

No. 6 8/90 –HSMD
Government of India
Ministry of Environment & Forests
Department of Environment, Forests & Wildlife

Subject: 2nd Meeting of the Genetic Engineering Approval Committee
held on 30.05.1991 – Minutes reg.

The second meeting of the Genetic Engineering Approval Committee (GEAC) was held on 30.05.1991 at 10.30 a.m. under the chairmanship of Shri A. Bhattacharjya, Additional Secretary (G) to discuss the environmental clearance of Bovine somatotropin (BST) use in cattle's in India. The list of participants is as per Annex I.

2. While welcoming the members, AS (G) pointed out that the second meeting of the GEAC is being convened after a lapse of over one year. He desired that this committee should meet more frequently. He recapitulated that in the last meeting of GEAC held on 15.5.90, a proposal submitted by M/s Indian Immunologicals, Hyderabad on BST was discussed. The experts who attended this meeting expressed concern about the controversy on BST in western countries and suggested that a more thorough study on the safety of this compound be done. The first meeting of the GEAC therefore did not accord environmental clearance to the import of six lakhs doses of BST. The matter was referred to the Department of Biotechnology which is the nodal ministry for promotion of biotechnology products. The DBT subsequently convened a workshop on BST on 1.10.90 and a committee under the chairmanship of Dr. K.K.G. Menon was constituted to look into the safety, chemical composition, quality control, etc. of BST. This committee recommended that the product can be cleared for use on an experimental basis with suitable controls under the supervision of National Dairy Development Board and National Dairy Research Institute, Karnal deferring formal clearance of registration subject to compiling data from indigenous experiments and evaluation of field trials results by GEAC. In the meantime, the Animal Husbandry Commissioner, Department of Agriculture and Cooperation has recommended to Drug Controller of India to grant permission for import of six lakhs doses of BST for large scale field trials in ICAR institutes and NDDB and deferring, at the same time, decision on registration to a later stage based on the evaluation of field trials. The summary report of Dr. K.K.G Menon committee and the letter of Animal Husbandry Commissioner was circulated to GEAC members and the comments received from some members have been summarized in the agenda notes.

3. AS (G) mentioned that the comments from health point of view are most important to take a view on the safety of the product. The comments of the Ministry of Health have not been received. He invited members to give their considered views as to whether the product can be cleared for experimental field trials in cattles in India.

4. Dr. B.B. Mallick, Director, Central Institute for Research on Goat (CIRG), Makhdoompur mentioned that, to start with, limited experimental trials should be undertaken at one or two districts under the experts' supervision. He emphasized the need to take views of the Ministry of Health as there are reports the BST causes irreversible changes in human beings. He cautioned against the supply of milk from BST treated cattles to humans unless adequate data are generated and examined. For the present, it may be allowed only for closed experimental trials. He was not in favour of involvement of National Dairy Development Board in undertaking experimental trials as Indian Immunologicals who have submitted the proposal are an agency of NDDB. He suggested the NDRI, Karnal should be involved in the experimental trials.

5. Dr. S.K. Mahajan of BARC wondered whether the letter sent by Animal Husbandry Commissioner does not indicate that the import of six lakh doses of BST has already taken place. AS (G) directed that this may be confirmed at an early date from the Animal Husbandry Commissioner. Dr. Mahajan also mentioned that one of the parameters to be examined during experimental trials should be to analyze the milk contents for any pesticides and heavy metals as the cattles in India are reported to carry pesticides in their adipose tissue. This problem is specific to India as the cattles in the country have negative energy balance in view of shortage of fodder. Therefore, the analysis of milk for any pesticides and heavy metals should be an important parameter examined during experimental trials.

6. Dr. K. Narayanswami, Director, Department of Biotechnology mentioned that according to reports, the milk and meat of BST treated animals is quite safe. As recommended by the Menon Committee, DBT is of the view that the import of BST should be allowed for experimental basis at IVRI, NDDB AND NDRI, Karnal. However, detailed protocol need to be developed before such experimental trials could be undertaken. The data thus generated should be considered by the GEAC to take a decision in the matter.

7. Dr. S.A.H. Abidi, Director, Department of Ocean Development agreed with the DBT that initially only controlled field trials should be permitted.

8. Dr. D. Kanungo, Medical Toxicologist, Directorate of plant protection, Quarantine and Storage agreed with the views of AS (G) that the comments of the Ministry of Health are necessary on the safety of BST to human beings. The protocols should include effects on animals, quality of milk in respect of presence of pesticides and heavy metals and effects on consumers.

9. Dr. S. Jayaraj, Vice Chancellor, Tamil Nadu Agricultural University, Coimbatore, described the metabolic pathways of BST in the body tissue. In tropical conditions, excretion of BST will be more. We should ensure that there are no adverse effects either on animals or human beings. The GEAC should not take any hasty decision in introducing the product. Only small quantities of BST under controlled conditions be tried in the first instance.

10. AS (G) expressed his apprehension for allowing the use of BST in the country when no other country has so far allowed its use. He also mentioned that there appears to be consensus for limited experimental trials with strict controls at captive farms. Shri K.M. Chadha, Joint Secretary (C) mentioned that we should immediately write to the Ministry of Agriculture to ask NDDB to suggest protocols so that experimental trials could be undertaken at ICAR institutes. JS(C) also mentioned that doses to be administered should be quantified. On the request of AS (G), the specific views of the experts were recorded:

Dr. Suman Sahai:

The Secretariat should check whether the product has already been imported. Small scale controlled trials be undertaken at ICAR institutes. The protocols should specify the number of animals and doses for a statistical interpretation.

DBT and DOD:

Experimental trials under the controlled conditions at NDRI, NDDB & IVRI be undertaken after developing detailed protocols.

Ministry of Health:

Milk should not be given to humans unless more data are generated and safety ensured. Views of Ministry Health will be conveyed by 15.7.91

CPCB:

The Secretariat should check whether the product already been imported. Small scale controlled trials be undertaken at ICAR institutes.

S. Jayaraj:

Suggested that a time be given to complete the limited experimental trials for the product.

BARC:

The protocol to be suggested by NDDB be discussed by GEAC experts. The experimental trials be done on BST should be open to inspection by GEAC members.

DPPQ & S:

The protocol should include effects on animals, effects on quality of milk and meat, type of fodder and effects on human beings. The studies also be undertaken at NIN, Hyderabad. Inspection of experimental trials of BST should be undertaken.

Dr. B.B. MALLICK, CIGR:

Controlled experimental trials of BST be undertaken. Instead of directly writing to the institutes, the Ministry of Environment and Forest should request the nodal ministry to provide protocols and undertake experimental trials. Nodal ministry for BST is the Department of Animal Husbandry and dairying under the Ministry of Agriculture. Monitoring and inspection of controlled experimental trials be periodically taken.

11. AS (G) suggested the following schedule for completing the work:
- (i) Protocols be obtained from Ministry of Agriculture and draft circulated to GEAC members by first week of July.
 - (ii) GEAC experts should send their response on the draft protocol by 31.7.91
 - (iii) Agenda items to be prepared and sent to GEAC members by 20.8.91.
 - (iv) Next meeting of GEAC to be convened by 30.8.91.

The meeting ended with a vote of thanks to the Chairman.

Annex- I

List of Participants

1. Shri A. Bhattacharjya, Additional Secretary, Ministry of Environment and Forests, New Delhi.
2. Shri K.M. Chanda, Joint Secretary, Ministry of Environment and Forests, New Delhi.
3. Dr. K. Narayanaswami, Director, Department of Biotechnology, New Delhi.
4. Dr. S.A.H. Abidi, Director, Department of Ocean Development, New Delhi.
5. Dr. B.B. Mallick, Director, Central Institute for Research on Goat, Mathura.
6. Dr. S.K. Mahajan, Head, Molecular Biology and Agri. Division, BARC, Bombay.
7. Dr. (Mrs.) S.V. Dharan, Additional Secretorate General of Health Services, New Delhi.
8. Dr. S. Jayaraj, Vice Chancellor of T.N. Agricultural University, Coimbatore.
9. Dr. Suman Sahai. TCS, Tilhar, U.P.
10. Dr. D. Kanungo, Medical Toxicologist, Directorate of Plant protection, Quarantine and Storage, Faridabad.
11. Dr. Sudhir K. Ghosh, Central Pollution Control Board, Delhi.
12. Dr. R.R. Khan, Scientist 'SE', Ministry of Environment and Forests, New Delhi.