

Regulatory Developments in India

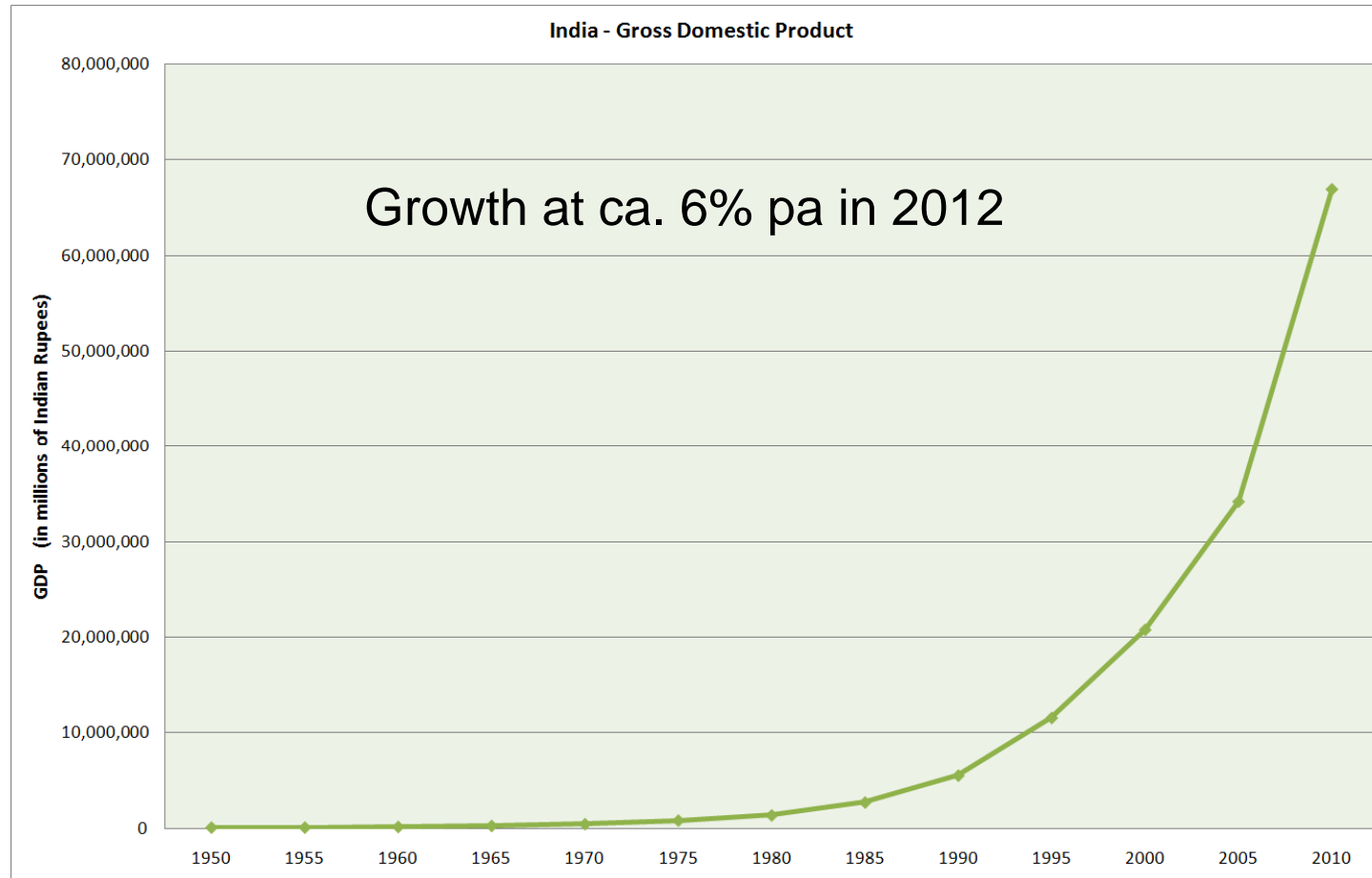
Alistair Irvine,
Smithers Pira
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Introduction

- Background
- New Regulatory Framework
- Pre-existing Standards
- New Draft Standards
- The Future

India; A fast growing economy



Source: www.wikipedia.org

India: Still Developing

Guest post: how fridges will transform India's milk market – and change lives

Apr 23, 2013 9:14am by beyondbrics

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By Tassos Stassopoulos of AllianceBernstein

Evolving trends in emerging markets are not always driven by macro-economic policies or demographics. Sometimes, something as simple as a fridge can change millions of people's lives and re-define an entire industry.

This is exactly what's happening in India's milk market. The world's second most-populous nation is also the world's largest market for milk, yet less than 20 per cent of households own a fridge. The popularity of the white stuff in India, combined with the proliferation of refrigerators from a very low base, are perfect conditions for a milk boom, driving by the unique consumer situation in this market.

Financial Times Web Site Apr 23, 2013

A Sense of Perspective

- It is clear that India is developing fast with a rapid process of urbanisation and is also looking outwards at a global market.
- There are some great opportunities for packaging companies.
- However, since only 20% of households have a refrigerator, bacterial contamination will remain the primary concern with packed foods and you would expect this to remain the primary focus of the Indian regulator.
- 10 ppb of NIAS simply doesn't pose the same sort of risks to the consumer as Campylobacter or E Coli (157).
- The same point applies in the EU. After all in the UK (where almost all houses have a refrigerator) there are over a million cases of food poisoning each year, 20,000 hospitalisations and 500 deaths. This costs the UK economy £1.5 billion each year.
- Not to mention the presence of IAH in foods (Intentionally Added Horsemeat)!

- India has recently carried out a revision of its food laws and repealed old legislation.
- Key items of legislation now;
 - Food Safety and Standards Act, 2006
 - The Standards Weights and Measures act, 1976 together with The Standards W&M (Enforcement) Act of 1985.
 - Food Safety and Standards (Packaging and Labelling) Regulations, 2011
- Standards for food contact materials laid out by Bureau of Indian Standards.



FSS (Packaging and Labelling Regulations) 2011

- Chapter 2 requires that food packaging materials should conform to The specifications of Indian Standards
 - Plastic materials (general)
 - Specific plastic materials.
 - Paper and board
 - Metals (Tin, Aluminium)
 - Glass
 - Food Specific Packaging (e.g. milk, oils/fats, fish, meat etc)

Responsibilities

- Food Safety and Standards Authority of India is responsible for the Food Safety Laws and Regulations
- The Bureau of Indian Standards is responsible for generation and maintenance of standards.

What has changed from the previous legislation?

- Centralised Control
- Regulations structured so that they can be updated more easily.
- Prosecution – penalties, authority and time frames defined
- Encourages self regulation, training and awareness
- Puts in place recall procedures.

Development of New Standards

- If you have a novel material not covered by existing national standards
 - Apply for a new standard via FSSAI
 - FSSAI will determine whether a new standard is required
 - If this is the case, development will be delegated to BIS.
 - From past experience of standards bodies (e.g. CEN), we know that development of standards may take some time!

India – Key Standards (A flavour)

IS No	Topic
9833:2001	List of Pigments and Colorants for use in plastics in contact with foodstuffs, pharmaceuticals and drinking water
9845:1998	Method of Analysis for determination of specific and/or overall migration of constituents of plastics materials and articles intended to come into contact with foodstuffs
2798:1998	Methods of test for plastic containers (1 st revision)
10171:1999	Guide on Suitability of Plastics for food packaging (2 nd revision)
10141:2001	Positive List of constituents of polyethylene in contact with foodstuffs, pharmaceuticals & drinking water
10146:2004	Specification for polyethylene in contact with foodstuffs, pharmaceuticals & drinking water
	And So on for PS, PVC, PP, PET etc

IS 10171:1999 (Reaffirmed in 2004)

- List of packaging materials considered as suitable for packaging of various classes of foods broken down by food type, plastic type and packaging type. For example, LLDPE, LDPE, HDPE, PP and Nylon are considered as suitable for manufacturing bags (plain or paper coated) for use with Tea.
- Reference to other standards for overall migration and for individual plastics (e.g. PE).
- Prohibition on use of recycled plastics in food contact.

IS 10141:2001 (Reaffirmed in 2007)

- Positive List of Constituents of PE in contact with foodstuffs, pharmaceuticals and drinking water.
- Covers LDPE, MDPE, HDPE and LLDPE
- Limit of 0.2% for ethylene and other hydrocarbons from ethylene and comonomer stock, aldehydes, ketones and organic peroxides etc.
- Limits on residues of Ca, Al, Si, Ti, Mg, Cr and other metals
- Limits on peroxides and other substances including catalyst residues
- Pigments to comply with IS 9833
- Positive List of additives (Irganox 1076 < 0.25%, GMS < 3%)

India – Other Standards

- Paper and Fibreboard (7 separate standards)
- Metals
 - IS 8221:1976 on corrosion prevention
 - IS 9991:1981 - Condensed milk tins
 - IS10339:1998 – Edible Oil Tins
 - IS 8970:1991 – Aluminium foil laminates for packaging (1st revision)
 - IS 8971:1978 - Paper aluminium foil laminates for general packaging
 - IS3603:1988 1998 Seamless aluminium bottles
- Glass (2 standards on milk bottles and glass containers)
- IS10106:1990 (Part 1/Sec 1) Packaging Code. Part I Product Packaging, Sec 1 Foodstuffs & Perishables). Split up into individual food types.

Indian Standards On-Line

- Available on-line from <http://www.standardsbis.in/Gemini/home/Home.action>
- Have a credit card available and around 30 minutes to work through all the stages and download the viewer.
- The two standards I downloaded cost 2100 Rupees each (around €25-30 per standard)
- Had I been based in India, the cost would have been 210 Rupees each.

Draft Standards

- During 2012, 4 draft amendments to the Indian packaging standards were published;
 - Amendment No 1 to IS10909:2001 (PP)
 - Amendment No 1 to IS 10141:2001 (HDPE)
 - Draft Amendment No 2 to IS 12229:1987 (PET and PBT)
 - First Revision of IS9833:1981 (Pigments and Colorants)
- Documents Circulated for consultation with close off dates in July/August 2012.
- Documents have not yet been translated into formal legislation (Decernis).

IS 10141:2001(PE) and IS10909:2001 (PP)

- Draft Amendment No 1 to 10141:2001(PE)
 - 139 Approved additives (all the useful ones)
 - Approved by composition – limits bear a passing resemblance to FDA limits
 - Some end use restrictions (food types, thickness, temperature) depending on which additives used.
- Draft Amendment No 1 to 10909:2001 (HDPE)
 - 143 Approved additives (all the useful ones)
 - Approved by composition – again limits bear a passing resemblance to FDA limits
 - Some end use restrictions (food types, thickness, temperature) depending on which additives used.

IS 12229:1987 (PET and PBT)

- Single clause amendment
 - Permits use of amorphous hydrogenated carbon in coating of PET/PBT containers through dry or wet process to enhance barrier properties with a maximum thickness of 0.15µm

IS 9833:1981 (Pigments and Colorants)

- Positive List Consisting of
 - 85 Organic Pigments
 - 7 Dyes
 - 22 Inorganic Pigments/Alloys
- Purity Specifications partly aligned with Council of Europe Resolution AP(89)1, but with some exceptions;
 - Limit for zinc (max 0.05%)
 - Tighter limits for As (50 ppm), Cr (250 ppm), Sb (250 ppm)
 - Additional limits for 22 Carcinogenic Amines
- Carbon Black < 2.5% in finished article
 - Benzene/Toluene extract < 0.1% (as per EC 10/2011)
 - 3, 4 benzopyrene < 0.01 ppm (EC 10/2011 < 0.25 ppm)

Summary

- India is a rapidly developing economy and the market for packaged foods will undoubtedly grow with it.
- The legislative Framework for Food Packaging has recently been clarified and updated.
- Most of the technical provisions are carried in IS documents.
- The provisions have elements that look like EU legislation (overall migration testing) and others which look like FDA regulations (e.g. Compositional limits for additives).
- 4 of these are currently under revision.
- The work of Standards Bodies (across the globe) is tortuous and slow, so rapid change seems unlikely.