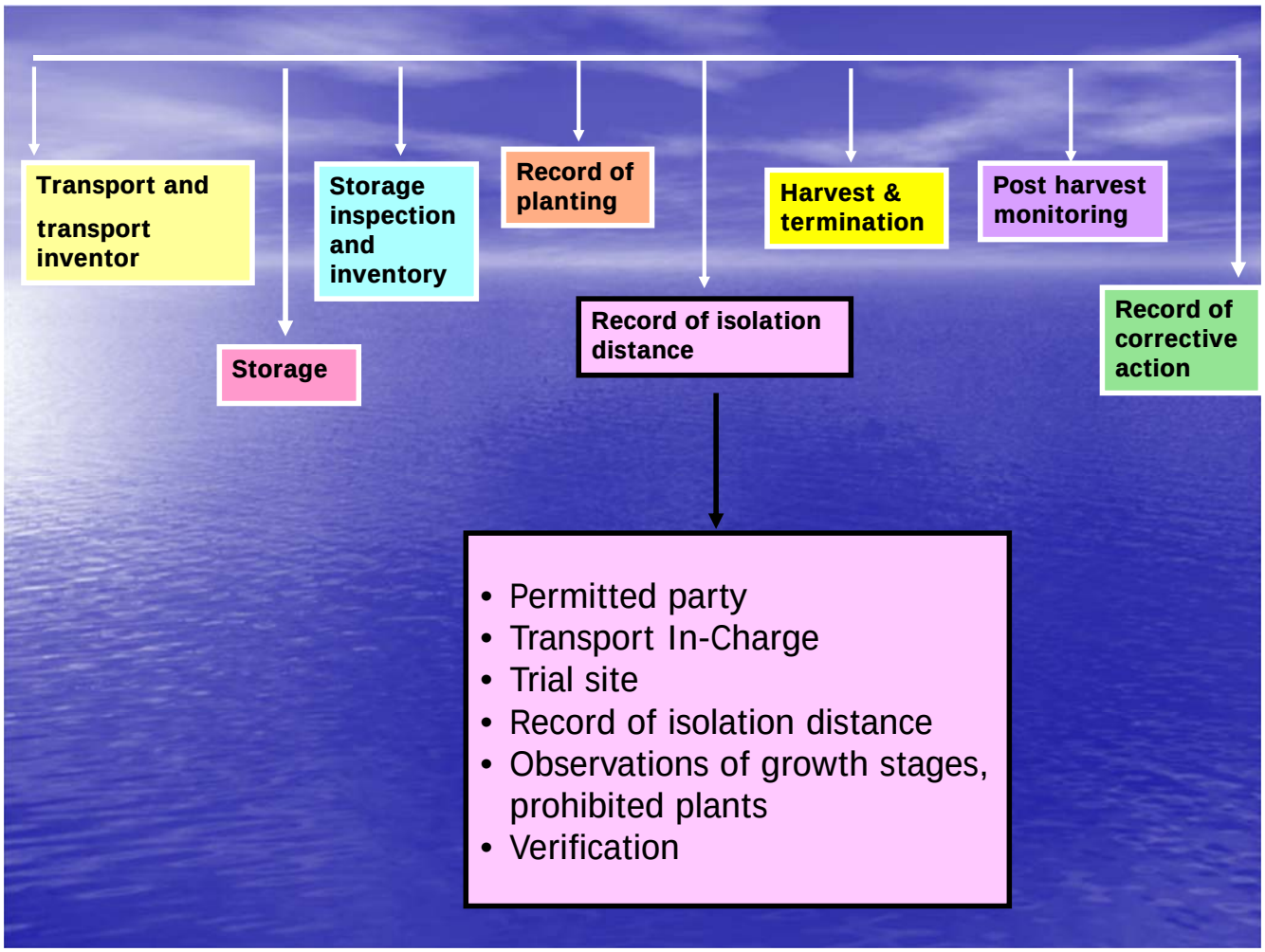


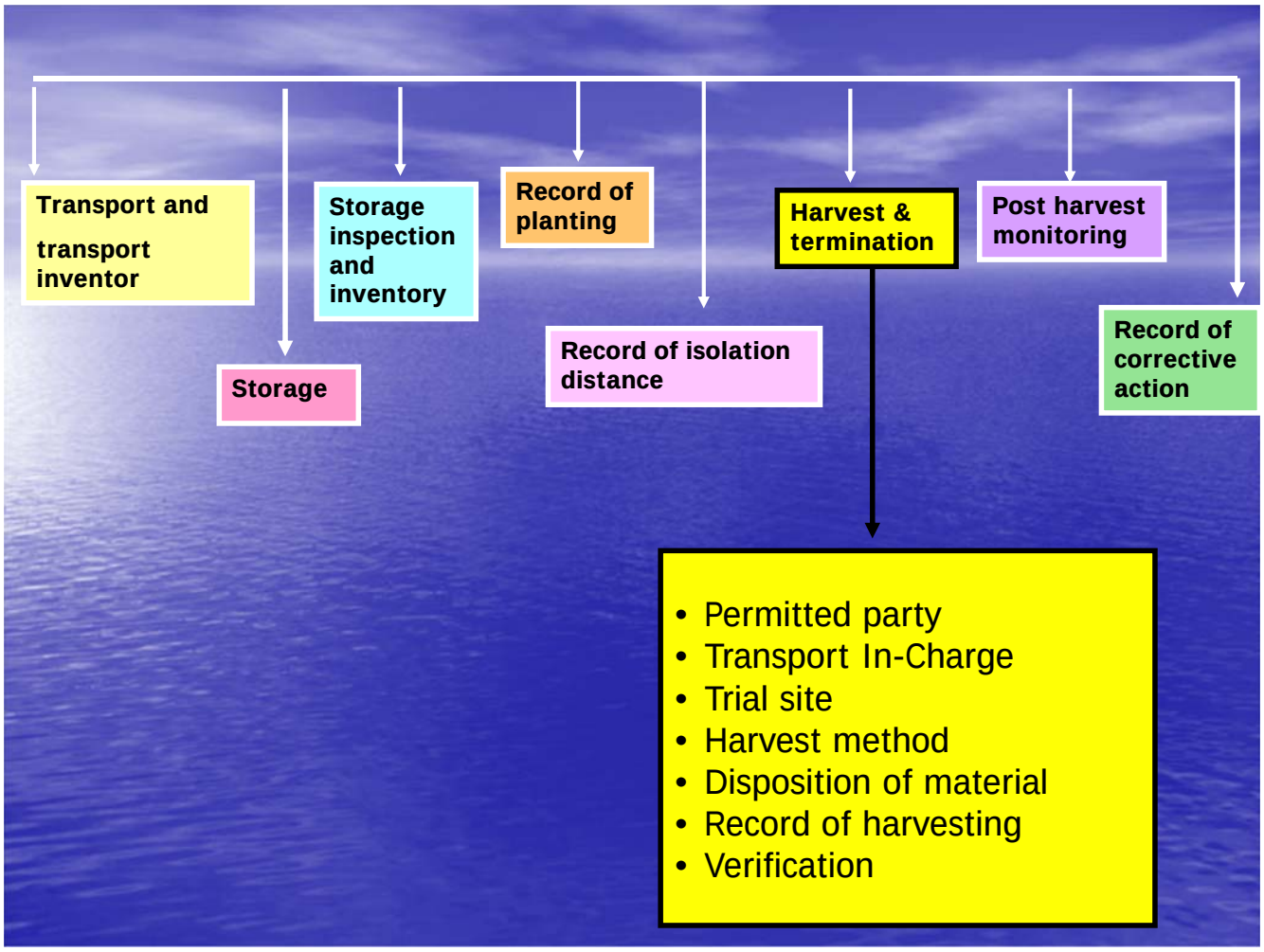


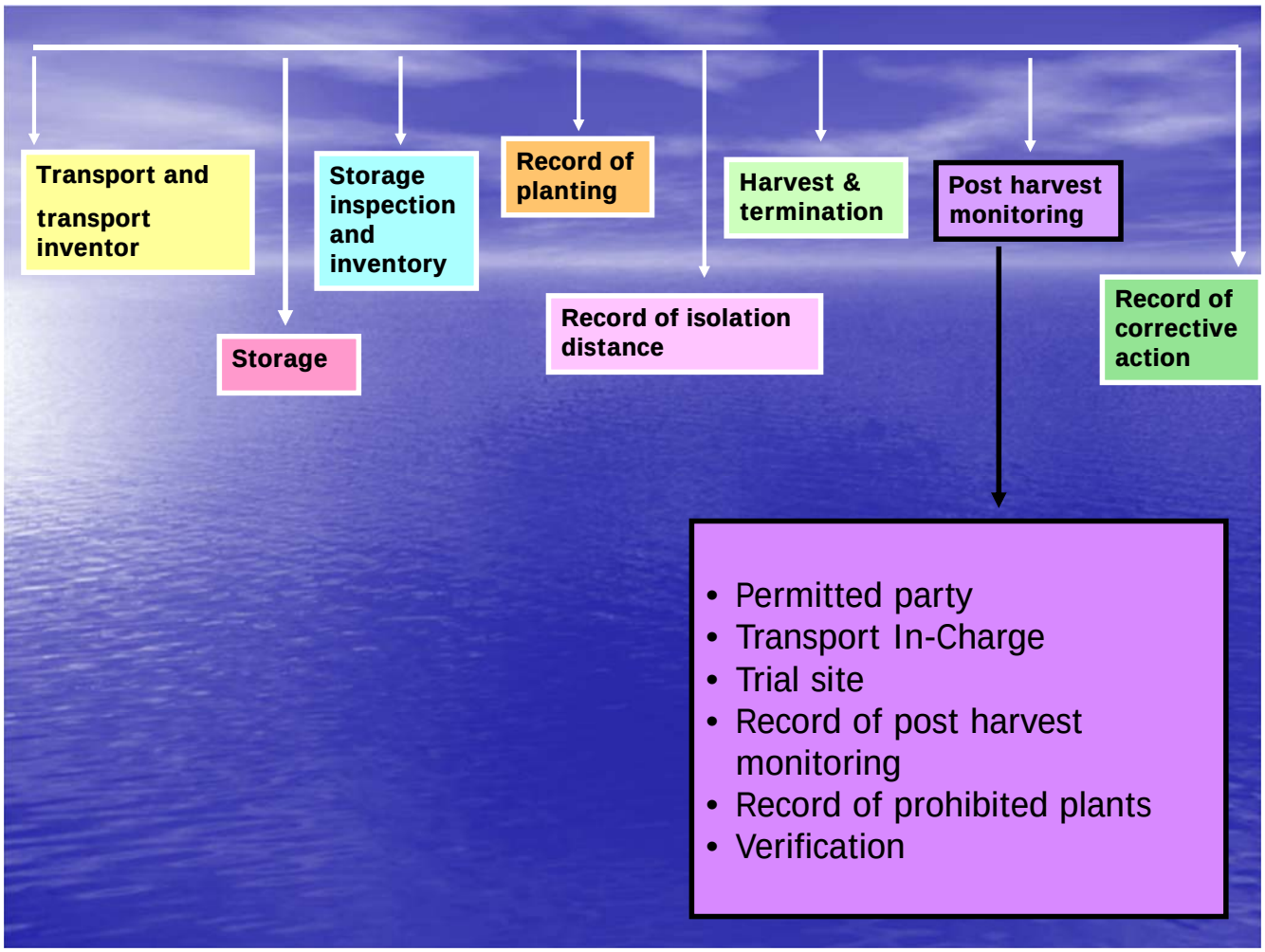

Transport and transport inventor
Storage inspection and inventory
Record of planting
Harvest & termination
Post harvest monitoring
Record of corrective action
Record of isolation distance
Storage
• Permitted party
• Facility In-Charge
• Storage facilities
• Transgenic plant material identification
• Inventory information
• Creation of record of storage
• Termination of record of storage
• Record of inventory change

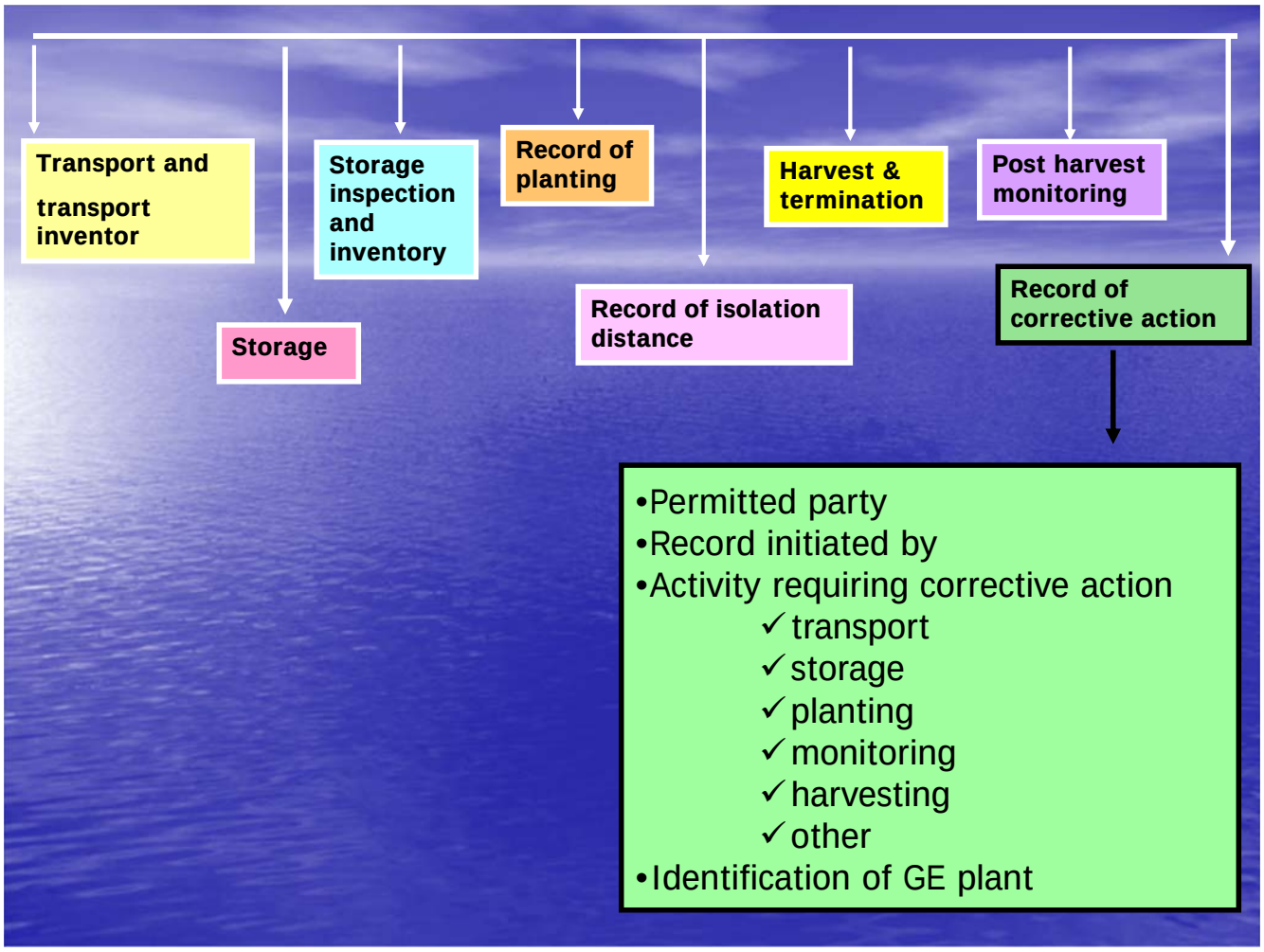

Transport and transport inventor
Storage inspection and inventory
Record of planting
Harvest & termination
Post harvest monitoring
Record of corrective action
Record of isolation distance
Storage
• Permitted party
• Facility In-Charge
• Record of storage inspection
• Facility In-charge verification

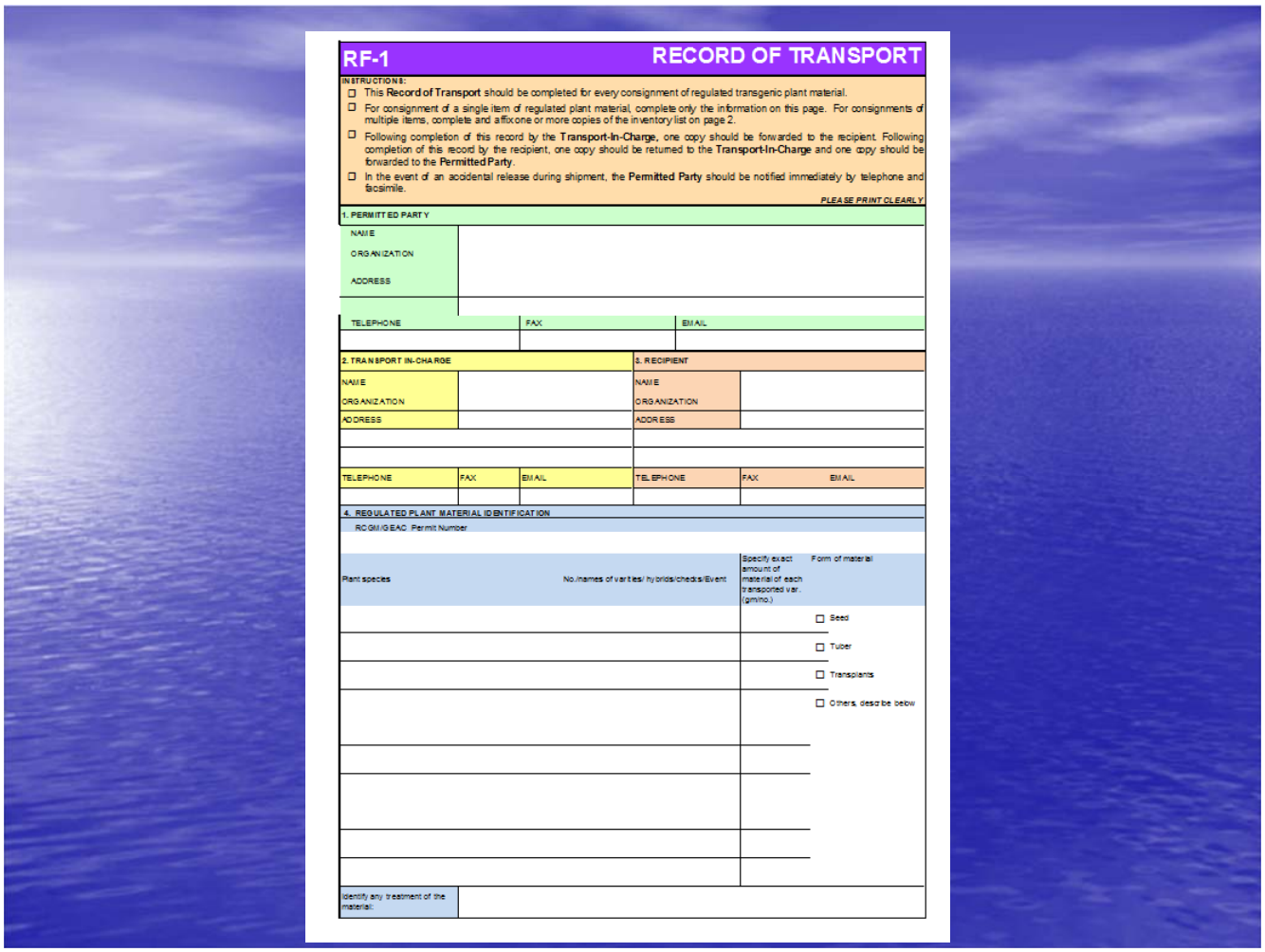

Transport and transport inventor
Storage inspection and inventory
Record of planting
Harvest & termination
Post harvest monitoring
Storage
Record of isolation distance
Record of corrective action
• Permitted party
• Transport In-Charge
• Trial site
• Planting isolation distance
• Transportation of regulated plant material
• Record of planting
• Verification


Transport and transport inventor
Storage inspection and inventory
Record of planting
Harvest & termination
Post harvest monitoring
Storage
Record of isolation distance
Record of corrective action
• Permitted party
• Transport In-Charge
• Trial site
• Record of isolation distance
• Observations of growth stages, prohibited plants
• Verification


Transport and transport inventor
Storage inspection and inventory
Record of planting
Harvest & termination
Post harvest monitoring
Storage
Record of isolation distance
Record of corrective action
• Permitted party
• Transport In-Charge
• Trial site
• Harvest method
• Disposition of material
• Record of harvesting
• Verification


Transport and transport inventor
Storage inspection and inventory
Record of planting
Harvest & termination
Post harvest monitoring
Storage
Record of isolation distance
Record of corrective action
• Permitted party
• Transport In-Charge
• Trial site
• Record of post harvest monitoring
• Record of prohibited plants
• Verification





RF-1 **RECORD OF TRANSPORT**

INSTRUCTIONS:

- ☐ This **Record of Transport** should be completed for every consignment of regulated transgenic plant material.
- ☐ For consignment of a single item of regulated plant material, complete only the information on this page. For consignments of multiple items, complete and affix one or more copies of the inventory list on page 2.
- ☐ Following completion of this record by the **Transport-In-Charge**, one copy should be forwarded to the recipient. Following completion of this record by the recipient, one copy should be returned to the **Transport-In-Charge** and one copy should be forwarded to the **Permitted Party**.
- ☐ In the event of an accidental release during shipment, the **Permitted Party** should be notified immediately by telephone and facsimile.

PLEASE PRINT CLEARLY

1. PERMITTED PARTY

NAME
ORGANIZATION
ADDRESS
TELEPHONE | FAX | EMAIL

2. TRANSPORT IN-CHARGE

NAME
ORGANIZATION
ADDRESS
TELEPHONE | FAX | EMAIL

3. RECIPIENT

NAME
ORGANIZATION
ADDRESS
TELEPHONE | FAX | EMAIL

4. REGULATED PLANT MATERIAL IDENTIFICATION

RCGM/GEAC Permit Number

Plant species	No./names of varities/ hybrids/checks/Event	Specify exact amount of material of each transported var. (gm/no.)	Form of material
			☐ Seed
			☐ Tuber
			☐ Transplants
			☐ Others, describe below

Identify any treatment of the material:

RF - 2 RECORD OF STORAGE

INSTRUCTIONS:

- ☐ This **Record of Storage** should be completed for **each event** of regulated plant material separately
- ☐ This **Record of Storage** should be completed for each lot of regulated plant material / seed placed into storage and each **Record of Storage** should be identified with a unique inventory control number. One or more copies of the **Record of Inventory Change** can be attached to the **Record of Storage** to document any removals of material from storage.
- ☐ The designated official of the **Permitted Party** is the person responsible for the regulated plant material in storage.
- ☐ No regulated plant material should be removed from storage for transport outside of the facility without completion of a **Record of Transport**.
- ☐ In the event of an **Accidental Release** of the regulated plant material during storage, the **Permitted Party** should be immediately informed by the designated official by telephone and fax. The incident and any corrective action taken should be recorded on a **Record of Corrective Action**.

PLEASE PRINT CLEARLY

1. PERMITTED PARTY			2. DESIGNATED OFFICIAL / FACILITY IN-CHARGE		
NAME			NAME		
ORGANISATION			ORGANISATION		
ADDRESS			ADDRESS		
TELEPHONE	FAX	E-MAIL	TELEPHONE	FAX	E-MAIL

3. STORAGE FACILITIES			4. TRANSGENIC PLANT MATERIAL IDENTIFICATION	
BUILDING NAME			PERMIT NO.	
ROOM NUMBER / DESCRIPTION			PLANT SPECIES	
ADDRESS			EVENT NAME	
TELEPHONE	FAX	E-MAIL		

5. INVENTORY INFORMATION		6. CREATION OF RECORD OF STORAGE
AMOUNT OF MATERIAL PLACED IN STORAGE		SIGNATURE OF DESIGNATED OFFICIAL / FACILITY IN-CHARGE
FIRST DATE OF STORAGE		EFFECTIVE DATE

7. TERMINATION OF RECORD OF STORAGE

REASON FOR TERMINATION OF STORAGE	SIGNATURE OF DESIGNATED OFFICIAL / FACILITY IN-CHARGE	EFFECTIVE DATE
☐ ALL MATERIAL REMOVED ☐ DESTRUCTION OF MATERIAL ☐ OTHER (detail below)		

RF - 3 RECORD OF STORAGE INSPECTION

INSTRUCTIONS :

- ☐ This **Record of Storage Inspection** should be completed ONCE EVERY FOUR (4) WEEKS by the Facility In-charge to ensure that storage conditions are maintained so that unintended releases of regulated transgenic plant material do not occur.
- ☐ This **Record of Storage Inspection** should be retained by the **Facility In-charge** and made available to regulatory officials upon request.
- ☐ In the event of an **Accidental Release** of the regulated plant material during storage, the **Permitted Party** should be immediately notified by telephone and facsimile. The incident and any corrective action taken should be recorded on a **Record of Corrective Action**.

PLEASE PRINT CLEARLY

1. PERMITTED PARTY			2. FACILITY IN-CHARGE		
NAME			NAME		
ORGANISATION			ORGANISATION		
ADDRESS			ADDRESS		
TELEPHONE	FAX	E-MAIL	TELEPHONE	FAX	E-MAIL

3. STORAGE FACILITIES			4. INSPECTION CHECKLIST	
BUILDING NAME			STOARGE AREA SECURE ☐ YES ☐ NO	STORAGE UNIT(S) SECURE ☐ YES ☐ NO
ROOM NUMBER/ DESCRIPTION			STORAGE AREA CLEAN AND FREE OF ANY WASTE OR PLANT DEBRIS ☐ YES ☐ NO	
ADDRESS			STORAGE AREA CLEARLY LABELED ☐ YES ☐ NO	
TELEPHONE	FAX	E-MAIL	MONTHLY RECORDS OF STORAGE INSPECTION AVAILABLE ☐ YES ☐ NO	

IN THE EVENT OF A NO ANSWER TO ANY OF THE ABOVE, PROVIDE ADDITIONAL OBSERVATIONS BELOW

5. FACILITY INCHARGE VERIFICATION

THIS ACTIVITY HAS BEEN CARRIED OUT TO MEET PERFORMANCE STANDARDS AND/OR SPECIFIC AUTHORIZATION PERMIT CONDITIONS FOR CONDUCT OF CONFINED FIELD TRIALS OF TRANSGENIC PLANT MATERIAL.

SIGNATURE OF FACILITY IN-CHARGE DATE SIGNED

BY MY SIGNATURE, ABOVE, I ATTEST THAT THE INFORMATION CONTAINED HEREIN IS ACCURATE AND COMPLETE TO THE BEST OF MY KNOWLEDGE AND BELIEF.

RF - 4 RECORD OF PLANTING

INSTRUCTIONS:

- ☐ This **Record of Planting** should be completed to document the planting of all regulated plant material at a field trial site.
- ☐ Use the following two-letter codes to designated the destruction method for excess planting material: DH - dry heat, SH - steam heat, BU - burning, DB - deep burial, CR - crushing, OT - other.
- ☐ Following completion of this record by **Trial In-Charge**, one copy should be forwarded to the **Permitted Party**. The original should be retained by the **Trial In-Charge** and made available to regulatory officials upon request.
- ☐ In the event of an **Accidental Release** during planting, the **Permitted Party** should be notified immediately by telephone and facsimile. The incident and any corrective action taken should be recorded on a **Record of Corrective Action**.

PLEASE PRINT CLEARLY

1. PERMITTED PARTY			2. TRIAL IN-CHARGE		
NAME			NAME		
ORGANISATION			ORGANISATION		
ADDRESS			ADDRESS		
TELEPHONE	FAX	E-MAIL	TELEPHONE	FAX	E-MAIL

3. TRIAL SITE

Site Location		Distance to nearest cultivation field of the same plant species (m)
Trial Site Size (ha or m^2)	No. of trials at this site	Distance to nearest commercial crop of any kind (m)
Legal or descriptive land location		Is the isolation distance under the Trial In-Charge's control? ☐ YES ☐ NO

4. PLANTING	5. TRANSPORT OF REGULATED MATERIAL
Method of Planting	Is a Record of Transport for all material transported to the trial site attached?
☐ HAND ☐ MACHINERY ☐ OTHER, DESCRIBE BELOW	☐ YES ☐ NO Consignment No.
Was the machinery cleaned, inspection and confirmed free of plant material prior to exiting the trial site?	Was any regulated plant material dispatched from the trial site during or after planting? If yes, enter consignment number.
☐ YES ☐ NO	☐ YES ☐ NO Consignment No.

6. COMPLETE THE FOLLOWING SECTION FOR EACH TRIAL AT THE TRIAL SITE

8. No.	Event Name/ Other variety	Permit Number	Area Planted	Date Planted
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				

7. TRIAL IN-CHARGE VERIFICATION

This activity has been carried out to meet the specific authorization permit conditions for conduct of confined field trials of regulated plant material.

Signature of Trial In-Charge _____ Date signed _____

By my signature, above, I attest that the information contained herein is accurate and complete to the best of my knowledge and belief.

RF - 6 RECORD OF HARVEST / TERMINATION

INSTRUCTIONS:

- ☐ This **Record of Harvest/Termination** should be completed following harvest or termination of confined field trials and disposition of regulated plant material at a single trial site. It should document the method of harvesting the regulated plant material, the harvest date(s), and the fate of all harvested material and any residual regulated plant material remaining on the trial site.
- ☐ A copy of the **Record of Harvest / Termination** should be forwarded to **the Permitted Party within FIFTEEN (15) DAYS** of harvest/termination of the trial. The original should be retained by the **Trial In-Charge.**
- ☐ In the event of an **Accidental Release** of regulated plant material during harvest, termination and/or disposition of the trial, the **Permitted Party** should be notified immediately by telephone and facsimile. The incident and any corrective action taken should be recorded on a **Record of Corrective Action.**

PLEASE PRINT CLEARLY

1. PERMITTED PARTY			2. TRIAL IN-CHARGE		
NAME			NAME		
ORGANISATION			ORGANISATION		
ADDRESS			ADDRESS		
TELEPHONE	FAX	E-MAIL	TELEPHONE	FAX	E-MAIL

3. TRIAL SITE

Site Location		Distance to nearest cultivation field of the same plant species (m)
Trial Site Size (ha or m^2)	No. of trials at this site	Distance to nearest commercial crop of any kind (m)
Legal or descriptive land location		Is the isolation distanace under the Trial In-Charge's control? ☐ YES ☐ NO

4. HARVEST / TERMINATION METHOD	
Date of harvest / termination	Describe harvest / termination method
Machinery or tools inspected, cleaned and confirmed free of plant material prior to leaving the trial site?	☐ hand ☐ machine ☐ burning ☐ other, describe below
☐ YES ☐ NO	
Machinery or tools inspected, cleaned and confirmed free of plant material prior to leaving the trial site?	Indicate how machinery was cleaned at the trial site following crop termina
☐ burning ☐ burial ☐ any other, describe below	☐ hand ☐ water ☐ other, describe below

RF - 7 RECORD OF POST HARVEST MONITORING

INSTRUCTIONS:

- ☐ Trial sites should be inspected for the presence of prohibited plants at least ONCE EVERY TWO (2) WEEKS during the growing season for the ONE YEAR post harvest period. Growth stages of any prohibited plants must be recorded. The post-harvest period begins on the date of harvest/termination of the trial.
- ☐ If any breach of reproductive isolation occurred during performance of the trial, the post-harvest restrictions, including the monitoring requirements for prohibited plants, will apply to the trial site and the spatial isolation area around the trial site.
- ☐ During the post-harvest period, if any **prohibited plants** are permitted to flower within the area under post-harvest restrictions, an additional post-harvest period of one year will be applied. The incident and any corrective action taken should be recorded on a Record of Corrective Action.
- ☐ The **Record of Post-Harvest Inspection** should be retained by the **Trial In-Charge** and made available to regulatory officials/monitoring committees upon request. Upon completion, a copy of the signed **Record of Post-Harvest Inspection** should be forwarded to the **Permitted Party**.
- ☐ In the event of a breach of reproductive isolation, the **Permitted Party** must be notified immediately by telephone and facsimile. The incident and any corrective action taken should be recorded on a **Record of Corrective Action**.

PLEASE PRINT CLEARLY

1. PERMITTED PARTY		2. TRIAL IN-CHARGE	
NAME		NAME	
ORGANISATION		ORGANISATION	
ADDRESS		ADDRESS	
TELEPHONE / FAX / E-MAIL		TELEPHONE / FAX / E-MAIL	

3. TRIAL SITE

Site location	Permit No.	Legal or descriptive land location
Name of the crop	**No. of trials at this site**	**Distance to nearest commercial crop of any kind (m)**
Area under post harvest restriction ☐ trial area only ☐ trial area + isolation area		**Post harvest year** ☐ 1 year ☐ 2 year ☐ 3 year ☐ Less than one year

4. REGULATED PLANT MATERIAL PREVIOUSLY PLANTED AT THE TRIAL SITE

S. No.	Event Name	Var.	Area planted	Date harvested*
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				

*Post harvest monitoring begins from this date

RF-8 RECORD OF CORRECTIVE ACTION

INSTRUCTIONS:

- ☐ The **Record of Corrective Action** is used to document all corrective actions taken to manage or resolve a situation involving the accidental release of regulated plant material during transport and/or storage or any breach of the terms and conditions of authorization of the confined field trial or during the post-harvest monitoring period.
- ☐ A copy of this **Record of Corrective Action**, together with any other relevant records (e.g., **Record of Transport**, **Record of Storage Inspection**, **Record of Spatial Isolation**, **Record of Harvest**, etc.), should be forwarded to the **Permitted Party** and RCGM/GEAC.

PLEASE PRINT CLEARLY

1. PERMITTED PARTY		2. RECORD INITIATED BY		
NAME		NAME		
ORGANISATION		POSITION		
		ORGANISATION		
ADDRESS		ADDRESS		
TELEPHONE / FAX / E-MAIL		TELEPHONE	FAX	E-MAIL

3. ACTIVITY REQUIRING CORRECTIVE ACTION

Indicate the category of activity requiring corrective action and then complete the relevant information requirements under transportation and storage, or trial site

☐ Transport ☐ Storage ☐ Planting
☐ Monitoring ☐ Harvesting ☐ Other

If other, describe below:

4. IDENTIFICATION OF AFFECTED REGULATED TRANSGENIC PLANT MATERIAL

Permit number	Plant species	Approximate amount of affected material

Form of material

☐ Seed ☐ Transplants ☐ Tubers ☐ *Others, describe below:*

5. TRANSPORT AND STORAGE

Consignment	Item number
Facility name	**Storage location identifier**
Building name	**Room number or description**

Address of facility

TELEPHONE / FAX / E-MAIL

6. TRIAL SITE

Site location	Trial site size (ha or m2)
No. of trials at this site	**Legal or descriptive land location**
Distance to nearest cultivated field of the same plant species (m)	**Distance to nearest commercial crop of any kind (m)**

Is the isolation distance under the Trial In-Charge's control?

Method of reproductive isolation

☐ Spatial isolation ☐ Crop termination ☐ *Other, describe below*

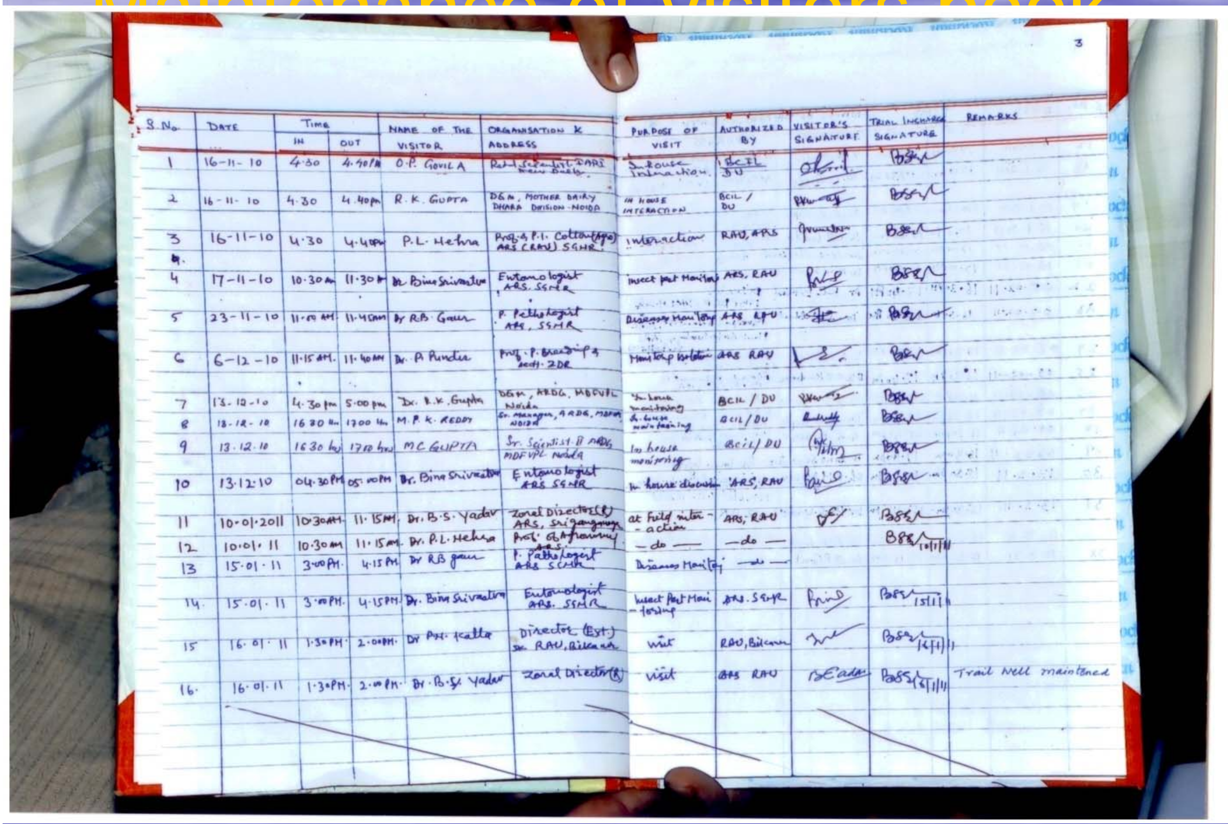

Eggplant confined field trial,

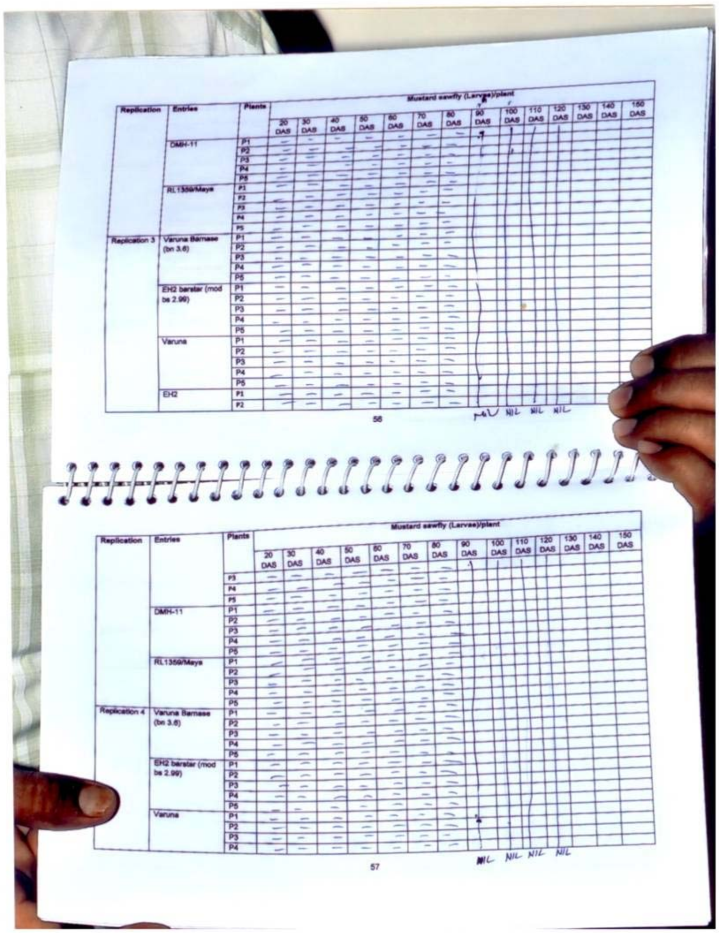

DUMPING
PIT

Disposal of material

Disposal of residual GE material

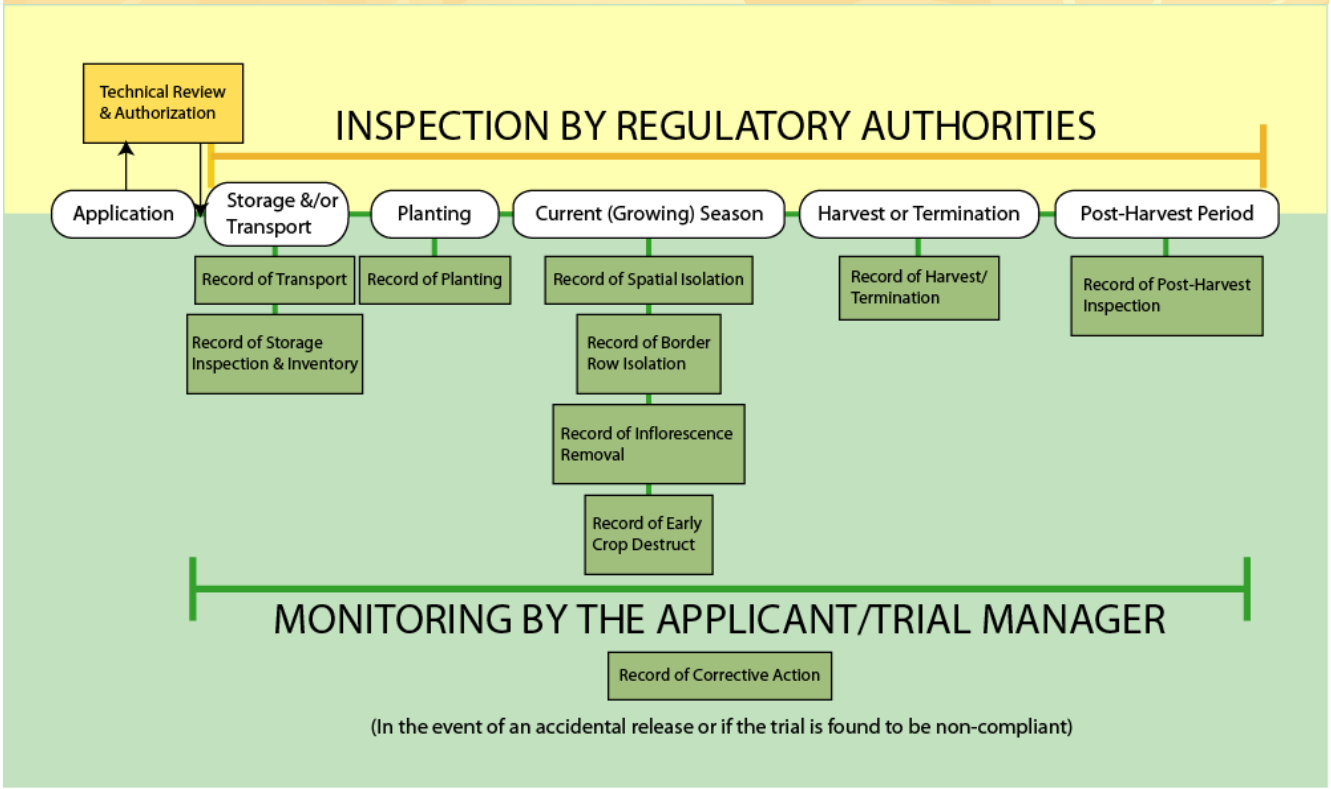
Maintenance of visitors book





Fencing of the trial site (if necessary)

Summary of procedures / monitoring and recording



"3-Ps" of risk mitigation for field trials

- **Prevent dissemination of new genes in experimental transgenic plant into and within the environment (*i.e.* prevent pollen-mediated gene flow).**
- **Prevent the persistence in the environment of the experimental transgenic plant and any progeny plants.**
- **Prevent the introduction of the experimental transgenic plant (or products) into the livestock feed and human food pathways.**

Inspection by Central Compliance Committee (constituted by Department of Biotechnology/MoEF)

- Expert scientist (Chairman)
- Scientist from concerned SAUs
- Officials of State Department of Agriculture
- DBT Nominee
- MoEF Nominee

Inspection Report on Documentation and Compliance

- Trial site information
- Reproductive Isolation
- Storage of regulated plant material
- Post harvest restrictions
- Documentation in record keeping
- Compliance assessment
  - No compliance deviation, all documentation in order
  - No compliance deviations, but with documentation deficiencies
  - Compliance deviations, but no documentation deficiencies
  - Compliance deviations And documentation deficiencies

8. PROFORMA CONFINED FIELD TRIAL INSPECTION REPORT

INSTRUCTIONS :

- ☐ Parts A – H of this report should be completed for each site location. Additional copies of Part B of this form can be completed in cases where there is more than a single confined field trial site at a given trial site location.
- ☐ A copy of this completed report should be submitted to the Regulatory Authority (RCGM/GEAC), the relevant monitoring body (CCC, SBCC, DLC), and the Permitted Party WITHIN FIVE (5) DAYS of the site visit.
- ☐ In the event of any compliance infraction discovered during a site visit that results in an accidental release of regulated genetically engineered plant material, Regulatory Authorities will be notified immediately by telephone and in writing within 24 hours. Regulatory Authorities will advise on the necessary corrective actions to be implemented and a Record of Corrective Action, detailing the incident and the corrective action taken, is to be initiated by the Permitted Part, Trial In-Charge or Facility In-Charge and provided to the Monitoring Team. Upon completion of the corrective action, copies of the Record of Corrective Action will be forwarded to the Regulatory Authority and the Permitted Party.

PART A: GENERAL INFORMATION

PERMITTED PARTY			TRIAL IN-CHARGE OR FACILITY IN-CHARGE		
Last Name	First Name	MI	Last Name	First Name	MI
Company/Organization		Contact	Company/Organization		Contact
Telephone	Fax	Email	Telephone	Fax	Email
Address			Address		

PART B: TRIAL SITE INFORMATION

Legal or Descriptive Land Location of Trial Site		Crop Planted at Trial Site	
		Date of sowing	

Timing of the Inspection and Stage of Crop Development

☐ At planting ☐ Vegetative, pre-flowering ☐ Flowering ☐ After flowering ☐ At harvest ☐ Post-harv

1	Are physical landmarks (PVC piping, fence post, etc.) at located each corner of the trial site?	☐ Yes ☐ No	7	Is there a bound log book including the name, address and affiliation of all personnel who have entered the trial site?	☐ Yes ☐ No
2	Do measurements of the trial size match information on the trial site map?	☐ Yes ☐ No	8	Was planting/harvesting equipment cleaned in the appropriate manner prior to, and after, use on the trial site?	☐ Yes ☐ No
3	Distance to the nearest cultivated fields of the same plant species as the plants in the confined field trial:	_____ Meters	9	Event(s) planted at the trial site (attach list if necessary)	☐ Yes ☐ No
4	Distance to the nearest cultivated crop of any kind:	_____ Meters	10	Can the trial be secured from unauthorized access (fencing in place and secure)	☐ Yes ☐ No
5	Is the trial site, including the spatial isolation distance, under the control of the trial in-charge and/or Permitted Party?	☐ Yes ☐ No	11	Provision for disposal material in place (dumpint pit etc.) or planned	☐ Yes ☐ No
6	Is there a Notice Board at the trial site indicating the purpose and duration of the confined field trials conducted at the trial site and the authorization under which the confined field trials were approved?	☐ Yes ☐ No			

PART C: REPRODUCTIVE ISOLATION

Method of Reproductive Isolation

☐ Spatial Isolation ☐ Other (list)

1	Do measurements confirm that the trial site has the appropriate isolation distance? (cotton: 50 m; brinjal: 300 m; etc)	☐ Yes ☐ No
2	Is the isolation distance free of any **prohibited plants**? (e.g., plants of any species sexually compatible with the regulated plants)	☐ Yes ☐ No
3	Is there a written **Record of Spatial Isolation**?	☐ Yes ☐ No
4	Does the Record of Spatial Isolation confirm that monitoring of the isolation distance has been performed at the required intervals? (see Letter of Permit from Regulatory Authority)	☐ Yes ☐ No
5	Were growth stages of the trial plants, including any prohibited plants observed in the isolation distance, recorded?	☐ Yes ☐ No
6	If records indicate that prohibited plants have been removed from the isolation distance during routine monitoring, do they also indicate the method of destruction, and was this appropriate?	☐ Yes ☐ No ☐ NA
7	Have there been any prior instances of non-compliance during the current growing season?	☐ Yes ☐ No
8	If the answer to C.7 was YES, was a Record of Corrective Action initiated and were the necessary actions implemented?	☐ Yes ☐ No ☐ NA

PART D: STORAGE OF REGULATED PLANT MATERIAL

ONLY COMPLETE IF REGULATED PLANT MATERIAL IS IN STORAGE AT TH

☐ Regulated plant material is stored at this location

1	Is the regulated plant material stored separately from conventional seeds in a fully enclosed, lockable space? (e.g., boxes, almirahs, cabinets, closet etc)	☐ Yes ☐ No
2	Is the storage area clearly labelled as containing regulated plant material and is it used exclusively for that purpose?	☐ Yes ☐ No
3	If multiple regulated articles are in storage, are they within separate, sealed containers?	☐ Yes ☐ No
4	Is the storage area clean and free of any waste or debris?	☐ Yes ☐ No
5	Is there a **Record of Inventory** that details all of the regulated plant material in storage and any additions to, or removals from, storage?	☐ Yes ☐ No
6	Based on a sampling of entries from the **Record of Inventory**, is there correlation between the physical presence of an inventory item and the **Record of Inventory**?	☐ Yes ☐ No
7	Is there a **Record of Storage Inspection**?	☐ Yes ☐ No
8	If it exists, does the **Record of Storage Inspection** confirm that the storage location has been inspected at least once per month?	☐ Yes ☐ No
9	Have there been any prior instances of non-compliance during the current year?	☐ Yes ☐ No
10	If the answer to D.9 was YES, was a **Record of Corrective Action** initiated and were the necessary actions implemented?	☐ Yes ☐ No ☐ NA

PART E: POST-HARVEST RESTRICTIONS				PART F: DOCUMENTATION AND RECORD KEEPING			
ONLY COMPLETE IF THIS IS A PRIOR-YEAR TRIAL SITE UNDER POST-HARVEST RESTRICTIONS							
☐ Prior-year trial site(s) under post-harvest land use restrictions at this location							
1	Is the post-harvest trial site clearly marked with physical landmarks at each corner?	☐ Yes	☐ No	1	Are copies of SOPs and related records readily accessible and up-to-date for this trial site location?	☐ Yes	☐ No
2	Does the post-harvest area under restriction include only the trial site proper? (If not, it also includes the spatial isolation distance)	☐ Yes	☐ No	2	Is a copy of the letter of permit for all events planted at this trial location readily accessible?	☐ Yes	☐ No
3	Does the Trial In-charge (or Permitted Party) have control of the entire area under post-harvest land use restrictions?	☐ Yes	☐ No	3	Are the **Record of Transport** documents complete?	☐ Yes	☐ No
4	Is the post-harvest trial site being managed in a way that enables the identification of volunteers, or other prohibited plants, and their destruction?	☐ Yes	☐ No	4	Has a **Record of Planting** and a trial site map been completed?	☐ Yes	☐ No
5	Is there a **Record of Post-Harvest Monitoring**?	☐ Yes	☐ No	5	Have the Record of Planting and trial site map been forwarded to the Regulatory Authority?	☐ Yes	☐ No
6	If it exists, does the **Record of Post-Harvest Monitoring** confirm that the post-harvest trial site has been monitored at least once every four weeks for the presence of prohibited plants?	☐ Yes	☐ No	6	Have all required observations been made accordingly to the defined methodology?	☐ Yes	☐ No
7	If records indicate that prohibited plants have been removed from the post-harvest site during routine monitoring, do they also indicate the method of destruction, and was this appropriate?	☐ Yes	☐ No ☐ NA	7	Has any sampling required being done according to the defined methodology and documented?	☐ Yes	☐ No
8	Have there been any prior instances of non-compliance during the current post-harvest period?	☐ Yes	☐ No				
9	If the answer to E.8 was YES, was a **Record of Corrective Action** initiated and were the necessary actions implemented?	☐ Yes	☐ No ☐ NA				
10	Are the trial site photographs are available?	☐ Yes	☐ No ☐ NA				
11	What following crops is being grown/processed?						
12	Does the following crop meet requirements?	☐ Yes	☐ No				

PART G: ADDITIONAL COMMENTS
Summarize
• Data/observation being recorded from the trial site
• Samples taken for various tests and transported to other organizations
• Feedback on the SOPs maintained
• Any discussions with the Trial In-charge or other Personnel
• Any recommended corrective actions and
• Any other pertinent details/observations

PART H: COMPLIANCE ASSESSMENT	
PLEASE INDICATE ONE OF THE FOLLOWING CATEGORIES OF INSPECTION STATUS	
☐ **No compliance deviations, all documentation in order.** Field trial conducted in accordance with SOPs for Confined Field Trials of Regulated Genetically Engineered Plants and the Compliance Documentation was up-to-date. • No actions required	☐ **Compliance deviations AND documentation deficiencies.** Field trial NOT conducted in accordance with SOPs for Confined Field Trials of Regulated Genetically Engineered Plants AND the Compliance Documentation was not up-to-date. • Request a Record of Corrective Action be initiated and consult with the Trial In-charge on the appropriate corrective actions to be taken. In the event of any accidental release, notify the Regulatory Authority immediately by telephone and in writing within 24 hours. • Instruct the Trial In-charge on actions needed to update the Compliance Documentation or other records. • Schedule a follow-up inspection as soon as practical to verify that appropriate corrective actions have been implemented • If the nature of the infraction is such that destruction of the trial site is warranted, consult with the Regulatory Authority prior to instigating this action
☐ **No compliance deviations, but with documentation deficiencies.** Field trial conducted in accordance with SOPs for Confined Field Trials of Regulated Genetically Engineered Plants, **BUT the Compliance Documentation was not up-to-date.** • Instruct the Trial In-charge on actions needed to update the Compliance Documentation or other records • Make a note to verify any corrective actions during the next site inspection	
☐ **Compliance deviations, but no documentation deficiencies.** Field trial **NOT conducted in accordance with SOPs** for Confined Field Trials of Regulated Genetically Engineered Plants BUT the Compliance Documentation was up-to-date. • Request a **Record of Corrective Action** be initiated and consult with the Trial In-charge on the appropriate corrective actions to be taken. In the event of any accidental release, notify the **Regulatory Authority** immediately by telephone and in writing within 24 hours • Schedule a follow-up inspection as soon as practical to verify that appropriate corrective actions have been implemented • If the nature of the infraction is such that destruction of the trial site is warranted, consult with the **Regulatory Authority** prior to instigating this action	

PART I: Monitoring Team VERIFICATION

This activity has been carried out to assess compliance with the Guidelines for the Conduct of Confined Field Trials of Regulated Genetically Engineered Plants in India and related Standard Operating Procedures. By my signature, below, I attest that the information contained herein is accurate and complete to the best of my knowledge and belief.

	Names and Designation of Monitoring Team	Affiliation	Signature and date
1			
2			
3			
4			
5			

THANK YOU

QUESTIONS ?

QUESTIONS ?

CONTAINED VS. CONFINED TRIALS

Contained use refers to work with GE organisms within contained facilities, such as a laboratory, a greenhouse, a screen house, and areas used for storage and handling. There is a physical barrier of material under research and development from the environment with no direct contact with viable GE organisms.

A confined field trial is a limited field experiment of growing a regulated, GE plant in the open environment under specified terms and conditions that are intended to mitigate the establishment and spread of the plant during the research experiments.

EVENT BASED APPROVAL SYSTEM OF A GE PLANT

Extensive safety assessment required; only limited lines under confined field trials are finally approved