F. No. C-12019/8/2011-CS III
Govt. of India
Ministry of Environment and Forests
CS Division

Email warrier@nic.in
Telex: 24363964

Paryavaran Bhawan
C.G.O.Complex Lodi Road
New Delhi-110003.

Dated 1.11.2011

Subject: Request for providing partial information under Right to Information Act-2005 by Shri Nishank, Alliance for Sustainable and Holistic Agriculture (ASHA) New Delhi.

Dear Shri Nishank,

1.0 This has reference to your application no. Nil dated 28.8.2011 received on 26.8.2011 seeking information on (i) List of all trials including name of the crop developer, crop and trait, promoter and marker genes used state, district, village and compliance report related to biosafety norms laid down for trials during **Rabi 2010 and Kharif 2011** and (ii) Copies of No objection certificates issued by the state Governments for Kharif 2011.

2.0 The point wise information is given below:

1. List of all trials (BRL-I and BRL-II) approved by the GEAC to various crop developers during Rabi -2010 and kharif-2011 is enclosed. The letters for conduct of event selection trials /BRL-1 trials are issued by the RCGM under Department of Biotechnology. The same may be viewed at www.igmoris.in.

The RCGM has been requested to forward the partial information vide this Ministry's letter of even no. dated 8.9.2011. (Copy enclosed). The GEAC only issues letters for conduct of BRL-II trials. The GEAC has approved following applications for conduct of BRL-II trials :

1. M/s Pioneer Overseas Corporation,
2. M/s Dow Agro sciences, and
3. M/s Mahyco.

Copies of BRL II trials (three) issued are enclosed along with the compliance report.

3.0 Copies of No Objection Certificate (nine companies) issued by State Government for Kharif 2011 are enclosed.

4.0 The GEAC has not received any reaction/response/ feedback from the state Governments on the issue of NOC.

5.0 With the above, the required information is fully furnished under the RTI Act, 2005. However, in case you have any grievances you may appeal and your case will be considered under the provisions of RTI Act.

With regards,

Yours sincerely,

(Dr R. Warrier)
Director

Shri Nishank,
Alliance for Sustainable and Holistic Agriculture (ASHA),
A-124/6, First floor
Katwaria Sarai,
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total - 158 pages (1)

File No. 12013/41/2008-CS-III
Govt. of India
Ministry of Environment and Forests
CS Division

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Paryavaran Bhavan
C.G.O. Complex, Lodhi Road
New Delhi-110003

Dated: 24.12.2010

Subject: **Permission to conduct Biosafety Research Level (BRL-II) trials on two transgenic corn hybrids namely Hishell & 900M Gold containing stacked *cry2Ab2, cry1A 105* (Event MON 89034) & *CP4EPSPS* (Event NK603) genes by M/s. Monsanto India Ltd., New Delhi.**

Dear Dr Kalia,

This has reference to your letter No.SK/116/2010 dated 21.10.2010 and 26.11.2010 regarding the above proposal. The Genetic Engineering Appraisal Committee (GEAC) set up by this Ministry in accordance with the Rules for Manufacture, Use, Import, Export and Storage of hazardous Microorganisms/Genetically Engineered Organisms or Cells 1989, under the Environment (Protection) Act, 1986 has considered your request in the meeting held on 15.11.2010 and 8.12.2010.

2.0 After careful and in-depth consideration of the findings of the biosafety studies, confined field trials and recommendations made by the Review Committee on Genetic Manipulation (RCGM), the GEAC accorded approval for Biosafety Research Level – II (BRL-II) trials with two transgenic corn hybrids namely Hishell & 900M Gold containing stacked *cry2Ab2, cry1A105* (Event MON 89034) & *CP4EPSPS* (Event NK603) genes during Rabi 2010 (five locations) and Kharif-2011 (nine locations) under the direct supervision of Director, Directorate of Maize Research (DMR), IARI, Pusa. DMR shall submit its monitoring report and recommendations directly to the GEAC.

3.0 The GEAC approval for conduct of BRL II trials with two transgenic corn hybrids namely **Hishell & 900M Gold** containing stacked *cry2Ab2, cry1A.105* (Event MON 89034) & *CP4EPSPS* (Event NK603) genes shall be subject to the following conditions:-

a) The hybrids shall undergo a minimum of one season BRL II trials during Kharif 2011 at nine locations namely BHU Varanasi, UP; Begusarai Bihar; Bhagalpur Bihra; TNAU Coimbatore; UAS Dharwad; ANGRAU Karimnagar; MPUAT Udaipur; AAU Vadodara and DWSR Jabalpur MP. prior to further consideration for environmental release. The applicant may undertake additional trials at five locations namely Begusarai / Samastipur, Bihar; Bhagalpur Bihar, TNAU Coimbatore, UAS Dharwad and ANGRAU Karimnagar during Rabi 2010.

b) The BRL II trials for assessing the environmental safety, efficacy and agronomic advantage of corn hybrids shall be carried out as per the protocol prescribed by the GEAC and Director, DMR. The locations for BRL II trials should be carefully chosen so as to represent adequately the various agroclimatic zones and agricultural practices in the region. The trials shall be conducted within the company's research

farms, or the research farms of Indian Council of Agricultural Research (ICAR)/ State Agricultural Universities (SAUs).

c) An isolation distance of 300 m from the periphery of the nearest row of transgenic corn would be maintained all around the experimental plot. Thirteen border rows of African maize will also be planted surrounding the trial plot to contain the pollen flow during trial.

d) The baseline susceptibility data for the target pests shall be generated during the BRL-II field trials.

e) The weed control efficacy in transgenic hybrids containing events (MON 89034 x NK 603) shall be studied with post application of glyphosate.

f) The level of expression of all the three candidate proteins expressed by the inserted genes i.e. cry1A.105, cry2Ab2 and *CP4EPSPS* in various plant parts will be estimated at different crop growth stages viz. at 15-20; 35-45; 65-70; 90-100; 110- and above days after crop emergence at all field trials and experimental sites.

g) The efficacy and comparison of the level of infestation of the target insect pests shall be studied on transgenic corn hybrids (MON 89034 x NK 603), their non-transgenic counterparts and checks.

h) Observations with respect to growth, life cycle, plant height, impact on pollinator species and indicators of changes in weediness potential shall be recorded on transgenic corn hybrids (MON 89034 x NK 603), non–transgenic counterparts and checks.

i) The occurrence of beneficial and non-target insects shall be monitored on transgenic corn hybrids (MON 89034 x NK 603), non–transgenic counterparts and checks. This would include impact of the transgenic hybrids on soil microbes, biological control organisms, predators, pollinators, parasites with and without treatment with Roundup Ready herbicide as the transgenic plant containing event NK603 and the Roundup Ready herbicide go together. The effect of plants containing event NK603 on the environment should be assessed only after the application of the Roundup Ready herbicide.

j) Soil impact assessment study should include observation and data on the total microbial counts, earth worms and soil insects related to Rhizosphere on the soil of transgenic corn (89034 x NK 603) growing area and normal plots. Data should be recorded during the pre and post spray of transgenic corn event 89034 x NK 603 containing *cry2Ab2*, *cry1A* 105 and *CP4EPSP* genes, data for pre planting and post harvesting will also be recorded. The changes in soil fertility may also be recorded, as per standard prescribed protocols. The study shall also assess the carry-over effects (within 30 days of post harvest) of protein residues, if any of the (89034 x NK 603) corn hybrids with reference to the presence /absence of Cry2Ab2, Cry1A.105 (Event MON 89034) & CP4EPSPS (Event NK603) proteins at different depths (maximum up to one meter) in the soil at any one location.

k) Final data should include yield and comparative economics of all treatments. The yield data and economics of crop production with specific reference to the assessment of any specific advantages, cost benefit analysis derived from transgenic corn (MON 89034 x NK 603) should be calculated and presented.

l) The applicant shall make available socio-economic data like cost of transgenic corn (MON 89034 x NK 603) seed/projected demand of seeds/cost of production v.s non transgenic corn production under various agro-climatic conditions and agricultural practices/ cost benefit analysis etc.

m) The applicant shall provide to the GEAC, Director, DMR, State Department of Agriculture, Director, Research and Director Extension of State Agricultural University, District Authorities and other field functionaries notified under the Seed Act, 1966 / EPA, 1986, the State/District wise details of BRL-II trials which includes locations, area, site plans, protocols, name of the lead scientists responsible for all aspects of the trials within 15 days of issue of this clearance letter.

n) The applicant shall keep full account of the transgenic materials and seeds, if any, set in the transgenic plants. All materials after experimentation including the seeds of corn for the trapper rows would be fully accounted for and information would be documented and preserved in a bound book that would be available to the Government as and when requested for. The harvested crop from the border rows and leftover plant and plant parts from entire experimental plot shall be destroyed by burning after completion of the experiment and records to this effect needs to be maintained and submitted to the GEAC/ State Department of Agriculture/ District Collector and other field functionaries notified under the Seed Act, 1966/EPA, 1986.

4.0 The GEAC further, accords approval for seed production with corn hybrids namely Hishell & 900M Gold *containing stacked* cry2Ab2, cry1A.105 *(Event MON 89034)* & CP4EPSPS *(Event NK603) genes* at two locations in an area not exceeding 25 acre per hybrid in confined conditions at two locations subject to the following conditions:

a) The applicant shall provide to the GEAC/Project Director DMR / State Department of Agriculture/ State Agricultural University, District authorities and other field functionaries notified under the Seed Act, 1966/ EPA, 1986, the State / District wise details of locations where it intends to undertake seed production within 15 days of issue of the clearance letter.

b) The applicant shall maintain records of the seed production and shall make them available for inspection if it so desired by the GEAC/State Department of Agriculture/ District Authorities and other field functionaries under the Seed Act./ EPA 1986.

c) Transgenic corn seeds (MON 89034 x NK 603) generated shall not be sold or diverted for commercial or any other purpose without the approval of the GEAC. A full account of seeds produced should be maintained by the lead scientist.

d) The plant residue after harvesting should be destroyed by burning and records to this effect need to be maintained and shown to GEAC/ State Department of Agriculture/ District Authorities and other field functionaries under the Seed Act/EPA, 1986.

e) In the event of non approval of the transgenic corn hybrids (MON 89034 x NK 603) for commercial release, the applicant will destroy the seeds produced by burning in the presence of a representative from State Department of Agriculture through its SBCC/DLCs or any other functionary notified under the Seed Act, 1966 / EPA, 1986.

5.0 Compliance Records: Records of all confined field trials regarding transport and transport inventory, storage, storage inspection and inventory, planting spatial isolation, harvest and termination, post harvest monitoring and corrective action activities related to trial site compliance (including subcontracts), shall be maintained and shall be made available to the GEAC or the designated monitoring agencies upon request. Mandatory

recording formats are referred in the RCGM/GEAC Standard Operating Procedures (SOPs) for Confined Field Trials of Genetically Engineered Crops: 2008 can be downloaded from http://www.igmoris.nic.in and http://dbtbiosafety.nic.in.

6.0 Field trial report: The applicant shall submit a field trial report to the GEAC within 3 months after termination/harvest of a confined field trial. The field trial report must summarize information on the completed trial, including methods, observations, data and analysis of any effects of the trial plants on the other plants, non–target organisms, or the environment.

7.0 The applicant shall be completely liable to pay compensation for damages to the environment caused by them while conducting the field trials.

8.0 The applicant shall mount a Notice Board at the site of experiment indicating the purpose and duration of the field trials as well as authorization under which the trials are being conducted.

9.0 The applicant shall extend full cooperation to the authorized personnel of the GEAC/DMR/ designated monitoring agencies / State Government officials/ State Agricultural University or their nominee to inspect the experimental sites and to have access, for official use only, the results of the field trials.

10.0 The Ministry may stipulate additional conditions or direct the applicant to generate additional biosafety data if so necessitated on the basis of feedback received from the Experts/State Department of Agriculture/ District Authorities / other field functionaries under the Seed Act /EPA 1986 and other sources.

11.0 The Ministry may revoke the clearance if implementation of stipulated conditions is not satisfactory, in case of submission of wrong information or if there is any evidence of harmful effects or negligence.

12.0 You are hereby directed to convey to the undersigned within 15 days of receipt of this communication, your unequivocal acceptance of the above conditions. The acceptance letter shall also include information on the field trials/seed production as well as the name and complete address of the lead scientist who will be responsible for all aspects of the trials, failing which, this approval is liable to be revoked.

13.0 This is issued with the approval of the Competent Authority.

Yours sincerely,

(Dr. R. Warrier)
Director

Dr. Sanjeev Kalia,
Regulatory Affairs Manager
M/s. Monsanto India Ltd.,
2nd Floor F Block
International Trade Tower
Nehru Place
New Delhi 110019.

received Sanjeev Kalia 24/12/10

Copy to:

1. Prof. S. K. Dutta, Deputy Director General (crop science), Indian Council of Agricultural Research, Krishi Bhawan, New Delhi-110 001.
2. Dr R Sai Kumar, Director, Directorate of Maize Research, Pusa Campus, New Delhi 110012.
3. Dr. K.K. Tripathi, Adviser, Dept. of Biotechnology, Lodi Road, CGO Complex, New Delhi -110003.
4. Mr. Anindo Majumdar., Joint Secretary, Department of Agriculture & Cooperation, Krishi Bhawan, New Delhi-110 001.

Tamil Nadu

5. Chief Secretary [Mrs. S Malathi, IAS, Government of Tamil Nadu, Secretariat, Chennai 600 009, Tel: 044- 25671555, Fax : 25672304]
6. Principal Secretary Agriculture [Mr P Rama Mohan Rao, Principal Secretary, Agriculture, Secretariat, Fort St. George, Chennai 600 009 Tel : 044-25674482 Fax : 044-25674857]
7. Secretary Environment [Dr. V Irai Anbu, IAS, Secretary to Government, Environment & Forest Department, Secretariat, Chennai 600 009 Tel : 044-25671511]
8. Commissioner of Agriculture [Commissioner of Agriculture, Chepauk, Chennai 600009 Tel: 044-28524894]
9. Director Research [Dr Paramathma , Director of Research, TNAU, Coimbatore-641003, Tamil Nadu Ph No: 0422-2431788, 2431672 Fax No: 0422-2431672]
10. Director Extension [Dr. P.Kalaiselvan, Director of Extension Education, TNAU, Coimbatore-641003, Tamil Nadu]

Karnataka

11. Chief Secretary [Mr. S V Ranganath, IAS, Chief Secretary, Vidhan Soudha, Bangalore 560001 Tel: 080-22252442 Fax : 22258913]
12. Secretary Agriculture [Mr. N C Muniyappa, IAS, Principal Secretary, Agriculture, 4th Floor, M S Building, Bangalore 560001,Tel : 080-22250284, Fax: 22251420]
13. Secretary Environment [Mr. Kaushik Mukherjee, IAS, Principal Secretary to Government, Forest, Ecology and Environment Department, Government of Karnataka, Room No.403, 4th Floor, M S Building, 2nd Stage, Bangalore 560 001]
14. Director of Agriculture [Dr. Baburao Mudbi, IAS, Commissioner of Agriculture, 1, Seshadri Road, Bangalore – 1 Ph : 080-22212804]
15. Director Research [Dr Shalimath , Director of Research, UASD, MARS, Dharwad-580005, Karnataka Ph No: 0836-2447783, 9448495300 Fax No: 0836-2448349]
16. Director Extension [Dr. B.S. Nadagoudar, Director of Extension, University of Agricultural Sciences (UAS) Krishi Nagar, Dharwad: 580 005. Karnataka]

Andhra Pradesh

17. Chief Secretary [Mr. S V Prasad IAS, Chief Secretary, C Block, Secretariat, Hyderabad 500 022 Ph: 040-23452269]
18. Secretary Agriculture[Mrs. Rachel Chatterjee, IAS, Special Chief Secretary to Govt Agriculture & Co-operation Dept, D Block, Secretariat Hyderabad 500 022]
19. Secretary Environment [Smt Janaki R. Kondapi, IAS, Special Chief Secretary to Government, Environment, Forest, Science & Technology Dept.,Government of Andhra Pradesh, D Block, Secretariat, Hyderabad 500 022 Ph: 040-23451440]
20. Commissioner of Agriculture [Mr. Sunil Sharma, IAS, Commissioner of Agriculture, Opp: L B Stadium, Hyderabad 500 001 Tel 040-23383520 to 24]
21. Director Research [Dr Sudhakar Rao , Director of Research , ANGRAU, Rajendranagar, Hyderabad-500030 Ph :040-24015011]

22. Director Extension [Dr. P. Gidda Reddy, Director of Extension , ANGRAU, Rajendranagar, Hyderabad-500030]

Bihar

23. Chief Secretary [Mr. Anoop Mukherjee, Chief Secretary, Govt of Bihar, Vikash Bhavan, New Secretariat Patna-800001]
24. Secretary Agriculture [A.K. Sinha, Agriculture Production commissioner, Government of Bihar,Vikash Bhavan, New secretariat, Bailey Road, Patna-800001Bihar]
25. Secretary Environment [J. L. Meena, Principal Secretary, Department, Environment and Forests, Govt. of Bihar, Patna - Tel: 0612-2217713, 94710-00299 (M)]
26. Commissioner of Agriculture [Mr. Arvinder Singh, Director Agriculture, 2nd Floor, Vikas Bhawan New Secretariat, Bailey Road, Patna-800001,Bihar]
27. Director Research [Dr. B.C. Chaudhury, Director Research, Rajendra Agriculture University, Pusa-848125, Distt- Samastipur, Bihar]
28. Director Extension [Dr. Madan Singh, Director Extension Education, Rajendra Agriculture University, Pusa-848125, Distt- Samastipur, Bihar]

Madhya Pradesh

29. Mr. Avani Vaish, Chief Secretary, Govt. of Madhya Pradesh, Vallabh Bhawan, Mantralaya, Bhopal-462001 Madhya Pradesh
30. Shri MM Upadhyay, Secretary (Agriculture), Department of Agriculture, Govt. of Madhya Pradesh, Vallabh Bhawan,Mantralaya, Bhopal-462001 Madhya Pradesh
31. Shri DN Sharma, Director of Agriculture, Department of Agriculture, Floor 2, Vindhyachal Bhawan, Bhopal- 462004, Madhya Pradesh
32. Shri. Alok Shrivastava, Principal Secretary ,Housing and Environment, Mantralaya Vallabh Bhawan, Bhopal
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34. Dr. S.S. Tomar, Director of Research, Jawaharlal Nehru Krishi Vishwa Vidhyalaya (JNKVV), Jabalpur, M. P. Ph.: 0761-2681714 Fax: 0761-2681714 e-mail: sst_drsjnkvv@yahoo.com
35. Dr. P.K. Jain, Director Extension, Jawaharlal Nehru Krishi Vishwa Vidhyalaya (JNKVV), Jabalpur, M.P. Ph.: 0761-2681710 ;Fax: 0761-2681710 e-mail: jainpk_jnau@rediffmail.com ,drpkjain51@yahoo.com

Rajasthan

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39. Shri VS Singh Principal Secretary Environment and Forest, 1139, Main Building Government Secretariat, Jaipur Ph: 0141-2709980, Fax: 2709980
40. Dr. S R Maloo, Director of Research, Rajasthan Agricultural University (RAU), *Udaipur, Rajasthan Phone No. 2417334 (O) 2420447 (O) 2493399 (R) Fo\No. O294-2420447 Email: dr@mpuot.oc.in*
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Uttar Pradesh

42. Atul Kumar Gupta, Chief Secretary, Lal Bahadur Shastri Bhawan, Secretariat, Uttar Pradesh, Lucknow
43. Sanjay Agrawal, Principal Secretary, Agriculture, Lal Bahadur Shastri Bhawan, Secretariat, Uttar Pradesh, Lucknow

44. Mukesh Gautam, Director Agriculture, Krishi Bhawan, Department of Agriculture, Govt. of Uttar Pradesh
45. Secretary Environment Lal Bahadur Shastri Bhawan, Secretariat, Uttar Pradesh, Lucknow
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Gujarat

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(Dr. R. Warrier)

File No. 12013/27/2009-CS-III
Govt. of India
Ministry of Environment and Forests
CS Division

Email: warrier@nic.in

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Paryavaran Bhavan
C.G.O. Complex, Lodhi Road
New Delhi-110003

Dated: 17.08. 2010

Subject: **Permission to conduct Biosafety Research Level-II (BRL-II) trials at 8 locations WideStrike™ cotton hybrids namely WS103 & WS106 containing *cry1F* (Event 281-24-236) + *cry1Ac* (Event 3006-210-23) in South zone during Kharif 2010 by M/s. Dow Agrosciences India Pvt. Ltd., Mumbai**

Dear Shri Babu,

This has reference to your letter No. Nil dated 9.4.2010 regarding the above proposal. The Genetic Engineering Appraisal Committee (GEAC) set up by this Ministry in accordance with the Rules for Manufacture, Use, Import, Export and Storage of hazardous Microorganisms/Genetically Engineered Organisms or Cells 1989, under the Environment (Protection) Act, 1986 has considered your request in the meeting held on 30.7.2010.

2.0 After careful and in-depth consideration of the findings of the biosafety studies as well as confined field trials and recommendations made by the RCGM, the GEAC accorded approval for BRL II trials WideStrike™ cotton hybrids namely WS103 & WS106 containing *cry1F* (Event 281-24-236) + *cry1Ac* (Event 3006-210-23) genes in South zone during Kharif 2010 (three locations) under the direct supervision of Director, Central Institute of Cotton Research (CICR), Nagpur. CICR shall submit its monitoring report and recommendations directly to the GEAC.

3.0 The GEAC approved the conduct of BRL II trials with WideStrike™ cotton hybrids namely WS103 & WS106 containing *cry1F* (Event 281-24-236) + *cry1Ac* (Event 3006-210-23) genes in the South zone subject to the following conditions:-

a) The hybrids shall undergo a minimum of two comparable seasons BRL II trials prior to further consideration for environmental release.

b) The BRL II trials for assessing the environmental safety, efficacy and agronomonic advantage of WideStrike™ cotton hybrids shall be carried out at 3 locations in the South zones as per the protocol prescribed by Director, CICR. The locations for BRII trials should be carefully chosen so as to represent adequately the various agro – climatic zones and agricultural practices in the region. The trials shall be conducted within the company's research farms, or the research farms of Indian Council of Agriculture Research (ICAR)/ State Agriculture University.

c) An isolation distance of 50 m from the periphery of the nearest row of transgenic Bt cotton would be maintained all around the experimental plot. In addition, at least five

rows of the non Bt counterpart at the immediate vicinity around the periphery of the outer row all around the plot. shall also be maintained to act as 'refugia source' to sustain susceptible bollworm populations.

d) The baseline susceptibility data for the target pests shall be generated during the two season field trials.

e) The level of expression of Cry 1F and Cry 1Ac proteins in various plant parts will be estimated at different crop growth stage. The protein expression data for Cry 1F and Cry 1Ac of the WideStrike™ hybrids in various plant parts will be recorded as previously prescribed for widestrike tm at 60, 80,100,120,140and 160 days after crop emergence at all field trials and experimental sites.

f) The efficacy and comparison of the level of infestation of the target insect pests shall be studied on WideStrike™ hybrids, non–transgenic counterparts and checks.

g) Observations with respect to growth rate, life cycle, plant height, impact on pollinator species and indicators of changes in weediness potential shall be recorded on WideStrike™ hybrids, non–transgenic counterparts and checks.

h) The occurrence of beneficial and non-target insects shall be monitored on WideStrike™ hybrids, non–transgenic counterparts and checks.

i) Soil impact assessment study should include observation and data on the total microbial counts, earth worms and soil insects related to Rhizosphere on the soil of WideStrike™ and normal plots. The changes in soil fertility may also be recorded, as per standard prescribed protocols. The study shall also assess the carry-over effects (within 30 days of post harvest) of protein residues, if any of the WideStrike™ cotton hybrids with reference to the presence /absence of Cry 1F and Cry 1Ac proteins at different depths (maximum up to one meter) in the soil at any one location.

j) Final data should include yield and comparative economics of all treatments. The yield data and economics of crop production with specific reference to the assessment of any specific advantages, cost benefit analysis derived from WideStrike™ should be calculated and presented.

k) The Applicant shall make available socio-economic data like cost of WideStrike™ Cotton seed/projected demand of seeds/cost of production v.s non Bt cotton production /released BG I and BG II cotton hybrids under various agro-climatic conditions and agricultural practices/ cost benefit analysis etc.

l) The Applicant shall provide to the GEAC/Director CICR/, State Department of Agriculture/, Director, Research and Director Extension, State Agriculture University, District Authorities and other field functionaries notified under the Seed Act, 1966 / EPA, 1986, the State/District wise details of BRL-II trials which includes locations, area, site plans, protocols, name of the lead scientists responsible for all aspects of the trials within 15 days of issue of this clearance letter.

m) The applicant shall keep full account of the transgenic materials and seeds, if any, set in the transgenic plants. All materials after experimentation including the seeds of cotton for the trapper rows would be fully accounted for and information would be documented and preserved in a bound book that would be available to the Government as when requested for. The harvested crop from the border rows and leftover plant and plant parts from entire experimental plot shall be destroyed by burning after completion of the experiment and records to this effect needs to be

maintained and submitted to the GEAC/ State Department of Agriculture/ District Collector and other field functionaries notified under the Seed Act, 1966/EPA, 1986.

4.0 The GEAC further, accords approval for seed production with WideStrike™ cotton hybrids namely WS103 & WS106 in the south zone at four locations in 8 plots of 1.0 acre each (8 acre) per hybrid in confined conditions in Attur, Salem District, Tamil Nadu subject to the following conditions:

a) The Applicant shall provide to the GEAC/ Director CICR / State Department of Agriculture/ State Agriculture University, District authorities and other field functionaries notified under the Seed Act, 1966/ EPA, 1986, the State / District wise details of locations where it intends to undertake seed production within 15 days of issue of the clearance letter.

b) The Applicant shall maintain records of the seed production and shall make them available for inspection if it so desired by the GEAC/State Department of Agriculture/ District Authorities and other field functionaries under the Seed Act./ EPA 1986.

c) WideStrike™ seeds generated shall not be sold or diverted for commercial or any other purpose without the approval of the GEAC. A full account of seeds produced will be maintained by the lead scientist.

d) The plant residue after harvesting should be destroyed by burning and records to this effect need to be maintained and shown to GEAC/ State Department of Agriculture/ District Authorities and other field functionaries under the Seed Act/EPA, 1986.

e) In the event of non approval of the WideStrike™ hybrids for commercial release, the Applicant will destroy the seeds produced by burning in the presence of a representative from State Department of Agriculture through its SBCC/DLCs or any other functionary notified under the Seed Act, 1966 / EPA, 1986.

5.0 Compliance Records: Records of all confined field trials regarding transport and transport inventory, storage, storage inspection and inventory, planting spatial isolation, harvest and termination, post harvest monitoring and corrective action activities related to trial site compliance (including subcontracts), shall be maintained and shall be made available to the GEAC or the designated monitoring agencies upon request. Mandatory recording formats are referred in the RCGM/GEAC Standard Operating Procedures (SOPs) for Confined Field Trials of Genetically Engineered Crops: 2008 can be downloaded from http://www.icmoris.nic.in

6.0 Field trial report: The Applicant shall submit a field trial report to the GEAC within 3 months after termination /harvest of a confined field trial. The field trial report must summarize information on the completed trial, including methods, observations, data and analysis of any effects of the trial plants on the other plants, non-target organisms, or the environment.

7.0 The Applicant shall be completely liable to pay compensation for damages to the environment caused by them while conducting the field trials.

8.0 The Applicant shall mount a Notice Board at the site of experiment indicating the purpose and duration of the field trials as well as authorization under which the trials are being conducted.

9.0 The applicant shall extend full cooperation to the authorized personnel of the GEAC/CICR/ designated monitoring agencies / State Government officials/ State Agriculture

University or their nominee to inspect the experimental sites and to have access, for official use only, the results of the field trials.

9.0 The Ministry may stipulate additional conditions or direct the applicant to generate additional biosafety data if so necessitated on the basis of feedback received from the Experts/Monitoring cum Evaluation Committee / State Department of Agriculture/ District Authorities / other field functionaries under the Seed Act /EPA 1986 and other sources.

10.0 The Ministry may revoke the clearance if implementation of stipulated conditions is not satisfactory or in case of submission of wrong information or if there is any evidence of harmful effects or negligence.

11.0 You are hereby directed to convey to the undersigned within 15 days of receipt of this communication, your unequivocal acceptance of the above conditions. The acceptance letter shall also include information on the field trials/seed production as well as the name and complete address of the lead scientist who will be responsible for all aspects of the trials, failing which, this approval is liable to be revoked.

12.0 This is issued with the approval of the Competent Authority.

Yours sincerely,

(Dr. R. Warrier)
Director

Shri B. Gajendra Babu,
Regulatory Specialist (Seeds & Traits)
M/s. Dow Agrosciences India Pvt. Ltd.,
1st floor, Unit No.1
Corporate Park, V.N. Purav Marg
Chembur
Mumbai 400071.

Copy to:

1. Prof. S.K. Dutta, Deputy Director General (crop science), Indian Council of Agricultural Research, Krishi Bhawan, New Delhi-110 001.
2. Dr. K.R. Kranthi, Director Central Institute of Cotton Research, Pos Bag NO.2 , Shankar Nagar P.O.Nagpur 440010.
3. Dr. K.K. Tripathi, Adviser, Dept. of Biotechnology, Lodi Road, CGO Complex, New Delhi -110003.
4. M/s Upma Chawdhary, Joint Secretary, Department of Agriculture & Cooperation, Krishi Bhawan, New Delhi-110 001.
5. Chief Secretary, Govt of Andhra Pradesh, Secretariat, Hyderabad-500001.
6. Chief Secretary, Government of Karnataka, Bangalore.
7. Chief Secretary, Government of Tamil Nadu, Chennai.
8. Principal Secretary, State Department of Agriculture, Govt. of Andhra Pradesh, Hyderabad.
9. Principal Secretary, State Department of Agriculture, Govt. of Karnataka, Bangalore.
10. Secretary & Agriculture Production Commissioner, State Department of Agriculture, Govt. of Tamil Nadu, Chennai.
11. Principal Secretary, Department of Environment, Forest, Science & Technology, D-Block, 2nd floor, A.P. Secretariat Building, Hyderabad-500 002, Andhra Pradesh.

12. Secretary, Department of Environment, Govt. of Karnataka, 7th floor, MS Building, Bangalore-1.
13. Secretary, Department of Environment & Forest, Govt. of Tamil Nadu, Chennai.
14. Commissioner & Director, State Department of Agriculture, Govt. of Andhra Praesh, Opp. Lal Bahadur Stadium, Basheer Bagh, Hyderabad-500001.
15. Director, State Department of Agriculture, Govt. of Karnataka, Bangalore.
16. Commissioner of Agriculture, State Department of Agriculture, Govt. of Tamil Nadu, Chepauk, Chennai-600005.
17. Director Research, Acharya NG Ranga Agricultural University, Rejendra Nagar, Hyderabad-500030.
18. Director Research, University of Agricultural sciences, Dharwad-580005, Karnataka.
19. Director Research, University of Agricultural Sciences, UAS, GKVK, Bangalore-560065, Karnataka.
20. Director Research, Tamil Nadu Agricultural University, Coimbatore-641003, Tamil Nadu.
21. Director Extension, Acharya NG Ranga Agricultural University, Rejendra Nagar, Hyderabad-500030, Andhra Pradesh.
22. Director Extension, University of Agricultural sciences, Dharwad-580005, Karnataka.
23. Director Extension, University of Agricultural Sciences, UAS, GKVK, Bangalore-560065, Karnataka.
24. Director Extension, Tamil Nadu Agricultural University, Coimbatore - 641003, Tamil Nadu.

(Dr. R. Warrier)

BRL II monitoring visit to UAS Dharwad 5th may 2011

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PART B: TRIAL SITE INFORMATION

Legal or Descriptive Land Location of Trial Site

Block F Plot No. 142, MARS, Dharwad

Crop Planted at Trial Site

☐ Cotton ☐ Brinjal ☑ Other (list) Zea mays

Date of sowing 6-1-2011

Timing of the Inspection and Stage of Crop Development

☐ At planting ☐ Vegetative, pre-flowering ☐ Flowering

☑ After flowering ☐ At harvest ☐ Post-harvest

Copies of inspection reports at various stages be made available to monitoring teams for all subsequent inspections.

1.	Are physical landmarks (PVC piping, fence post, etc.) at located each corner of the trial site?	☑ Yes	☐ No
2.	Do measurements of the trial size match information on the trial site map?	☑ Yes	☐ No
3.	Distance to the nearest cultivated fields of the same plant speciesas the plants in the confined field trial	400 Meters	
4.	Distance to the nearest cultivated crop of any kind.	03 Meters	
5.	Is the trial site, including the spatial isolation distance, under the control of the Trial In-Charge and/or Permitted Party?	☑ 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
7.	Is there a bound log book including the name, address and affiliation of all personnel who have entered the trial site?	☑ Yes	☐ No
8.	Was planting/harvesting equipment/implements cleaned in the appropriate manner prior to, and after, use on the trial site?	☑ Yes	☐ No

9. Event(s) planted at the trial site (attach list if necessary)

MON 89034 + NK 603

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 themethod 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 – NOT APPLICABLE

ONLY COMPLETE IF REGULATED PLANT MATERIAL IS IN STORAGE AT THIS LOCATION ☐ 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 a correlation between the physical presence of an inventory item andthe **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 NOT APPLICABLE

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	
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	
3.	Does the Trial In-charge (or Permitted Party) have control of the entire area under post-harvest land use restrictions?	☐ 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	
5.	Is there a **Record of Post-Harvest Monitoring**?	☐ 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	
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
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

PART F: DOCUMENTATION AND RECORD KEEPING

1.	Are copies of SOPs and related records readily accessible and up-to-date for this trial site location?	☑ Yes	☐ No
2.	Is a copy of the letter of permit for all events planted at this trial location readily accessible?	☑ Yes	☐ No
3.	Are the **Record of Transport** documents complete?	☑ Yes	☐ No
4.	Has a **Record of Planting** and a trial site map been completed?	☑ Yes	☐ No
5.	Have the **Record of Planting** and trial site map been forwarded to the **Regulatory Authority**?	☑ Yes	☐ No

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PART G: ADDITIONAL COMMENTS

Summarize :-

- any discussions with the Trial In-charge or other Personnel,

  The weed population and insect pest incidence was very low.

- feedback on the SOPs maintened

  SOP were OK

- any recommended corrective actions and

  Before planting NK 603 event treatment in future the permission from competent authority may be obtained

- 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

☐ **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

☐ **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

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 - Signature and date

LEADER PRADYUMN KUMAR 5/5/11

Members 1. Shankar Lal Jat

2. K. Khappa G.K

3. B.M. Khadi Dean (PGS), UAS, Dharwad 05/05/11
GEAC Nominee

4.

5.

Monitoring report of Green House studies on the bioefficacy of Bt traits in corn (MON 89034+NK 603) hybrids (900 M Gold and Hishell transgenics) and their non transgenic counterparts against major lepidopteran pests

Monitoring was done in the Green House in Corn Breeding Station Dodaballapur, Bangalore on 4th May, 2011. The trial was planted as per the recommended protocol. The details of operations and observations made are as given below. The recording of *Sesamia inferens* was over, hence the symptoms could not be noticed at the time of monitoring, and however, the data of trial was available. The time of monitoring was appropriate for *Helicoverpa*, the symptoms and larvae of *Helicoverpa* were seen in non transgenic hybrids only. No incidence of *Helicoverpa* larvae were found on transgenic corn hybrids. The data record was checked and found in order.

	MON 89034 x NK 603		
Date of sowing	21-Feb, 2011		Completed
Date of emergence	28-Feb, 2011		
//	**Activities**	**Date**	
1	Tissue collection for trait and event purity	9-Mar	Completed
2	Rougueing negative plants	15-Mar	Completed
	Sesamia infestation	15-Mar	Completed
	Tissue collection for protein expression & Observations		
	S1 (L and S)	15-Mar	Completed
3	Recording observations for *Sesamia*	9-Apr	Completed
4	S2 (L and S)	4-Apr	Completed
5	*Helicoverpa* infestation	21-Apr	Completed
6	S3 (L, S,E and Si)	4-May	Completed
7	Recording observations for *Helicoverpa*	6-May	
	L- Whorl Leaf, S- Stem, Si - Silk, E - Ear;		

Names of Monitoring team **Signature**

1. Pradyumn Kumar
2. Chikkappa GK