TERMS OF REFERENCE FOR R&D PROJECT

Petroleum, coal and related products department, Methods of sampling and test for plastics sectional Committee, PCD 27

1) Title of the Project

Study on Overall Migration from different types of plastic packaging materials intended for food contact applications.

2) Introductory Background

Plastic packaging materials are extensively used in food packaging due to their mechanical strength, barrier properties, and adaptability. However, the migration of substances surpassing the safe limit from these plastics into food may pose a potential health risk, which is regulated under FSS Packaging regulations, 2018 when tested as per IS 9845:1998. The Standard prescribes methods for evaluating overall migration under specified conditions using specified food simulants.

Considering the diverse climatic conditions in India and the nature of the distribution chain, plastic packaging is often subjected to extreme environmental conditions such as high temperature and humidity. These factors can significantly influence migration behaviour. While standard test conditions are defined in IS 9845, it is imperative to evaluate the performance of packaging materials under more extreme Indian conditions to validate the adequacy of current limits.

This project aims to undertake comprehensive overall migration testing across a variety of packaging types and under both standard and extreme conditions, as specified in Annex A.

3) Objective

To assess the overall migration of constituents from various plastic packaging materials intended for food contact applications as per Annex A under:

- Standard test conditions as prescribed in IS 9845, and
- Extreme conditions.

4) Scope

a) Identification of packaging material manufacturers, converters, and brand owners across the Indian market for packaging specified in Annex A.

- b)Collection of representative samples of plastic packaging used for food contact, based on classifications provided in Annex A.
- c) Identification of laboratory/laboratories accredited to IS/ISO/IEC 17025, capable of conducting overall migration testing as per IS 9845 and also under extreme conditions (temperatures higher than those specified in IS 9845) as per Annex A.
- d)Conducting overall migration testing on each packaging material under conditions specified in Annex A.
- e) Comparison of migration results obtained under both Standard test conditions and extreme conditions.
- f) Preparation of a final report outlining observations from testing.

5) Testing Methodology

- a) Source plastic packaging material samples (details as per Annex A) through engagement with manufacturers, brand owners.
- b) Coordinate with laboratory/laboratories accredited to IS/ISO/IEC 17025 to conduct testing as specified in Annex A.
- c) Ensure uniformity in sampling and replication across both standard conditions and extreme test conditions.
- d) Analyse test data to understand variation in migration behaviour.

6) Expected Deliverables

- a) Comprehensive R&D report covering:
- Packaging types tested (as per Annex A)
- Test methods, conditions (standard and extreme), and simulants used (as per Annex A)
- Test results and analysis; and
- Comparative evaluation of standard vs. extreme condition outcomes
- b) Annexures containing:
- Source-wise details of packaging samples

- Raw test data and laboratory reports; and
- Photographs and documentation of testing.

7) Timeline and Method of Progress Review

Total Duration: 6 months

Stage I – End of 1st Month

- Submission of inception report including manufacturer details, sample plan, identified labs.

Stage II – End of 4th Month

- Progress report detailing sample collection and preliminary testing results.

Final Stage – End of 6th Month

- Final comprehensive report with all test results and analysis.

8) Support from BIS:

- a) BIS will provide access to relevant Indian and international standards.
- b) BIS will facilitate communication with manufacturers, testing laboratories, and user industries for support.

9) Nodal Officer:

Shri Shivam Dwivedi, Sc. C/Deputy Director, PCD, BIS, may be contacted at [pcd@bis.gov.in/pcd27@bis.gov.in] for any queries related to the research project.

| | | Overall | Migration Tes | sting - Under I | Extreme Climatic Co | ndition - Ir | ı line wi | th IS 9845 | |
|----------|--------------|--------------------|--------------------------|------------------|--|--------------------------------------|------------|----------------------------|------------|
| Category | Sample No | Sample Category | Product | Temperature C | Simulant | Simulant category (IS 9845) | Time | No of samples to be tested | Cumulative |
| 1 | 1 | PET Bottle | Water | 40 | Distilled water or water of equivalent quantity | A | 10 days | 3 | |
| | 2 | | | 60 | Distilled water or water of equivalent quantity | A | 10 days | 3 | 6 |
| 2 | 3 | PET Bottle | Carbonated Soft Drink | 40 | 3% Acetic Acid (w/v) in aqueous solution (using simulant A) | В | 10 days | 3 | |
| | 4 | | | 60 | 3% Acetic Acid (w/v) in aqueous solution (using simulant A) | В | 10 days | 3 | 12 |
| 3 | 5 | PET Bottle | Alcohol 12% | 40 | 10% Ethanol in Aqueous solution (v/v) | C1 | 10 days | 3 | |
| | 6 | | | 60 | 10% Ethanol in Aqueous solution (v/v) | C1 | 10 days | 3 | 18 |
| 4 | 7 | R-PET Bottle (30%) | Water | 40 | Distilled water or water of equivalent quantity | A | 10 days | 3 | |

| | 8 | | | 60 | Distilled water or water of | A | 10 days | 3 | 24 |
|---|----|--|--------------------------|----|---|----------------|------------|---|----|
| | | | | | equivalent quantity | | | | |
| 5 | 9 | R-PET Bottle (30%) | Carbonated Soft Drink | 40 | 3% Acetic Acid (w/v) in aqueous solution (using simulant A) | В | 10 days | 3 | |
| | 10 | | | 60 | 3% Acetic Acid (w/v) in aqueous solution (using simulant A) | В | 10 days | 3 | 30 |
| 6 | 11 | R-PET Bottle (30%) | Alcohol 12% | 40 | 50% Ethanol in Aqueous solution (v/v) | C1 | 10 days | 3 | |
| | 12 | | | 60 | 50% Ethanol in Aqueous solution (v/v) | \mathbf{C}^1 | 10 days | 3 | 36 |
| 7 | 13 | Polycarbonate Cans 20L | Water | 40 | Distilled water or water of equivalent quantity | A | 10 days | 3 | |
| | 14 | | | 60 | Distilled water or water of equivalent quantity | A | 10 days | 3 | 42 |
| 8 | 15 | Laminate with Food Contact Coating | Aqueous | 40 | Distilled water or water of equivalent quantity | A | 10 days | 3 | |

| | 16 | | | 60 | Distilled water or water of equivalent quantity | A | 10 days | 3 | 48 |
|---|----|------------------------------------|--------|----|---|---|------------|---|----|
| | | | | | | | | | |
| 8 | 17 | Laminate with Food Contact Coating | Acidic | 40 | 3% Acetic Acid (w/v) in aqueous solution (using simulant A) | В | 10 days | 3 | |
| | 18 | | | 60 | 3% Acetic Acid (w/v) in aqueous solution (using simulant A) | В | 10 days | 3 | 54 |
| 8 | 19 | Laminate with Food Contact Coating | Fatty | 38 | n heptane -freshly distiiled before use | D | 30 min | 3 | |
| | 20 | | | 45 | n heptane -freshly distiiled before use | D | 30 min | 3 | |
| | 21 | | | 55 | n heptane -freshly distiiled before use | D | 30 min | 3 | 63 |
| 9 | 22 | Laminate with sealant film | Snacks | 38 | n heptane -freshly distiiled before use | D | 30 min | 3 | |
| | 23 | | | 45 | n heptane -freshly distiiled before use | D | 30 min | 3 | |
| | 24 | | | 55 | n heptane -freshly distiiled before use | D | 30 min | 3 | 72 |

| 9 | 25 | Laminate with sealant film | Water / Sugar syrup | 40 | Distilled water or water of equivalent quantity | A | 10 days | 3 | |
|----|----|----------------------------|--|----|---|----|------------|----|---|
| | 26 | | | 60 | Distilled water or water of equivalent quantity | A | 10 days | 3 | 78 |
| | 27 | Laminate with sealant film | Pickles | 40 | 3% Acetic Acid (w/v) in aqueous solution (using simulant A) | В | 10 days | 3 | |
| | 28 | | | 60 | 3% Acetic Acid (w/v) in aqueous solution (using simulant A) | В | 10 days | 3 | 84 |
| 10 | 29 | Film / Laminate | Filled Pickle Pack Market sample - Kirana Shop | NA | NA | NA | NA | NA | Will be checked in CIPET by Ultra High performance Liquid Chromatography or equivalent instrument for migration |
| 11 | 30 | PE Fillm LD / | Aqueous | 40 | Distilled water or water of equivalent quantity | A | 10 days | 3 | |
| | 31 | | | 60 | Distilled water or water of equivalent quantity | A | 10 days | 3 | 90 |

| | 32 | PE Fillm LD / LLD | Acidic | 40 | 3% Acetic Acid (w/v) in aqueous solution (using simulant A) | В | 10 days | 3 | |
|----|----|----------------------|---------|----|---|---|------------|---|-----|
| | 33 | | | 60 | 3% Acetic Acid (w/v) in aqueous solution (using simulant A) | В | 10 days | 3 | 96 |
| | 34 | PE Film LD / LLD | Fatty | 38 | n heptane -freshly distiiled before use | D | 30 min | 3 | |
| | 35 | | | 45 | n heptane -freshly distiiled before use | D | 30 min | 3 | |
| | 36 | | | 55 | n heptane -freshly distiiled before use | D | 30 min | 3 | 105 |
| 12 | 37 | PE EVOH | Aqueous | 40 | Distilled water or water of equivalent quantity | A | 10 days | 3 | |
| | 38 | | | 60 | Distilled water or water of equivalent quantity | A | 10 days | 3 | 111 |
| | 39 | PE EVOH | Acidic | 40 | 3% Acetic Acid (w/v) in aqueous solution (using simulant A) | В | 10 days | 3 | |

| | 40 | | | 60 | 3% Acetic Acid (w/v) in aqueous solution (using simulant A) | В | 10 days | 3 | 117 |
|----|----|---------|---------|----|---|---|------------|---|-----|
| | 41 | PE EVOH | Fatty | 38 | n heptane -freshly distiiled before use | D | 30 min | 3 | |
| | 42 | | | 45 | n heptane -freshly distiiled before use | D | 30 min | 3 | |
| | 43 | | | 55 | n heptane -freshly distiiled before use | D | 30 min | 3 | 126 |
| 13 | 44 | СРР | Aqueous | 40 | Distilled water or water of equivalent quantity | A | 10 days | 3 | |
| | 45 | | | 60 | Distilled water or water of equivalent quantity | A | 10 days | 3 | 132 |
| | 46 | СРР | Acidic | 40 | 3% Acetic Acid (w/v) in aqueous solution (using simulant A) | В | 10 days | 3 | |
| | 47 | | | 60 | 3% Acetic Acid (w/v) in aqueous solution (using simulant A) | В | 10 days | 3 | 138 |
| | 48 | СРР | Fatty | 38 | n heptane -freshly distiiled before use | D | 30 min | 3 | |

| | 49 | | | 45 | n heptane -freshly distiiled before use | D | 30 min | 3 | |
|----|----|-------------------------------|----------------------------|-----|---|---|--------|---|----------|
| | 50 | | | 55 | n heptane -freshly distiiled before use | D | 30 min | 3 | 147 |
| 14 | 51 | Laminate with sealant film | Pickles - Hot fill | 100 | 3% Acetic Acid (w/v) in aqueous solution (using simulant A) | В | 2 hr | 3 | |
| | 52 | Laminate with sealant film | Pickles - Hot fill | 60 | 3% Acetic Acid (w/v) in aqueous solution (using simulant A) | В | 10days | 3 | 153 |
| 15 | 53 | Laminate with Sealant film | Fruit juices - Hot fill | 100 | 3% Acetic Acid (w/v) in aqueous solution (using simulant A) | В | 2 hr | 3 | |
| | 54 | Laminate with Sealant film | Fruit juices - Hot fill | 60 | 3% Acetic Acid (w/v) in aqueous solution (using simulant A) | В | 10days | 3 | 159 (53) |
| | | | | | | | | | |

Guidelines : Test Method : 1. Simulant Selection IS 9845 2. Worst Case EU 10/2011 Contact time and Temperature