12/13/2007-CS II
Government of India
Ministry of Environment and Forests

सत्यमेव जयते

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Paryavaran Bhavan,
CGO Complex, Lodi Road,
New Delhi - 110 003

Dated: 1.6.2009

Subject: Permission for commercial release of MH 5125 Bt and MH 5174 Bt cotton hybrids expressing synthetic *cry 1C gene* (event 9124) for central and South zones by M/s Metahelix life Sciences Pvt. Ltd, Bangalore.

Dear Dr. Vasudeva Rao,

1.0 This has reference to your applications dated 23.4.2009 & 30.4.2009 regarding the above proposal. The Genetic Engineering Approval 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 13.5.2009.

2.0 After careful and in-depth consideration, of the findings of the MLRT/LST and SAU trials and taking into consideration the recommendations of MEC and RCGM, the GEAC accorded approval for commercial cultivation of Bt cotton hybrids MH 5125 Bt and MH 5174 for the Central zone (Gujarat, Madhya Pradesh & Maharashtra) and South zone (Andhra Pradesh, Karnataka & Tamil Nadu).

3.0 The commercial release of MH 5125 Bt and MH 5174 expressing synthetic *cry 1C gene* (event 9124) is subject to the following conditions:

i Every field where Bt cotton is planted shall be fully surrounded by a belt of land called 'refuge' in which the same non-Bt cotton variety or non Bt cotton seeds of popular hybrids or an alternate host such as pigeon pea shall be sown. The size of the refuge belt should be at least five rows of non-Bt cotton equivalent to 20% of the total sown area or a minimum of two to three rows of pigeon pea equivalent to 10% of the total sown area, whichever is more.

ii To facilitate this, each packet of seeds of the approved varieties should also contain a separate packet of the seeds of the non Bt cotton variety or pigeon pea which is sufficient for planting in the refuge defined above.

iii Each packet should be appropriately labeled indicating the contents and the description of the Bt hybrid including the name of the transgenes, the GEAC approval reference, physical and genetic purity of the seeds. The packet should also contain the package of agricultural practice with detailed directions for use including sowing pattern, pest management, suitability of the hybrids specifically for irrigated conditions etc., in vernacular language.

iv The Applicant shall enter into agreements with their dealers/agents, that will specify the requirements from dealers/agents to provide details about the sale of seeds, acreage cultivated, and state/regions where Bt cotton is sown.

v The Applicant shall prepare annual reports by 31st March each year on the use of Bt cotton hybrid varieties by dealers, acreage, locality (state and region) and submit the same in electronic form to the GEAC.

vi The Applicant shall develop plans for Bt based 'Integrated Pest Management' and include this information in the seed packet.

vii Monitoring of susceptibility of bollworms to the Bt gene shall also be undertaken by the Central Institute of Cotton Research, Nagpur, the nodal agency identified by the Ministry of Environment and Forests at the applicant's cost.

viii The Applicant shall undertake an awareness and education program, interalia through development and distribution of educational material on Bt cotton, for farmers, dealers and others.

ix The Applicant shall also continue to undertake studies on possible impacts on non-target insects and crops, and report back to the GEAC annually.

x The label on each packet of seeds, and the instruction manual inside the packet should contain all relevant information.

xi The Applicant shall deposit 100 g seed each of approved hybrids as well as their parental lines with the National Bureau of Plant Genetic Resources (NBPGR) and communicate the same to the Ministry of Environment & Forests within 30 days of issue of this clearance letter.

xii The Applicant shall develop and deposit with the NBPGR, the DNA fingerprints of the approved varieties within 30 days of issue of this clearance letter.

xiii The Applicant shall also provide to the NBPGR, the testing procedures for identifying transgenic traits in the approved varieties by DNA and protein methods.

4.0 You are hereby directed to convey to the undersigned within 15 days of receipt of this communication your unequivocal acceptance of the above conditions, failing which, this approval is liable to be revoked.

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

Yours Sincerely

(Dr R. Warrier)
Director

Dr. M.J. Vasudeva Rao
President Ag Technologies
M/s Metahelix life Sciences Pvt. Ltd,
Plot No. 3, KIADB 4th Phase,
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Copy to:

1. **The Joint Secretary**, Department of Agriculture & Cooperation, Krishi Bhawan, New Delhi-110 001.
2. **The Deputy Director General** (crop science), Indian Council of Agricultural Research, Krishi Bhawan, New Delhi-110 001.
3. **Dr. K.K. Tripathi, Adviser**, Dept. of Biotechnology, Lodi Road, CGO Complex, New Delhi - 110003
4. **Shri Ramesh Inder Singh,** Chief Secretary, Govt. of Punjab, Punjab Civil Secretariat, Sector 1 , Chandigarh.
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10. **Shri P. Ramakanth Reddy**, Chief Secretary, Govt of Andhra Pradesh, Hyderabad-500001.
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30. **Dr. B. S. Sidhu**, Director (Agriculture), State Government of Punjab, SCO 85-89, Sector-34, Chandigarh. (01712-2601567)
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(Dr R. Warrier)
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