TERMS OF REFERENCE FOR THE R&D PROJECT
(Plastics Sectional Committee, PCD 12 under Petroleum, Coal and Related Products Division Council, PCDC)

1. **Title of the Project**: Study on Safety and quality aspects of Positive List of Constituents for Polymers in contact with foodstuffs, pharmaceuticals and drinking water **(*see* Annex A for the list).**

2. **Background:**

Plastics are being used on a large scale for packaging of foodstuffs, pharmaceuticals and drinking water. The packaging of foodstuffs and pharmaceuticals is essential for their conservation, transport and handling. It also avoids contamination and maintains hygienic conditions.

Where direct contact occurs between the packed commodity and the plastics, the high-molecular mass polymer itself does not pose a toxic hazard being inert and essentially insoluble in food. There is, however, a likelihood that migration of polymer additives, adventitious impurities, such as monomers, catalyst remnants and residual polymerization solvents and of low molecular mass polymer fraction will occur from the plastics into the packaged material with consequent toxic hazard to the consumers of products packed in plastics.

BIS has already published several Indian Standards with positive list of constituents for different polymers for their safe use in contact with foodstuffs, pharmaceuticals and drinking water (*see* Annex A). However, few of these standards are quite old (prior to 2000) and were published prior to 2000, therefore, a need was felt to review the content of the standards as there may be an updated list of substances which can be used safely with the foodstuffs, pharmaceuticals and drinking water.

Therefore, it is important that a thorough analysis of migration of polymer additives, adventitious impurities such as monomers, catalyst remnants and residual polymerization solvents and of low molecular mass polymer fraction shall be done along with the limits for their safe use for food contact applications for different polymers. Information gathered from the analysis will help in revision of Indian Standard listed in Annex A.

3. **Objective**

To collect and analyse the data from primary and secondary sources for positive list of constituents for their safe use in contact with foodstuffs, pharmaceuticals and drinking water for different polymers along with their safe migration limits.

4. **Scope**:

4.1 Undertake extensive and thorough examination of the available literature for positive list of constituents for their safe use in contact with foodstuffs, pharmaceuticals and drinking water for different polymers (*see* Annex A) along with their safe migration limits including international standards, if any, research papers, SOP's and guidelines issued by regulatory bodies and any study conducted by any organization or any other available sources.

4.2 Identify and collect the data on the positive list from the manufacturers of base polymers available in the country in various categories i.e. large, medium, small, and micro units.

4.3 Identify and collect the data from the manufacturers of food grade polymers, manufacturers of additives, catalysts, solvents, etc available in the country in various categories i.e. large, medium, small, and micro units.

4.4 Gather import-export data and identify importers of the material in India. Based on the gathered information, study the regulations and standard followed in the exporting countries.

4.5 Identify and collect the data on the users of these substances in the country.

4.6 Identify and collect the data on the laboratories involved in the testing of constituents as mentioned in 4.1.

4.7 Carry out visits to manufacturing facilities, users, laboratories to gather the information on the subject.

4.8 Study and comparative analysis of various documents/literature gathered from different sources.

4.9 Prepare analytical report covering the entire scope.

5. Research Methodology

5.1 Literature review available from primary and secondary sources.

5.2 Contact the relevant organizations, industry associations to gather the information on the subject.

5.3 Collect feedback from industries, users, labs through questionnaires. The questionnaires to be circulated to all the available industry, users, labs.

5.4 Visits to industries (of each category), users, labs to observe the facilities and processes followed and gather information. At least two industries each from large, medium, small, micro, users, laboratories (Public and private each) to be visited, if available. However, the number of visits to be finalized after gathering the information on available industries, users, and labs.

5.5 Analyze the findings from the literature review, visits.

6. Deliverables

6.1 Study report covering all the aspects mentioned in the scope.

6.2 Feedbacks from questionnaires, discussion with the focused groups, report of the sample shall be appended in in digital and hard copy forms with the study report.

7. Timeline and Method of Progress Review

7.1 Final report to be submitted within 4 months from the date of the award of the project.

7.2 Stages for Review:

7.2.1 Stage I – At the end of 4th week, allottee shall prepare the following:

a) Literature review carried out and summarized report;
b) Identified manufacturers and importers; and
c) Format of questionnaire for manufacturers and importers;
d) Visit plan.

7.2.2 Stage II – At the end of 12th week, project allottee to submit draft report having information as mentioned in the scope.

NOTE: Sectional Committee will evaluate the draft report and provide feedback / recommend changes, if required, within 1 week.

7.2.3 Stage III – At the end 16th week, project allottee to submit final report incorporating recommendations/feedback of Committee.

7.3 Sectional committee will evaluate the final report and take decision for acceptance and recommend release of balance funds.

7.4 The project allottee shall comply to the provisions given in the BIS guidelines for Research & Development Projects for Formulation and Review of Standards, i.e., doc no. SCMD/R&D Guidelines/20230909.

8 Support from BIS

8.1 Letters from BIS to manufacturers and industry associations introducing the awardee.

8.2 Access to Indian and International Standards.

8.3 Member secretary of the Plastics Sectional Committee, PCD 12, Shri Shivam Dwivedi shall be the Nodal point from BIS. His email id is pcd12@bis.gov.in.

Annex A

(List of Indian Standards)

Sl. No.	*IS Number*	*Title*
i)	IS 10148 : 2023	Positive list of constituents of polyvinyl chloride and its copolymers for safe use in contact with foodstuffs, pharmaceuticals and drinking water
ii)	IS 10149 : 1982	Positive list of constituents of styrene polymers in contact with foodstuffs, pharmaceuticals and drinking water
iii)	IS 11435 : 1985	Positive list of constituents of ionomer resins for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
iv)	IS 12248 : 1988	Positive list of constituents of nylon-6 polymer for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
v)	IS 13449 : 1992	Positive list of constituents of ethylene vinyl acetate (EVA) copolymers in contact with foodstuffs, pharmaceuticals and drinking water
vi)	IS 13557 : 1992	Positive list of constituents of ethylene methacrylic acid (EMAA) copolymers and terpolymers in contact with foodstuffs, pharmaceuticals and drinking water
vii)	IS 14972 : 2001	Positive list of constituents of polycarbonate resins in contact with foodstuffs, pharmaceuticals and drinking water
viii)	IS 14996 : 2001	Positive list of constituents of modified poly (Phenylene Oxide) (PPO) in contact with foodstuffs, pharmaceuticals and drinking water
ix)	IS 14998 : 2001	Positive list of constituents of melamine - Formaldehyde resins in contact with foodstuffs, pharmaceuticals and drinking water
x)	IS 16738 : 2018	Positive list of constituents for polypropylene, polyethylene and their copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water