The House re-assembledat twelve of the clock.

MR. DEPUTY CHAIRMAN in the Chair.

WRITTEN ANSWERS TO STARRED QUESTIONS

Reconstitution of body for regulating GM Crops

*101. SHRI SANJAY RAUT: Will the Minister of ENVIRONMENT AND FORESTS be pleased to state:

(a) whether Government will reconstitute the body to regulate Genetically Modified (GM) crops;

(b) whether applications seeking nod for field trials of GM crops are piling up;

(c) whether Supreme Court's appointed technical expert committee called for a ten year ban on GM crops; and

(d) if so, the reasons for Government's decision to reconstitute the body?

THE MINISTER OF STATE OF THE MINISTRY OF ENVIRONMENT AND FORESTS (SHRIMATI JAYANTHI NATARAJAN): (a) Yes Sir, there is a proposal to establish an independent 'Biotechnology Regulatory Authority of India (BRAI)' for the regulation of GM Crops through an Act of Parliament, and the BRAI Bill has been submitted to Lok Sabha Secretariat for introduction by the Department of Biotechnology, Ministry of Science and Technology. Currently, the regulation of GM crops is being carried out by the Genetic Engineering Appraisal Committee (GEAC) a statutory body constituted by the Ministry of Environment and Forests (MoEF) notified under the 'Rules for Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells 1989', of the Environment (Protection) Act, 1986.

(b) Permission for conduct of confined Biosafety Research Level (BRL) trials by the GEAC is subject to recommendations from the Review Committee on Genetic Manipulation (RCGM) constituted under Rules 1989 and 'No Objection' from the State Government. At present about 70 applications recommended by RCGM are pending consideration of the GEAC. In addition about 50 applications for BRL trials approved by the GEAC are awaiting consent of the State Government.

(c) and (d) As per the directions of Hon'ble Supreme Court Order dated 10.5.2012, in Writ Petition (Civil) No. 260/2005 of Aruna Rodrigues & Others vs Union of India & Others a Technical Expert Committee (TEC) was constituted to address issues related to genetically modified (GM) crop field trials. The TEC in its interim report has recommended (i) 10-year moratorium on field trials of Bt food crops used for human consumption on the basis of review of Bt cotton and Bt brinjal biosafety data; (ii) Ban on field trials of herbicide tolerant (HT) crops till an independent committee of experts has examined the potential impact of the HT technology including livelihood issues; and (iii) Ban on GM crop field trials in the centers of origin and centers of diversity. The other key recommendations of the TEC include need assessment, strengthening and restructuring of the current regulatory system, reassessment of the biosafety data on Bt cotton and other data that is generated by all field trials; ensuring there is no conflict of interest; a ban on outsourcing or subcontracting field trials; designation of sites for field trials, and requirement of preliminary bio-safety tests etc; as a prerequisite to all GM crop field trials.

The Union of India has not accepted the recommendations on the ground that the interim report does not address the terms of reference (TOR) and has not only exceeded the mandate assigned to TEC but are also outside the scope of the Writ Petition itself. A Joint Affidavit in this regard has been filed by the Ministry of Agriculture on behalf of Union of India. The Hon'ble Supreme Court vide Order dated 9.11.2012 has directed the TEC to consider the objections filed by all respondents, interested parties and the Union of India and submit its report within six weeks. The TEC has sought extension of time till March, 2013 for submission of the final report. The matter is now listed for 1.4.2013.

Compensation for clinical trial victims

*102. SHRI PRAKASH JAVADEKAR: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether any deaths have occured while conducting clinical trials of various drugs since 2004;

(b) if so, the details thereof, year-wise; and

(c) the compensation provided to families of the deceased, year-wise?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) and (b) Detailed requirements of reporting of Serious Adverse Events including deaths in clinical trials in a time-bound manner were incorporated