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Food Contact Materials controls in India

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1

Summary of Topics

- Food Contact Materials
- Food Framework Law in India
- FSSAI Notification
- Food Safety and Standards Packaging Regulations 2018
- Key BIS standards in Plastics
 - Example: Polyethylene
 - Colorants in plastics in contact with Food.
 - Laminating Adhesives
 - Printing Ink
- Key issues
- A possible way forward



2

Food Contact Materials

Food Contact substance (FCS)

- A single substance, such as a polymer or an antioxidant in a polymer
- Reasonably pure (even though a polymer may be composed of several monomers, it still has a well-defined composition)

Food Contact Material (FCM)

- Made with the FCS and other substances
- Often a mixture, such as an antioxidant in a polymer (The composition may be variable)

Food Packaging Material Type

- Materials such as cardboard, paper, glass, metal, plastic, multi-layer packaging material used for packaging of food products.*
- Primary food packaging: packaging material in direct contact with food products*
- Secondary food packaging: packaging material which encloses the primary food packaging and does not come in direct contact with food products*

Food Contact Article

- Finished film, bottle, tray, or whatever that is formed out of the FCM.

*Source: Food Safety and Standards (Packaging) Regulations, 2018 (India)



3

Food Framework Law in India

Food Adulteration Act (Act 37 of 1954) & Adulteration Rules 1955

- Adulterant approach
- Food adulteration if use or process
 - endanger human health
 - result in an unacceptable change in the composition of the food or the organoleptic characteristics
 - result in any sensory change
 - does not conform to the quality demanded by the purchaser and is to his prejudice
 - is not of the nature, substance or quality which it purports or represented to be

Food Safety and Standards Act, 2006 (Act 34 of 2006)

- The Indian government's goal
 - Integration and consolidation of pre-existing food laws and standards into a single, science-based regulatory scheme
 - To encompass the manufacture, storage, distribution, sale and import of food,
 - To ensure the safety of materials that may contact food intended for human consumption
- Creation of Food Safety Standards Authority of India (FSSAI)



4

FSSAI Notification Areas

- Legislative Title Areas
 - Contaminants, Toxins and Residues
 - Food Products Standards and Food Additives
 - Laboratory and Sample Analysis
 - Licensing and Registration of Food Businesses
 - Packaging and Labeling
 - Food Safety and Standards (Packaging and labelling) Regulations, 2011
 - Food Safety and Standards (Packaging) Regulations, 2018
 - Food Safety and Standards (Labelling and Display) Regulations, 2019
- Prohibition and Restriction on Sales



5

Food Safety and Standards (Packaging) Regulations, 2018

- Every food business operator shall obtain the certificate of conformity issued by NABL accredited laboratory against these regulations for the packaging material which comes in direct contact with food or layers likely to come in contact with food to be used.
- Provided where Indian Standards are not available, then relevant International Standards may be complied with.
- Plastics
 - IS 9845 OML 60mg/kg or 10mg/dm²;
 - Table 1 SML listed for some metals and metalloids.
 - IS 9833: Colorants in plastics
 - IS15495: Food Packaging inks to conform
- Three Packaging Materials types: Bureau of Indian Standards (BIS)
 - Schedule 1: Paper and board material
 - Schedule 2: Metal and Metal Alloys
 - Schedule 3: Plastic Materials
- Suggested packaging materials for certain product categories



6

Some Key BIS Standards on Plastics

| | | |
|----------|------|---|
| IS 10146 | 1982 | Polyethylene for its safe use in contact with foodstuffs, pharmaceuticals and drinking water |
| IS 9843 | 1991 | Code of practice for use of adhesives for packaging |
| IS 9845 | 1998 | Determination of overall migration of constituents of plastics materials and articles intended to come in contact with foodstuffs |
| IS12229 | 2013 | Positive list of constituents of polyalkylene terephthalates (PET and PBT) for their safe use in contact with foodstuffs, pharmaceutical and drinking water |
| IS 9833 | 2018 | Colorants for use in plastic in contact with foodstuffs and pharmaceuticals |
| IS 15495 | 2020 | Printing Ink for food packaging - Code of practice |



7

FCM controls in packaging in India

- Substances used in a coating in direct contact with food. **ResAP(2004)1**
- Substances used in the barrier.
 - Absolute barrier (such as glass etc.)
 - Functional barrier
 - Plastics: **EU 10/2011**
 - In India it goes by each type of plastic. PE/PET/...
 - Paper and paperboard: A Positive list is wip in EU **2007/42/ec.**
 - Active and intelligent materials **EC 450/2009**
 - Colorants EU: **Criteria ResAP(89)1**; India: **IS 9833 (2018)-Positive List**
- Substances used across the functional barrier. Like printing inks.
 - **Swiss Ordinance (817.023.21); ResAP(2005)2 (wip in the EU)**
 - **India: IS15495-2020 Printing Ink for food packaging - Code of practice**
- Substances used in secondary packaging. (Permeation/Incidental contact with surface inks)
 - **India: IS15495-2020 Printing Ink for food packaging - Code of practice**

Migration

- Ficks Migration
- Set off
- Permeation
- Incidental surface contact

Applicable to Europe.

Applicable to India



8

FCM example: Polyethylene Key BIS certification

- BIS mandatory certification for LDPE, LLDPE, HDPE.
 - Bureau of Indian Standards (Conformity Assessment) Regulations, 2018
 - Polyethylene Material for Molding and Extrusion (Quality Control) Order, 2021 EIF: October 13, 2021
- BIS certification for LDPE, LLDPE, HDPE
 - Residues including catalysts (NIAS) and impurities.
 - Colorants IS 9833
 - Antioxidant, secondary antioxidants.
 - Waxes including amide waxes
 - Haze agents, extenders, nucleating agents
 - Migration limits as per foods intended
 - Marking including ISI mark.
 - Sampling



- IS 7328 2020 PE for molding and extrusion
- IS 10146 (1982) Polyethylene for its safe use in contact with foodstuffs, pharmaceuticals and drinking water;
- IS 16738 : 2018 Positive List PE/PP foodstuff, pharma and DW.
- IS 2508 (1984): LDPE
- IS 14500 (1998): LLDPE
- IS 10889:2004 HDPE



9

Colorants for Use in Plastic: IS 9833 (2018)

- IS 9833 (2018)
 - Pigment quality tests like AP(89)1. Carbon black free from PAH with using BaP as marker.
 - Pigments listed by CI Number

THE CONTEXT

- France Circulaire N0 176 Du Decembre 1959 relative aux pigments et colorants des matières plastiques et emballages.
- Germany BfRIX. Colorants for Plastics and other Polymers Used in Commodities.

- Remark
- Colorants used to color foodstuffs may be technically unsuitable for coloring plastics. Colorants are required to withstand temperatures ranging from approximately 150° to 300 C while the plastic is being processed.



10

IS9843-CODE OF PRACTICE FOR USE OF ADHESIVES FOR PACKAGING

- Table 1: Classification of Adhesives by chemistry
- Annex A: Cross links to BIS standards
- Annex B: Adhesives by Application
- Revamp on anvil (work in progress)
 - Workplace requirements
 - Migration Limits Food Packaging
 - Special controls by use: Retort and Lidding



11

Food Packaging Inks –practical compliance in India

- Framework Law (Incorporates a duty-of-care) FSSA 2006
- Good Manufacturing Practices;
 - Converters and Food Business Operators.
 - IndiaHACCP
 - EUPIA GMP for ink makers 4th Edition.
- LISTS
 - IS 15495-2020 Printing Ink for food packaging - Code of practice
 - Positive Lists: Swiss Ordinance 817.023.21 Annex 10; All ingredients MUST be listed here.
 - Negative List: Japan Printing Ink Makers Association 2017
 - Special Lists: California Prop.65; Nestle; Perfetti etc.
- Solvent Retention: ASTM: F1884 – 04; EN 13628-1 and EN 13638-2
- Worst Case Calculations (WCC)
- Migration: By computer simulation, by experiment
 - Migration across functional barrier EN 1186 & EN13130; IS 9845 OML/SML
 - Permeation: Like Nitrosamine and formaldehyde permeation
 - Set off: Visible and Invisible testing.
 - Surface Ink Testing EN71
- Workplace controls for solvents, uv monomers and isocyanates.
 - COSHH Essentials.
 - India Factory Act 1948 Schedule II Section 41F



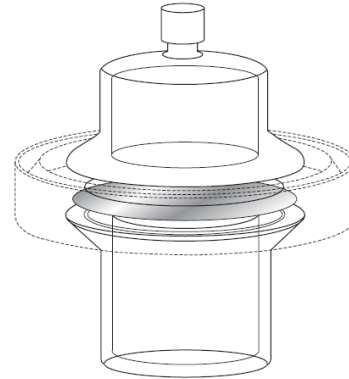
12

Migration Testing

- Food simulant (Tenax for dry foods)
- Time
- Temperature

| Food Simulant | Abbreviation |
|--|------------------|
| Ethanol 10 % (v/v) | Food simulant A |
| Acetic acid 3 % (w/v) | Food simulant B |
| Ethanol 20 % (v/v) | Food simulant C |
| Ethanol 50 % (v/v) | Food simulant D1 |
| Vegetable oil (*) | Food simulant D2 |
| poly(2,6-diphenyl-p-phenylene oxide), particle size 60-80 mesh, pore size 200 nm | Food simulant E |

| No | Food Category | Food Simulant |
|----|--|----------------|
| A | Non acid (pH > 5.0) | Water |
| B | Acidic (pH <= 5.0) | 3% Acetic acid |
| C1 | Alcoholic beverages < 10% | 10% Ethanol |
| C2 | Alcoholic beverages > 10% | 50 % Ethanol |
| D | Oils and fats, aqueous and non-aqueous with free oil or fat including water in oil emulsions | n-Heptane |



Glass migration cell for one-sided contact (courtesy FABES, Munich).

$$D = D_0 \cdot e^{\frac{-E_A}{RT}}$$

D - diffusion coefficient [cm²/s]

D₀ - pre-exponential factor
E_A - activation energy [J]
R - gas constant [8.314 J/mol K]
T - temperature [K]

Fick's 2nd law of diffusion (one dimensional):

$$\frac{\partial c}{\partial t} = D \cdot \frac{\partial^2 c}{\partial x^2}$$

c - concentration
t - time
x - distance
D - diffusion coefficient



How SMLs are calculated

Chronic toxicity data is evaluated.

Buffers are used to compensate for data quality, vulnerable groups and species used.

Routes of intake are studied.

Intake to food and water and assessed for an 'average individual'.

Assume that 1kg of food is packed in 6dm² of packaging.

Drinking water limits and food migration limits are then calculated..

| Parameter | Value | Units | Reference |
|---|----------|------------------|--|
| Oral Mouse LOAEL | | | hepatotoxicity 5d/w 13 day Ref.: NTP-TR-371,1990 (USA); RTECS #: X55250000; Klimisch 1 |
| 5d/week | 312 | µg/kg bw | |
| LOAEL | 222.8571 | µg/kg bw | |
| uncertainty | 1000 | safety | standard assumption |
| Daily water | 2 | L/person | standard assumption |
| body weight | 60 | kg | standard assumption |
| water ingestion intake | 10% | | |
| other intake | 90% | | |
| food intake of sources other than water | 10% | | |
| water intake | 22.29 | µgm/kg bw | |
| water intake | 1,337.14 | µgm/person | |
| toluene limit water | 668.57 | µgm/L | |
| WHO limit | 700 | µgm/L | |
| Odor threshold | 24 | µg/person | odor threshold toluene |
| food intake | 20.06 | µg/kg bw | |
| food intake | 1.20 | mg/person | |
| | | 1 kg food/person | |
| SML | 1.20 | mg/kg food | |



Printing Ink: IS 15495-2020—Code of Practice

INK categories:

- Inks for direct food contact: Use of food additives and GRAS ingredients
 - Food Packaging Inks used on Primary Packaging with a functional barrier: Annex A conformance
 - Inks for secondary food packaging: Annex A conformance
 - Disposables: Annex A conformance. Visible and Invisible migration. Biodegradability of ink
- Normal and foreseeable conditions of use
 - Communication in supply chain on substance identity and communication to converters and Food Business Operators
 - Responsibilities of ink maker, converter and food business operator

*Migration: Fick's migration, Set off, Permeation, Incidental surface contact



15

IS 15495-2020 Annex A

Changes over IS15495-2004

- 'CONEG' statement inclusion.
 - Excluded by deliberation
 - Titanium acetylacetonate
 - Certain Ortho phthalates
 - Toluene
 - Heavy metals limit procedure corrected to IS 9873-2019 (like EN71-3).
- Interesting substances earlier in the exclusion list
 - Nitrosamines (no details)
 - TDI
 - Vinyl chloride monomer (78/142/EEC)
 - Dioxins (PV-23)
 - Cellosolve



16

Key Issues

Regulation

- GHS: not yet adopted
- Ink Exclusion laws: difficult to implement for inks and coatings
- No guidelines to mixtures
- Substance Identity: not universally followed
- NLS and NIAS concerns: not easily addressed
- Traceability: difficult to address.
- Confidential Business Information: Important to specialty chemicals

Market

- Regulation issue to export: The Indian diaspora in Africa, South Asia, Europe and the Middle East
- "Anybody who intends to export wastepaper to India will have to comply with our strict regulations," said Sujeet Samaddar, from Niti Aayog, India's top planning body that is now formulating a national recycling policy. (BBC March 2019)

Standards

- 'Indian National Strategy for Standardization Evolving a Quality Ecosystem' 2018 CII: a policy to upgrade its standards
- The operational system yet to be fully implemented



17

Recycled plastics in food packaging

- Food Safety and Standards (Packaging) Regulations, 2018. Recycled plastic Not allowed in Food Packaging
- Plastic Waste Management (Second Amendment) Rules, 2021 September 17th 2021, Recycled Plastic allowed in Food Packaging.
- Food Safety and Standards (Packaging) Regulations 2022: With immediate effect... products made of recycled plastic may be used for packaging, storage, carrying & dispensing food products...as and when standards and guidelines are framed by FSSAI. Guidelines for PET are detailed in Annex 1.



18

Food Safety and Standards (Packaging) Regulations 2022

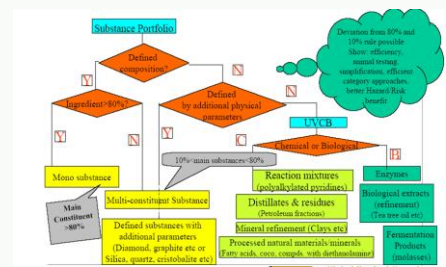
- Currently much PET is downcycled into textiles in India.
- Guidelines in Annexure I include:
 - Main focus is PET bottles but legally could be flexible packaging also.
 - Requires source and purity of the recycled components. Does not permit PET bottles used in Industrial (non food context) to enter food PET packaging recycle chain.
 - Processing: Discusses Super Clean Recycling Process. Discusses Process Validation. Conventional recycling prohibited in food applications. Discusses hybrid recycle using mechanical and chemical recycling (glycolysis)
 - Testing: Discusses Challenge Test system, Extraction Tests and Migration Tests.
 - Declaration: By the Business Operator AND by a Regulatory Authority like the EU/US FDA.
 - Documentation. PERFORMA for rPET is stated in the notification.
 - **Recyclers need Registration and Authorization. In India the informal sector is often involved in recycle. No mention of conversion to the formal sector via co-operatives etc.**
 - **Does not discuss sandwiching of rPET using vPET.**
 - **Does not discuss advanced recycling of hydrocarbon polymers, yet.**



19

A Possible Way Forward: Food Packaging Inks

- Substance Identity (Awaits ICMSR-20XX)
 - Adoption of Exclusion Rules similar to EUPIA. Awaits GHS implementation.
 - Adoption of GHS criteria for mixtures. Awaits GHS implementation
 - NIAS and NLS Similar to EUPIA guidelines. Awaits GHS implementation
- UV based inks.
- **Offset lithographic inks used in food packaging.**
 - Mineral oils MOAH and MOSH
 - Cobalt siccative 50ppb Co SML (No. 535 Food Safety and Standards (Packaging) Regulations, 2018)
 - Odor due to certain vegetable oils.
- NCO and PAA
- Solvent Retention
- IS 9845 (1998): concerning OML/SMLs.



20

Possible Adoption of Exclusion Criteria of EUPIA (GHSRev8)

GHS Red: Not permitted; Blue: With communication and risk assessment; Black: Dried ink expected to conform

H350: May cause cancer

H340: May cause genetic defects

H360: May damage fertility or the unborn child (threshold)

H330: Fatal if inhaled

H331: Toxic if inhaled

H311: Toxic in contact with skin

H301: Toxic if swallowed

H310: Fatal in contact with skin

H300: Fatal if swallowed

H370: Causes damage to organs

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled

H317: May cause an allergic skin reaction

H372: Causes damage to organs through prolonged or repeated exposure



21

Summaries

- Food contact materials and articles (FCM) in India are regulated by:
 - Food Safety and Standards (Packaging) Regulations, 2018
 - Food Safety and Standards (Labelling and Display) Regulations, 2019
- The competent authority: Food Safety Standards Authority of India (FSSAI)
- Compliance advices for food business operators:
 - Allowing the use of appropriate International Standards where Indian Standards are not available
 - Certificate of conformity issued by National Accreditation Board for Testing and Calibration Laboratories
 - Prohibition of recycled plastics for the manufacture of FCM?



22

Thank You.

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