ANNEX

Response of the Competent Authorities of India to the recommendations of Mission report ref. DG (SANCO) 7854/2008 – from the 28/01/08 – 05/02/08 concerning the evaluation of food irradiation facilities.

Recommendation		Action taken/ proposed by Competent Authority
(1)	The competent authorities should provide adequate official control guarantees in respect of the applicant facilities, in particular with regard to dosimetry and process control in the facilities (Article9 2(a) of Directive 1999/2/EC).	**The schedule and protocols of regulatory inspections of AERB in respect of gamma radiation food processing facilities, which has main focus on radiological safety, has been reviewed by AERB and updated to include the relevant provisions of the Atomic Energy (Control of Irradiation of Food) Rules, 1996 and schedule III & IV of the rules on the food dosimetry and process control aspects.**
(2)	The competent authorities should ensure that all three companies comply with the provisions of Article 9 (1) second indent of Directive 1999/2/EC concerning the information which is required to accompany consignments referred to in Article 8 of the same Directive.	**Requirements of Article 8 of Directive 1999/2/EC are synonymous to Rule 11 of the Atomic Energy (Control of Irradiation of Food) Rules, 1996. The licensee is responsible for ensuring compliance with requirements of Rule 11. In case of non-conformance by the licensee with the provisions relating to safety and efficiency criteria, the competent authority may suspend the certificate of approval in accordance with Rule 6 of above rules . This will be strictly enforced.**
(3)	The competent authorities should ensure that all three companies comply with the provisions of point 2.1 of Annex III to Directive 1999/2/EC relating to validation measurements.	**Regulatory control procedures have been reviewed and updated for dosimetry qualification of the facility as per schedule IV of the Atomic energy (Control of Irradiation of Food) Rules, 1996. Procedures for validation of food dosimetry system of the facility have also been reviewed by AERB in accordance with point 2.1 of Annexu III to Directive 199/2/EC. It will be strictly enforced by AERB for all the food irradiation facilities.**
(4)	The competent authorities should ensure that facilities comply with the conditions which are set out in Regulation (EC) No 852/2004 on the hygiene of foodstuffs.	**This is basically the responsibility of the licensee to maintain good sanitation and hygiene practices in the facility. However revised inspection protocols reflect these aspects also.**