

## CENTRAL MARKS DEPARTMENT II

**Our Ref: CMD II/16:14543**

**09 02 2005**

**Subject: Dispatch of Packaged drinking water by the licensee  
on availability of test results for microbiological requirements**

This has reference to the Scheme of Testing and Inspection of Packaged drinking water, Doc: STI/14543/5 June 2004 and Amendment No. 1, July 2004 to STI. As per the STI, the Package drinking water can be dispatched only after test results for the requirements applicable for hourly/ four hourly/ each control unit are available. This implies that dispatches can be made only after 5 days on receipt of conformity results including microbiological parameters.

A number of representations were received from various Bottled Water Manufacturers Associations in Ministry of Consumer Affairs as well as in BIS. The issue was discussed at length in the meeting held with the representatives of the Bottled Water Manufacturing Association at BIS on 9 November 2004 and was further discussed in the meeting of Expert Group of microbiologist of FAD 14 on 3 December 2004. During the last meeting following decisions were taken:

- “1. Each batch (batch refers to “each control unit” as given in the Scheme of Testing & Inspection of BIS) of packaged drinking water be held for 48 hours so as to ensure that it conforms to all the microbiological requirements applicable for “each control unit” except for the tests of aerobic microbial count at 21°C and “yeast and mould”, which shall be reviewed for conformity on availability of their test reports after 72 hours and five days respectively.
2. As and when a failure is noticed in any of the microbiological test requirements in a batch during in-process quality control as per the Scheme of Testing and Inspection of BIS, the same shall not be dispatched. Also the previous batches available in stock shall not be permitted for release into the market. The manufacturer should reject or re-process the entire previous stock including the batch found failing.
3. Further, the manufacturer would be required to take immediate corrective action, which would involve complete investigation and analysis of the reasons for contamination and non-conformity. Only after the completion of satisfactory corrective action, the manufacturer should re-start production and only after the availability of satisfactory results of all microbiological tests as applicable for each control unit for five consecutive batches produced, stocks can be released in the market including the batches reprocessed if any. All these batches will be held for five days until satisfactory results of all tests are available. The original frequency of dispatch after 48 hours will be restored, if all the above batches are

found conforming to the microbiological requirements. The manufacturer will inform BIS in all such cases regarding the corrective action taken and keep complete records of the same for review by BIS.

4. The manufacturer would be required to give an undertaking to this effect to BIS.
5. **For consideration of Resumption of Marking** - In case of stoppage of marking on account of failure of sample in any of the microbiological requirements in independent testing when drawn by BIS, the following procedure be adopted:

After taking corrective actions and availability of satisfactory test results of five consecutive batches, the manufacturer shall inform BIS and offer sample for independent testing and only after the availability of satisfactory test results of the sample, resumption of marking would be permitted. Till such time the manufacturer may not be allowed to mark the product or release any stock in the market. This would also imply that the original frequency of dispatch after 48 hours will be restored only after resumption of marking.”

The above guidelines will come into force w.e.f. 15 February 2005. All ROs/BOs are advised to inform the licensees accordingly.

(Dr. A.K. Goyal)  
Director (CMD II)

**DDGM**

**All ROs/BOs**