TERMS OF REFERENCE FOR R&D PROJECT
PETROLEUM, COAL, AND RELATED PRODUCTS DEPARTMENT
PLASTICS PACKAGING SECTIONAL COMMITTEE, PCD 21

1) **Title of the Project**: Study of Toxicological effect of colourants and pigments in plastics feeding bottle on infant health.

2) **Introductory Background**

a) Feeding bottles are universally used for feeding infants. BIS has published IS 14625 Plastics Feeding Bottles which also comes under compulsory BIS certification, contains provision of using colorants and pigments conforming to IS 9833 for printing on plastics feeding bottle. IS 14625 also mentions that the transparency of the plastic feeding bottle shall not be less than 70% in any light source transmittance. IS 9833 contains lists of colourants and pigments permitted for use in plastics that may be regarded as safe for use in contact with foodstuff and pharmaceuticals. However, the toxicological effect of these colourants and pigments has not been investigated indigenously.
b) In recent years, lot of coloured feeding bottles are manufactured and circulated in the Indian market to attract consumers. Even lot of coloured feeding bottles are imported in the country. Since, feeding bottles are reused several times after so many washes and multiple exposures to heat, there is a high chance of leaching of colourants and pigments in the food content (e.g. Milk) of feeding bottle.
c) Further, infants are more vulnerable to the potential health impacts and concentration of colourants and pigments in the food content may cause huge damage to the health of infants. The toxicological effect of these colourants and pigments on infant health are unknown till date. In this context, a need was felt of decisive study about the toxicological effect of these colourants and pigments on infant health. This study will provide much needed technical and scientific evidences of toxicological effects of colourants and pigments in plastics feeding bottle on infant health which will help to ensure the safety and well-being of this vulnerable population.

3) **Objective**

To collect technical and scientific evidences in regard to toxicological effect of commonly used colourants and pigments in plastics feeding bottle.

4) **Scope**

a) Extensive and thorough examination of the available literature on coloured feeding bottles, including but not restricted to the following:
   - International standards;
   - Research papers;
   - Guidelines by ministry/ regulatory bodies;
   - Any studies being conducted by any organizations; and
   - Any other sources.

b) Identification of manufacturing base of coloured feeding bottle in India along with categorization of large, medium, small and micro units. Collection of information on commonly used colourants and pigments in plastics feeding bottle as well as whether they are used in masterbatches or printing or in both from identified manufacturing base.
c) Identification of importers /exporters of coloured feeding bottles in India. Collection of information on product quality, commonly used colourants and pigments and technical regulations/standards followed for export.
d) Visit to the manufacturing unit of colourants and pigments and manufacturing units of coloured feeding bottle ensuring that minimum one for former and minimum three for later (preferably 1 large, 3 MSME, if any) to gather information through questionnaire and structured interaction. Data on requirements laid down by user relevant to plastics feeding bottle, if any, to be collected during visit.

e) Identification of one NABL accredited laboratory for testing following parameters (but not restricted to) in coloured feeding bottle :
   - Pigment / colorant and finished product toxicity test by systemic injection
   - Pigment leaching test (absorption spectroscopy based)
   - Global/overall Migration test
   - Specific migration test
   - Heavy metals

   NOTE - For performing tests, simulants shall be used as prescribed in IS 14625. Temperature condition for conducting tests shall be 100 °C and time period for performing tests shall be 1 hr. Minimum number of sample for performing tests shall be as prescribed in IS 14625.

f) Testing of collected samples from NABL accredited laboratory and submission of analytical report covering comprehensive study on toxicological effects of commonly used colourants and pigments in coloured feeding bottle.

5) **Research Methodology**

a) Undertake thorough literature review in respect of areas explained in scope and prepare summary report.
b) Identify manufacturing base of coloured feeding bottle categorized into Large, medium, small and micro. Contact the manufacturers and collect information using structured questionnaire.
c) Identify exporters / importers of coloured feeding bottles . Contact them and collect information using a structured questionnaire.
d) Undertake visit to identified manufacturing units, considering criteria set in **4(d)** and find out commonly used colourants and pigments in manufacturing of coloured plastics feeding bottles for carrying out toxicological study.
e) Identify NABL accredited laboratory for carrying out tests as prescribed in **4(e).** Explore NABL accredited laboratories where complete testing can be carried out.
f) Collect samples of coloured feeding bottles and commonly used colourants and pigments.
g) Undertake testing of samples collected from manufacturers and importers. The testing shall be conducted in identified NABL accredited laboratory.
h) Based on the tests reports and information collected through questionnaires, visits and discussion, interpret results in context of potential health risks for infants and submit final analytical report.

6) **Expected Deliverables**

a) Project report, in hard copy and digital format, covering all aspects mentioned in scope.
b) Questionnaires, discussion, visit reports and test reports to be appended with final analytical report.

7) Timeline and Method of Progress Review

a) Timeline for the project is 4 months from the date of award of the project.

b) **Stages for Review:**

Stage I: At the end of 1st month, shall prepare a comprehensive plan identifying the following:

a) Details of literature review carried out and summarized report;

b) Identified manufacturers, exporters, importers, laboratories, and users;

c) Information obtained through questionnaires from the above-mentioned stakeholders and visits to be carried out;

d) Laboratory where testing is to be carried out; and

e) Associated sample volume and sampling plan.

Stage II – At the end of 3rd month, submit draft report with the following information:

a) Reports of visits carried out to manufacturing units;

b) Number of samples collected with information related to source of the sample (manufacturer/importer) and type of colourants and pigments;

c) Test reports; and

d) Analysis of data and interpretation in context of potential health risks for infants.

After 4 months, final report shall be submitted.

8) Support from BIS

a) BIS will provide access to latest editions of Indian and International Standards and available literature with BIS

b) BIS will facilitate introduction to manufacturing industries, laboratories, and user industries for carrying out the project

9) Nodal Officer

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