RECOMMENDATIONS OF THE SUB-COMMITTEE ON BT COTTON AND RELATED ISSUES CONSTITUTED BY MINISTRY OF ENVIRONMENT & FORESTS UNDER THE CHAIRMANSHIP OF DR S NAGARAJAN, DIRECTOR IARI, NEW DELHI.

Interested Parties/Individuals are invited to give their comments on the recommendation by 31st December 2005.

12th December 2005 Ministry of Environment and Forests New Delhi

The views/recommendation are solely that of the Sub-Committee and not that of Ministry of environment and Forests or the Genetic Engineering Approval Committee.

Recommendations of the Sub-Committee on Bt cotton and related issues.

1.0 In accordance with the decision taken in the 56th meeting of the GEAC, MoEF had constituted a Sub-Committee under the chairmanship of Dr. S. Nagarajan Director IARI to look into the existing processes, protocols for large scale trials and other related issues to Bt Cotton and give recommendation for rationalization of the same.

- 2.0 The Composition of the Sub-Committee is as follows: -
- i. Dr. S. Nagarajan*, Director, Director IARI, Pusa. N. Delhi. Chairman
- ii. Dr B.M. Khadi, Director, Central Institute for Cotton Research, Nagpur.
- iii. Dr. T.V. Ramanaiah, Director, Department of Biotechnology.
- iv. Dr. T. P. Rajendran, ADG, ICAR, New Delhi.
- v. Dr. B.S. Dhillon, Director NBPGRI. (Scientist with Background of Bio-Statistics nominated by Chairman).
- vi. Dr. S. Srinivasan Director CIRCOT, Mumbai.(co-opted Member)
- vii Dr. Ranjini Warrier, Member Secretary GEAC. Member Secretary
- * Presently, Chairman, Protection of Plant Varieties and Farmer's Rights Authority
- 3.0 The Committee has made the following recommendations in respect of:

a. Number of locations for LST.

1. The number of LST trials from the present requirement of 80 per zone has been optimized as given below.

Cotton	Zones** /Locations***										
hybrids*	Southern	Central	Northern								
НхВ	10	10	-								
аха	20	30	15								
НхН	40	60	40								
hxa	10	30	-								

Table 1 Number of locations for LST of hybrid Bt cotton

*H hirsutum; B barbadance; h herbaceum; a arborium

** To be optimally divided between irrigated, rain-fed and suppressive soils (the trial may also accommodate both normal sown and late sown conditions)

*** The number of locations has been reduced taking into consideration the area under cotton cultivation in each zone and type of hybrids grown in the region. This rationalization and significantly reduced number of LST will cut down the work load in generating data, time and man power needed and thus will permit even smaller seed companies reap the benefit of Bt technology. This will permit more number of Bt cotton hybrids come for official testing. This reduced expenditure in developing better Bt cotton hybrids would reduce the

b. Parameters to be monitored during LST.

1. The LST field data book has been designed consisting of part A, B & C. This would substantially simplify collection and analysis of pest-dynamics information and that of natural enemies of boll worm in part A; plant morphology and yield related information in part B and fiber/seed oil quality or industrial application in part C (*Refer Annexure-I*)

cost of Bt cotton seed and may reduce illegal Bt cotton growing.

c. Number of years for LST*.

 The LST design and information on planting details are given in yield book. AICCIP recommended fertilizer dose should be adopted. When the GEAC cleared Bt gene is used in a CVRC released hybrid background to develop a new Bt cotton hybrid (para 3.15.1) then one year of LST is enough (Figure 1).

Para 3.15.1 is reproduced below:-

New variant of a safe gene in CVRC released hybrid:

A given Bt gene family can have number of variants within it and this may not drastically change the insecticidal protein and altogether alter the manner it controls the target pest. There are several variants within generic Cry 1Ac and are designated using subscripts as Cry 1Ac-1; Cry 1Ac-2 etc. This indicates that these are variants of Cry 1Ac but do not have complete DNA homology, but do have some base pair differences and hence may have some variation in the protein system. Such micro variants put together form the family and

they need one year of LST if the Bt variant is in the background of a CVRC notified hybrid.

 For GEAC cleared Bt gene (para 13.15.2) but parked in a new hybrid/variety back ground or new inter specific hybrid background, one year of LST are suggested (Figure-2). Para 3.15.2 is reproduced below:-

GEAC cleared Bt gene in new hybrids:

If the GEAC cleared Bt gene or its variant is used to develop a Bt cotton hybrid using a non CVRC notified hybrid as the basis, there all two years of ICAR trials and one year of LST is needed. It is because the public and research system never had an opportunity to asses the performance stability of the material and so needs a two year testing to assess it properly.

- 3. When a new variant of the GEAC approved Bt gene, that has completed biosafety and other related tests and is comparable to the GEAC cleared Bt gene for the insectical protein properties, and is developed as a Bt cotton hybrid in a CVRC released background, then one year of LST is adequate (Figure 1).
- 4. For all other conditions* two years of LST is recommended, namely for a altogether new crop hybrid say H x B; a x a; h x a or totally new gene or when a non CVRC approved background is used (Figure 3).

*This category includes pyramided as well as fused genes.

Based on the above recommendations, the period of LST is summarized below:

Material	Bt gene												
	GEAC cleared Bt gene	Variant of the GEAC cleared Bt gene	New Bt gene/not cleared by GEAC	Pyramided genes	Fused gene(s)								
CVRC approved Hybrid	One year	One year	Two years	Two years	Two years								
Not put up to CVRC or not approved by CVRC	one year	one year	Two years	Two years	Two years								

* As per the prevailing practice, for CVRC notified variety/hybrid containing GEAC approved transgene, one year of LST is necessary; for non-CVRC notified variety/hybrid containing GEAC approved transgene, one to two years of LST based on merit of the case and for CVRC and non-CVRC notified varieties containing new gene including fusion or pyramided two years of LST is mandatory.

d. The stage at which seed production should be permitted.

- The best genotype should be sent to ICAR trial on the basis of performance in the MLT assessed by MEC/GEAC. Simultaneously the LST and other seed production requirements can be approved in one go. For seed production approval of 100 hectares for each case is recommended.
- For situations when two years of LST/ICAR are essential then for the first year seed production 10 hectares and during second year LST/ICAR trial 100 hectares can be given.

e. The stage at which the Bt cotton hybrid should enter ICAR trials.

 After the MLT data is evaluated by MEC and recommended to RCGM/GEAC, the GEAC can permit the performing entry for ICAR/LST/Seed Production. The number of years of test in this box will depend where the material falls in the above listed grouping (Figure 1, 2).

f. Other recommendations

- 1. Identifying the Designated Officer (DO) in the SAU to monitor the MLT/LST falling in their jurisdiction is suggested. There can be a fee levied for this purpose to meet out the cost of service extended by the SAU.
- One copy of all MLT/LST field data record, properly bound should be submitted to the concerned DO of the SAU by the agency that tests their produce apart from sending it to the Member Secretary of the MEC.

4.0 The recommendations of the sub-committee to the GEAC/MoEF to be operationalized from the time it is adopted.

5.0 Annexure

The following Annexure are attached:-

- Annexure I: The LST field data book containing part A, B & C as mentioned in <u>b</u> above.
- Annexure II: Figure 1: Flow Diagram on the recommended Protocol for Released Event/Gene in CVRC notified hybrids/varieties.
- Annexure III: Figure-2: Flow Diagram on the recommended Protocol for New hybrids/variety with released Event/Gene;
- <u>Annexure IV</u>: Figure-3: Flow Diagram on the recommended Protocol for (i) CVRC released hybrid/variety with new gene and (ii) New hybrid /variety with new gene.

All information provided in italics has been added as an explanatory note for further clarification:

FIELD NOTE BOOK

	Field note Book*
	crop year
	Date of sowing
	Date of harvest
LST size	Below 0.5h trials
Sub-plot size	15x25m three or more
Plot size	(15x25m)*3 or n, n = number of candidates + commercial
	Bt – hybrid + commercial hybrid if any or another released Bt. cotton
Space between plant to plant	60-90 cm (depending on the genotype)
Space between row to row	90-120 cm (")
Space between replication	2 m
Quadrat comprises of four plants	(two each of adjacent rows)
Row length (m)	(25 m) cotton plant $\longrightarrow \bullet \bullet \mid$ line
Row width (m)	(15 m) •••
Space between experimental area and refuge/border	2 m - row -
Data to be monitored on three fixed qua	drats in each sub-plot. All observation related to pest
predator noted on this. Each quadrat sh	ould be atleast 3 metres apart from one another and from the border
Specifications on entries	
Bt cotton tests hybrids	
Analogues non-Bt cotton hybrids (wherever available	le)
Specifications on checks	
Recently released Bt cotton as check (zone wise)	
Regional (non Bt cotton hybrid of the zone)	
No. of locations	
North -	
Central -	refer para 3 (a) of recommendation in the text
South -	
*retain one copy and send the second copy to	the Head, Department of Plant Breeding of the SAU where the trial is
located	

Yield Data Book Part – A. Pest-predator dynamics



Table A-1 : Summary of Larval Counts of Bollworm complex including Spodoptera in LST

Table A-2: Summary of damage in fruiting bodies, Open boll & Locule												
		over	loc	ations_	Zo	one						
			Dama	ge (%) per	^r quadrat							
SI.	Hybrid				Fruiting	bodies			Open boll	Locule		
No.			60		90		120	135				
`	Quadrat 1 :			_(Location	S)						
1												
2												
3												
4												
a b												
	Quadrat 2 ·			(Location	6)						
1	Quadrat 2				S	/						
2												
3												
4												
а												
b												
с												
	Quadrat 3 :			_(Location	s)						
1												
2												
3												
4												
a												
b												
С					、							
	Mean		(LO	cations _)							
1												
2												
3												
4												
a												
b												
С												

Table A-3: Summary of Sucking Pest Population of G.M. cotton hybrids & checks overlocationsZone																					
			_			Suc	king	Pest	ts/pe	r qua	adrat		 								
SI.	Hybrid		Aph	id				J	assi	d				Thri	р				Whi	tefly	
No.		6	60 90	120	135			60	90	120	135		 60	90	120	135		60	90	120	135
`	Quadrat 1			_(Loc	atior	າຣ)					 								
1																					
2													 								
3													 				 				
4							-														
a b																					
D O													 								
C	Quadrat 2				tiona			\ \					 								
1			<u> </u>																		
2													 								
3																					
4													 								
a .																					
b													 				 				
с																					
	Quadrat 3			Loca	tions	3)													
1																					
2																					
3																					
4																					
а																					
b																					
с																					
	Zone :		(Loc	ation	IS		_)														
1	Mean																				
2																					
3																					
4																					
а																					
b																					
С																					

Tab	Table A-4: Summary of Beneficial Insect Population of G.M. cotton hybrids & checks																							
													Ber	nefic	ial Ir	nse	cts							
SI.	Hybrid				Ca	ndid	ate	Bt		Sec	cond	d Bt					Bt.	Che	eck			Hyb	orid	
No.			60	90		120	135		60	90		120	135		60	90		120	135	60	90		120	135
`			<u>(Lo</u>	cati	ons			_)																
1	Quadrat 1																							
2	Coccinellids																							
3	Chrysopa																							
4	Syrphids																							
а	Spider																							
b																								
с																								
			(Lo	cati	ons			_)																
1	Quadrat 2																							
2																								
3																								
4																								
а																								
b																								
С																								
			(Lo	cati	ons			_)																
1	Quadrat 3																							
2																								
3																								
4																								

Table	Table A-5: Summary of Viral, bacterial & fungal diseases incidence of G.M. cotton hybrids & checks overZone																						
											Inci	dence	e (%) ([DAS)								
SI.	Hybrid			Cott	on L	eaf C	Curl V	/iru	s I	Bac	teria	l Blig	ht			Wilt			Any	othe	er (Sp	pecify)
No.				60	90	120	135			60	90	120	135		60	90	120	135	60	90	120	135	
`	Quadrat 1			(Lo	ocatio	ons _)															
1	Bt Cotton A																						
2	Bt Cotton B																						
3	Non Bt Check of	A																					
4	Non Bt Check of	B																					
а	Hybrid																						
b																							
С																							
	Quadrat 2			(Lo	pcatio	ons _)															
1																							
2																							
3																							
4																							
а																							
b																							
С																							
	Quadrat 3			(Lo	ocatio	ons _)															
1																							
2																							
3																							
4																							

Yield Data Book

Part – B. Yield data



Field note Boo	ok - B				

Table B-2: Summary of Bartlett's Index & Picking wise Yield of G. M. Cotton Hybrid and check.

SI. Hybrid Date Seed Cotton Yield - Kg / picking (P) (DAS) Iotal Iotal No. of I II III IV V VI (final) Iotal Yield Sow ing 120 135 150 165 180 >180 (Kg) (Qtl/na Entry 1: (Locations)	Bart- lett's Index
No. ot I II III IV V VI(final) Iotal Yield Sowing 120 135 150 165 180 >180 (Kg) (Qtl/ha Entry 1: (Locations)	lett's Index
Image: solution series Solution series	Index
Entry 1: (Locations) 1 2 3 4	
1 2 3 4 <td></td>	
1 2 3 4 6 <td></td>	
2 3 4	
Entry 2: (Locations)	
3	
4	
b b b b b b b b b b b b b b b b b b b	
4	
a a a a a a a a a a a a a a a a a a a	
D d d d d d d d d d d d d d d d d d d d	
C	
Entry 4:(Locations)	
	_
Bartlett's Index $(BL) = (6xIP+5xIIP+4xIIIP+3xIVP+2xVP+1xVIP)$	_

Yield Data Book

Part-C. Fiber and oil details

(see text for sample size and authentic laboratory

for testing on payment basis)

						Field n	ote Boo	k - C				
Tabl	e C-1 : *Su	mmai	ry of fibre	e prope	rties 8	oil (%)	of G.M.	cotton hy	orids & ch	ecks fro	om	
		thre	e LST (e	ach is a	mean	of 5 ob	servatio	ns).		Zone :		
						2.5%	Unifor-	Fineness	Strength	Spinn-	Count	
SI.	Location /		Ginning	Seed	Lint	Span	mity		3.2 mm	able	Strength	Oil
No.	Entry		out-turn	Index	Index	length	ratio	(Micro-	gauge	counts	Product	
			(%)	(g)	(g)	(mm)	(%)	naire)	(g/tex)		(CSP)	(%)
`				(Loo	cations		_)					
1	LSI-1											
2	Entry A											
3	Entry B											
4	Entry C											
0	спеск											
a h												
0												
C												
•					rations							
							_/					
1	LST-2											
2	Entry A											
3	Entry B											
4	Entry C											
_	check											
а												
b												
С												
`				(Loo	cations		_)					
1	LST-3											
2	Entry A											
3	Entry B											
4	Entry C											
_	спеск											
a h												
U U												
-												
	LSI-4											
	LSI-5											
	*To be don	e by (CCTI, Mat	hunga,	Mumba	i (Fee to	be deci	ded by the l	nstitute			

Annexure-II:

Figure:1 Flow Diagram on the recommended Protocol for Released Event/Gene for CVRC notified hybrids/varieties

Institutional Biosafety Committee (IBSC)

(forwarding applications for approval of RCGM)

Review Committee on Genetic Manipulation (RCGM)



Annexure-III Figure2: Flow Diagram on the recommended Protocol for New hybrids/variety with approved gene

Institutional Biosafety Committee (IBSC)

(forwarding applications for approval of RCGM)

Review Committee on Genetic Manipulation (RCGM)

(green house experiments, contained field trials i.e. in-house trials/initial hybrid trials, generation of data on gene stability and expression, confirmation on sub-licensee of the released event/gene to GEAC & ICAR)

RCGM

[approval for conduct of multi-location field trials on the selected variety(ies)/hybrids(s)]

Monitoring-cum-Evaluation Committee (MEC) [evaluation of multi-location field trials data and recommending to GEAC under intimation to RCGM on the suitable variety(ies)/hybrid(s) for large-scale trials (LST)] Genetic Engineering Approval Committee (GEAC) Seed Production 10 ha ICAR trials1st Year MEC **GEAC** (environmental clearance of the event/gene in a given background)

Material cleared from Environmental sensitivity by MoEF/or otherwise

Annexure IV Figure 3: Flow Diagram on the recommended Protocol for i) CVRC released hybrid/variety with new gene and (ii) New hybrid/variety with new gene

Institutional Biosafety Committee (IBSC)

(forwarding applications for approval of RCGM)

Review Committee on Genetic Manipulation (RCGM)

(green house experiments, contained field trials i.e. in-house trials/initial hybrid trials, generation of data on gene stability and expression, confirmation on sub-licensee of the released event/gene to GEAC & ICAR)

RCGM

[approval for conduct of multi-location field trials on the selected variety(ies)/hybrids(s)]

