Bio-economy: Perspective from Indian Context

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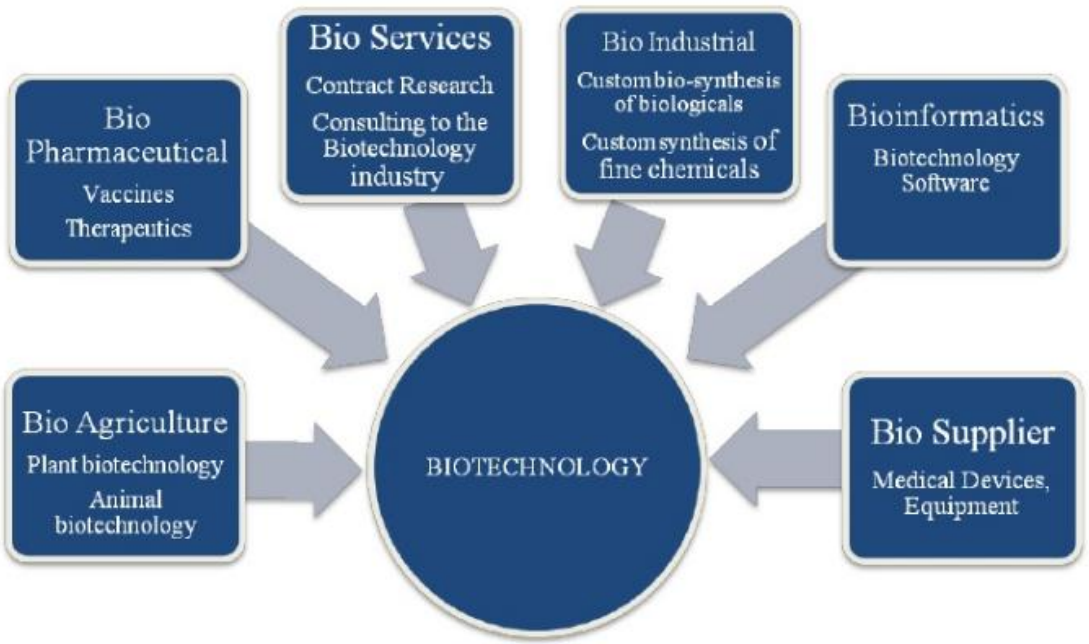
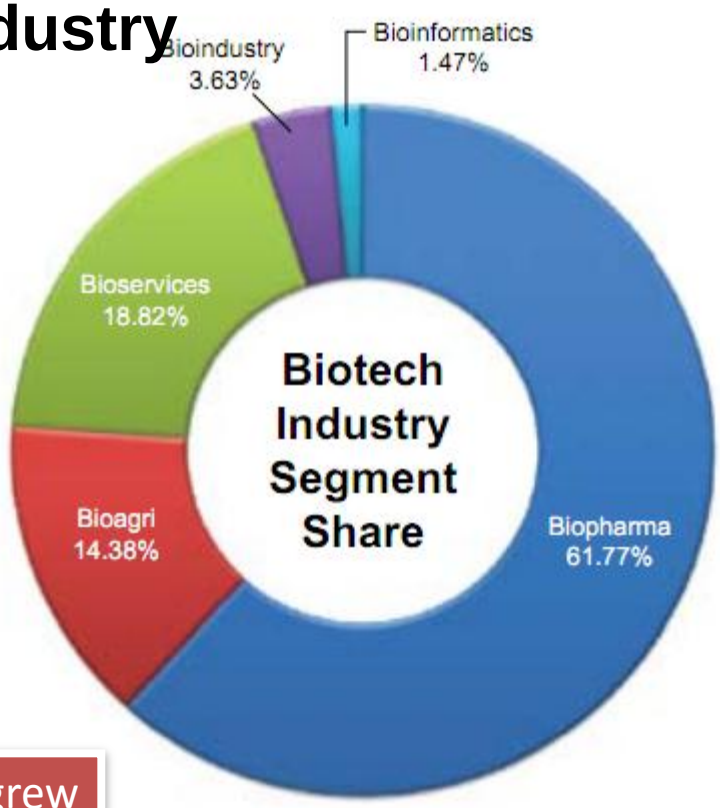
Indian Biotech industry





During the fiscal year 2010-11 the Indian biotech sector grew at 21.5% to reach Rs 17,400 crores in revenues

Source: Biospectrum Vol.9, 2011

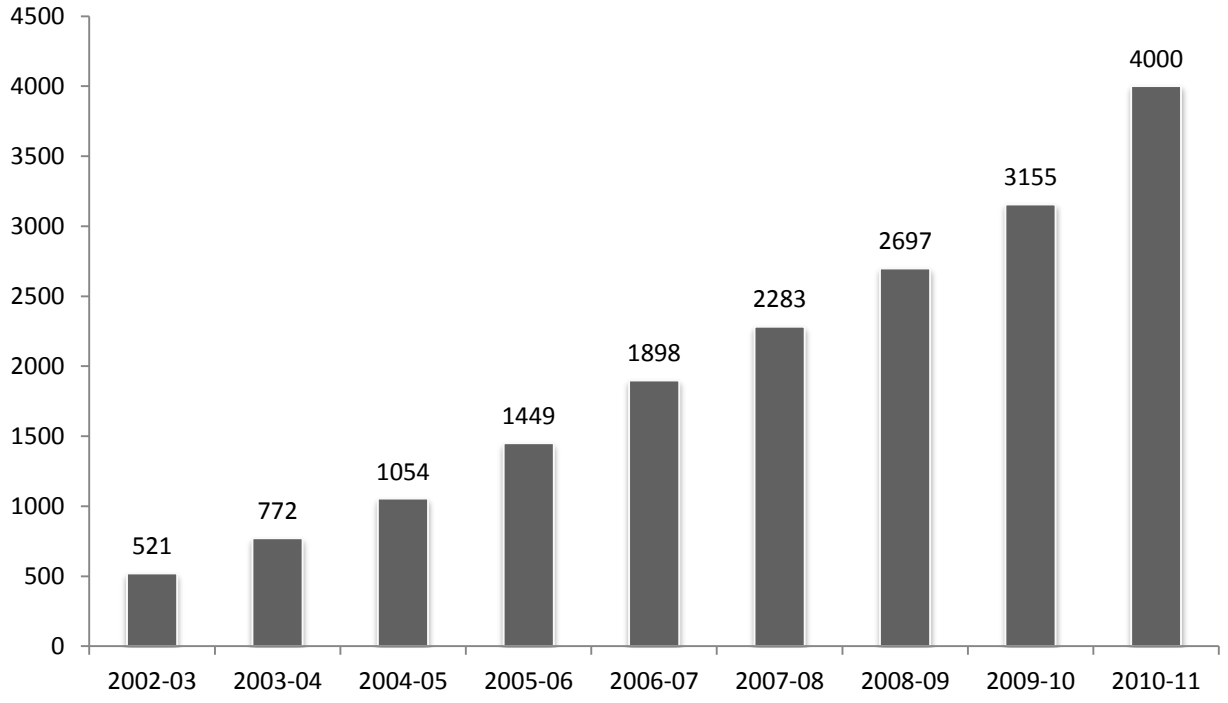
- The biopharma segment continues to maintain dominance, followed by the bioindustrial segment and then by bioagri segment.
- Biocon retained it position at the top of the table in the overall revenue ranking, followed by Serum Institute of India and Panacea Biotec.
- The southern region (Karnataka, Andhra Pradesh and Tamil Nadu) contributed to 44.22% share of the industry, slightly higher than the western region's (Gujarat and Maharashtra) share of 43.60%. The northern region (Delhi, Haryana) chipped in with 12.18%.

Source: Biospectrum-ABLE Biotech Industry Survey 2011

The Growth of Indian Biotech Industry

Growth rate: **20-22%**

Revenue: **US$ 530 m in 2003**
US$ 4 b in 2011



The growth of Indian biotechnology sector from 2003-2011

The Growth of Indian Biotech Industries– Expectations/target - 2025

Growth rate: **25-30%**

Revenue: **US$ 100b**

Indian Bio-economy – the goals for RTD for Biotech sector

- Food security
- Energy security
- Healthcare

Indian Bio-economy-
The Targeted areas for RTD

- Bio-pharma and healthcare
- Bio-services
- Bio-agri
- Bio-industrial
- Bioinformatics & System Biology

Indian Bio-economy: Recommended Guiding Principles

1. Create a strong, streamlined and transparent regulatory foundation that fosters innovation.
2. Reshape and build Government infrastructure to build capacity for research and development and facilitate translation and commercialization potential.
3. Facilitate technology access as well as market access for innovative products to achieve scale through public procurement.
4. Promote biotech entrepreneurship and provide a channel to access risk capital for all stages of biotechnology product lifecycle.
5. Nucleate and foster networks and triple helix collaborations.

Source: ABLE report 2012

Indian Bio-economy: Recommended Guiding Principles

GOI has to make a quick strategy on how to re-vamp the existing regulatory system and make it single window, efficient, transparent and scientific evidence based.

***Source: ABLE report 2012**

BIO-PHARMA & HEALTHCARE

The biopharmaceutical and healthcare sector is the largest component of the biotechnology industry in India. This sector primarily comprises of biologics (especially vaccines and biosimilars), diagnostics, devices, medical informatics, contract manufacturers and healthcare delivery systems.

Bio-pharma and Healthcare

Healthcare at affordable cost

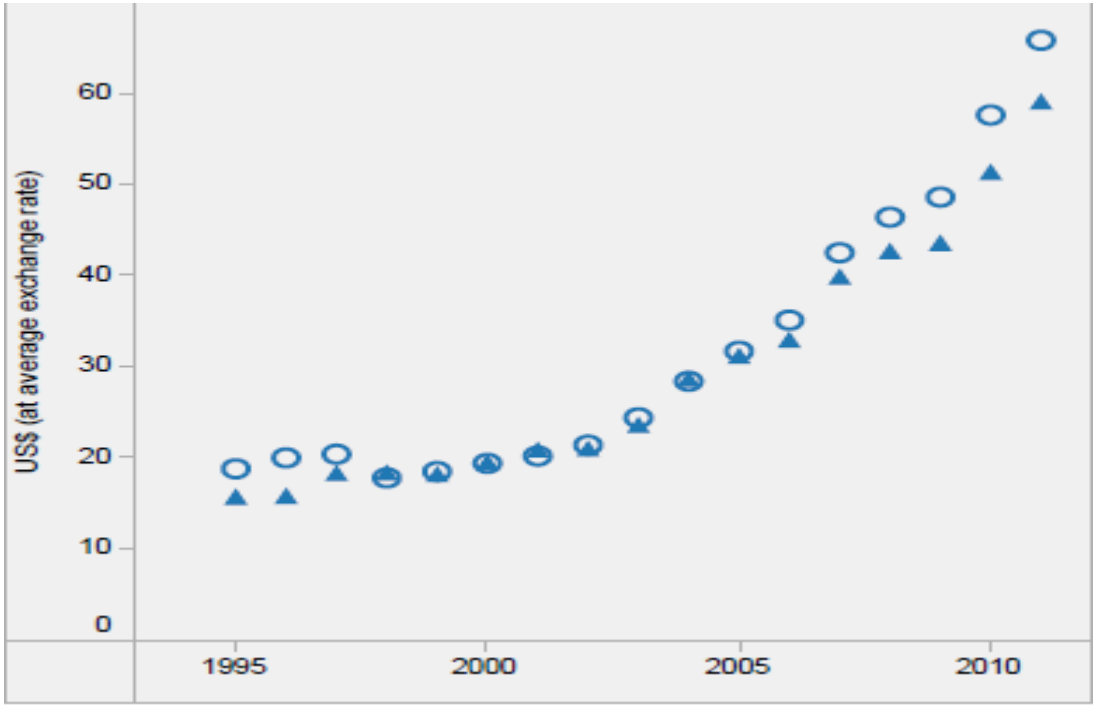


Figure Per Capita total expenditure on health
[http://www.who.int/gho/countries/ind.pdf],

Doctors/Physicians	60 per 100,000 people (PwC report, 2009)
Nurses/Midwives	130 per 100,000 people (WHO estimate)
Pharmacies	367,000 (urban), 185,000 (rural). (PwC report, 2009)
Hospitals	30,000 (67% public; 23% private). (PwC report, 2009)
Hospital Beds	1.7 million. One per 1000 people. (PwC report, 2009)
Health Centers	171,687. (PwC report, 2009)
Population using improved water facilities	~90% (urban); ~80% (rural). (WHO estimate)
Access to improved sanitation	~60% (urban); ~20% (rural). (PwC report, 2009)

Table :Healthcare indicators in India([http://www.who.int/gho/countries/ind.pdf], [PwC report , 2009: Global Pharma Looks into India- Prospects for Growth])

Indian Vaccine Scenario

Growth rate: 10-13%
Market size: 60% of world market in 2011

Indian Vaccine Scenario: Some leading examples

Hepatitis B - Shantha Biotech (1997- 30-times cheaper)

Rotavirus vaccine - Bharat Biotech (US$1)

Vaxi-Flu-S- Cadila Healthcare (2010)

Swine flu vaccine – Serum Institute of India, Bharat Biotech

Indian Biosimilars Scenario-Main Focus

- Human insulin
- Human growth hormone
- Granulocyte colony stimulating factor (G-CSF)
- Erythropoietin
- Streptokinase

Indian Biosimilars Scenario

- **Recombinant therapeutic: available - 25**
- **Recombinant therapeutic: manufactured - 15**
- **Biosimilars companies – 20**
- **Brands of biosimilars commercialized – 50**
- **Leadings companies - Biocon, Shantha Biotechnics, Reliance Life Sciences, Wockhardt, Intas Biopharmaceuticals, Dr Reddy's Lab, Cipla, etc**
- **Recombinant drugs currently undergoing different stages of clinical trials – 72**

Source: Vision 2020: A Biopharma Strategy for India, an ABLE–PwC report for Department of Pharmaceuticals, Ministry of Chemical and Fertilizers, Government of India; ABLE-BioSpectrum Survey, Volume 9, Issue 6, June 2011

Indian Biologics Scenario- Key Challenges

- Lack of GLP Certified protein characterisation facilities
- Lack of Animal testing and breeding facilities
- Lack of extensive Viral Testing Facilities
- Cumbersome Import Regulations for Genetically Modified Organisms (GMOs) and Living Modified Organisms (LMOs)
- Cumbersome approval process for establishing manufacturing sites
- Lack of Biologic Specific SEZ manufacturing policy

Source: Biotechnology-Industry Recommendations to Department of Biotechnology (DBT) for the 12th Plan, A report prepared by Association of Biotechnology Led Enterprises (ABLE), July 2011.**; ABLE-BioSpectrum Survey, Volume 9, Issue 6, June 2011**

Regenerative Medicines
Indian Stem Cell Research Scenario

- About 40 R&D organizations
- Market US $450 million in 2010
- Growth 15%

Source: ABLE-BioSpectrum Survey, Volume 9, Issue 6, June 2011

Indian Stem Cell Research Regulation

- Ministry of Health (Drug Controller General India-DCGI and Indian Council of Medical Research-ICMR)

- Ministry of Science and Technology (Department of Biotechnology- DBT)

Medical Devices, Diagnostics and Imaging- Indian Scenario

Device market- medical instruments (25.1%), orthopaedic and ophthalmic devices (20%), syringes, needles, catheters (12.5%), scanning devices such as X Ray, CT scan (9.5%), electro-medical (10.2%), bandages & other supplies (7.5%), others (15.3%).

US $2.75 billion in 2008 and US $10.7 billion by 2019

Source: Medical Technology Industry in India Riding the growth curve. CII & Deloitte, July 2010

Indian Healthcare - Needs

- Affordable cost
- Diagnostic services
- Healthcare monitoring services
- Wellness services (preventive care)
- Telemedicines

BIOSERVICES: Indian Scenario

- Comprises contract and clinical research organizations (CROs) & contract manufacturers (CMOs)
- second largest sector of the biotechnology industry
- Growth (2010-11) – 23%
- Market revenue – US$ 721 b
- Accounted for 19% of total revenue for biotech industry.

Source: ABLE-BioSpectrum Survey, Volume 9, Issue 6, June 2011

BIOSERVICES: Indian Scenario

Leading CROs in India include Quintiles, Syngene International, SIRO Clinpharm and Ecron Acunova, Lambda Therapeutic, Advinus, Aurigene, Jubilant, Sai Advantum, Suven Lifesciences, etc

Around 30 CROs are involved in Bioavailability (BA)/ Bioequivalence (BE) trials and around 50 CROs are involved in Phase I-IV trials.

Source: ABLE-BioSpectrum Survey, Volume 9, Issue 6, June 2011

Contract Manufacturing in Biopharmaceuticals: Indian Scenario

>200 USFDA and UK MHRA approved manufacturing plants.

Source: http://www.icra.in/Files/Articles/CRAMS%20Note,%20Overview%20and%20Outlook.pdf

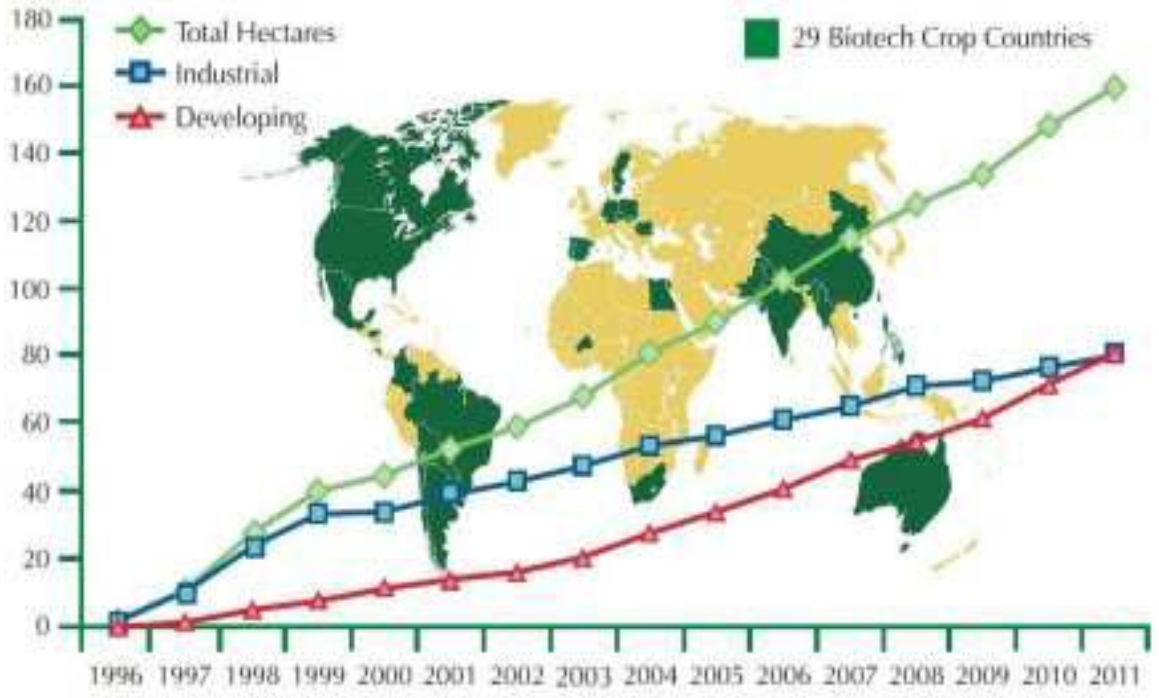
BIO-AGRI: Indian Scenario

- Food production108 mt in the 1970s to 234 mt in 2008-09
- Revenue in FY 2010-2011 US $516.67
- Growth rate ~ 10% over previous year
- India has the world's largest population of undernourished people

BIO-AGRI: Indian Scenario- Major Challene

- **To increase the food productivity the options are:**
  - hybrid technology
  - reducing losses through environmental and pesticide stresses via Marker Assisted Selection (MAS) and genetic engineering techniques.

GM Crops



GM crop acreage in million hectares from 1996-2011

Source: Food Security and AgBiotech News

BIO-INDUSTRIAL: Biorefineries and White Biotechnology

- Bioprocess and product development
  - Enzymes
  - Biofuels
  - Biopolymers
  - Amino acids
  - Organic acids
  - Antibiotics and other drugs
  - Etc

BIO-INDUSTRIAL: Biorefineries and White Biotechnology- Indian Scenario

- Revenue US $130.4 million in 2010-2011
- 3.6% contribution for biotech industries
- Growth rate ~ 10%
- Growth rate predicted to be 15% till 2015

Indian Enzyme industry

- **India** is an **attractive market** with high growth rates in the past years.
- Enzyme use is still in its **infancy** with growing awareness of enzyme potential and benefits providing attractive growth perspectives.
- **Pharmaceutical enzymes** represents most of the industrial enzyme demands in India and cover almost **50 percent** of the total enzyme demand, followed by detergent enzymes (20 percent) and textile enzymes (20 percent).
- Though the **overall enzyme consumption figures of India are comparatively low** with respect to other countries and **60-70 percent of domestic demand is imported**.

The bioIndustrial market in India clocked 625.94 crore in 2010-2011, growing at a rate of 10.98 percent for 2010-2011, as against 564 crore in 2009-2010.

India has a marginal share in the global market for industrial enzymes, which is estimated to be at about $3.3 billion (14,904.4 crore). The segment is forecasted to grow at a CAGR of 15 percent till 2015.

Indian Enzyme industry

- Though there is a prevailing domestic demand, the segment is largely **export driven**. Major export **markets include the US** (global share of 40 per cent), **Europe** (global share 25 percent) **China** (Global share: 20 percent). Others include Rest of Asia (Global share of 15 percent).
- Realizing the potential of the **opportunities outside India**, many Indian companies are expanding their base outside the country even into difficult markets such as China. Advanced Enzymes starting its European and Chinese subsidiaries for market expansion. And this is how the company expects to achieve its 1,000 crore revenue-milestone in the next five years.
- The **investment in research and development** by the Indian companies continues to remain on the conservative side. Few companies have their own R&D and manufacturing set-ups. The common strategy for most of the home-grown companies is to import enzymes from foreign companies and then resell them into the Indian markets.
- India has a **small share in the total global market due to the declining price points** of enzymes every year. The price drop can be as much as 10 percent depending on the type of enzyme.
- MNCs have dominated the market for a number of years, yet the segment is gradually **witnessing the entry of Indian companies**, who are building capacity and capability to compete with the MNCs. With respect to global enzyme industry, India still needs to do a lot of catching up.

Leading players in Indian Enzyme industry

- There are about 20 players in this market.
- Most of these companies are either into marketing or into formulations, and a very few manufacture enzymes .
- The product range and services are growing rapidly as the use of enzymes is gaining widespread acceptance.
- The Indian manufacturers are not only supplying to local market but are also exporting to number of countries.

Major players

- Novozymes - Market share of 50%
- Advanced Enzymes - Market share of 20%
- Rossari Biotech - market share 13%
- Maps (India) - Market share 6%
- Zytex – 3%
- Lumis Enzymes
- Kerry Biosciences
- Richcore Life Sciences
- Anthem Cellutions
- Danisco
- Enzyme Development Corp.
- Dyadic International
- Excel Industries and Concord Biotech
- CHR-Hansen and Quest International

Novozymes in 2007 had acquired the enzyme activities of Biocon Limited, till then was the market leader in India.

Danisco is opening up two new separate manufacturing units for functional systems and for enzymes to serve South-Asian customers. The plant is primarily produce enzyme blends to service the markets of animal nutrition, food and beverages, fuel ethanol, grain processing, laundry detergents and textiles.

Top five companies

Source: Biospectrum

Top 5 BioIndustrial Companies by Revenue (2010-11)

Rank	Company	Revenue in ₹ Crore 2010-11	Revenue in ₹ Crore 2009-10	Revenue in ₹ Crore 2008-09	Change over 2008-09 (%) 2010 (%)	Change over 2009-10 (%) 2011 (%)
1	Novozymes South Asia *	242.00	224.00	205.50	9.00	8.04
2	Advanced Enzymes	154.00	121.00	88.60	36.57	27.27
3	Rossari Biotech*	72.00	55.38	—	—	30.01
4	Zytex	21.00	18.00	14.00	28.57	16.67
5	Maps (India)	19.60	19.10	19.17	-0.37	2.62

1 novozymes Rethink Tomorrow

Established in 1983.
Detergent, food, feed, textile, leather, oils & fats, beverage alcohol, and biofuel industries.
Has over 700 products used in 130 countries. Novozymes has 5,200+ employees working in research, production and sales.

2 advanced enzymes Where ENZYME is Life

Established in 1957.
One of the few manufacturers in the world that produces a full-spectrum of enzymes derived from all four natural origins: plant, fungal, bacterial and animal.
More than 400 unique enzyme products

3

ROSSARI
making you more competitive

Established in 1997. Manufacturer of Textile, Spinfinish, Coning Oils, Sewing Thread Lubricants and Knitting Oil, Construction Chemicals, Laundry Chemicals, Animal HealthCare and nutrition, Pharmaceuticals Products. Manufacturing facility is spread over l0 acres of lush greenery at Village Naroli, Silvassa near Vapi

4

Zytex
Better Technology. Better World.

Established in 1996 starting with textile enzymes; Zytex has established a new manufacturing facility at Savli Biotech Park, Baroda . Today Zytex products are sold for Nutraceutical,Cosmetics, Textile, Ethanol, Animal Feed and Baking industry

5

MAPS

Maps Enzymes Limited
(FORMERLY MAPS (INDIA) LIMITED)

Established in 1975.
Amylases, proteases, cellulases, xylanase, beta glucanase, glucoamylase and Catalase
Sales network spread across 4 continents in 22 countries and a product portfolio of 60+ products for more than 10 different industries

BIO-INDUSTRIAL: Enzymes- CSIR-NIIST Contribution

- CSIR-NIIST has developed and transferred technologies on food grade alpha amylase, xylanase for paper and pulp industry and phytase for feed industry to various industries in India.

- Phytase technology has been scaled-up by the company with the support of DBT under SBIRI scheme.

- We have also undertaken consultancy projects on enzymes to other industries in India.

BIO-INDUSTRIAL: Biorefineries

- Algal Biorefineries
- Paper mills and Wood-based Biorefineries
- Sucrose-based biorefineries: The Sugarcane Value Chain
- Vegetable oil biorefineries
- Biogas biorefineries
- Civilisation Biorefineries: Efficient utilization of urban waste-based bioresources
- Biomass-based biorefineries

BIO-INDUSTRIAL: Biomass-based Biorefineries

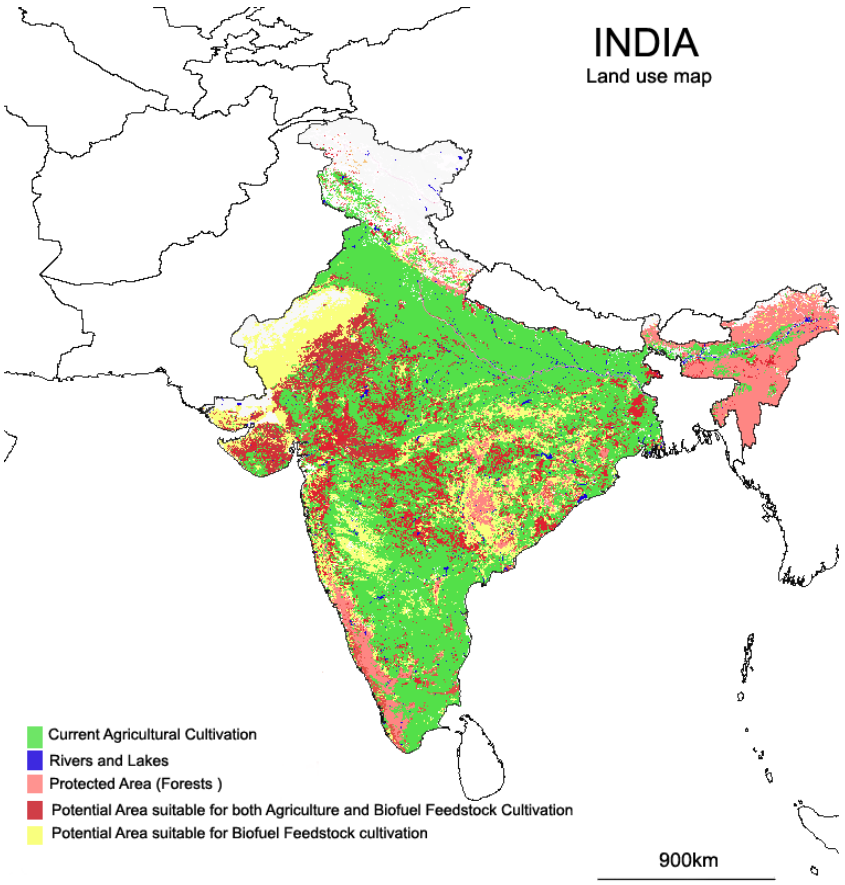
Process:

- Biochemical conversion
- Thermo-chemical conversion

Products:

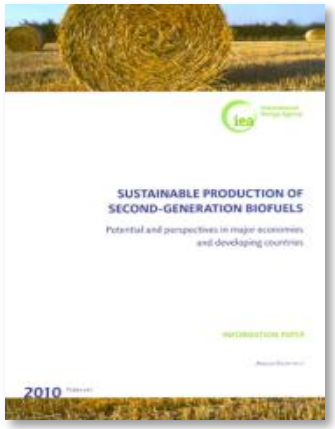
- Bioalcohols
- Biopolymers
- Organic acids
- Other industrial chemicals

Why bioethanol from Agro-residues ?



- India do not have surplus vegetable oil and biodiesel production should depend on imported oil !
- The nation does not have land resources to support the cultivation of oil crops or any energy crops at levels which can meet the production demand !
- India generates ~600 MMT of agricultural residues annually and this could be a potential feedstock for fuel production.

~51 % of the land surface in India is cultivated and the cultivated lands are mostly rain-fed !!!!



Sukumaran & Pandey 2010, India Country report , In: Eisentraut A (ed), Potential for sustainable production of 2nd generation biofuels, IEA 2010

BIO-INDUSTRIAL: Lignocellulose Bioethanol- CSIR-NIIST Contribution

- Survey on the identification of surplus lignocellulosic biomass to determine the potential of production of bioethanol in India.

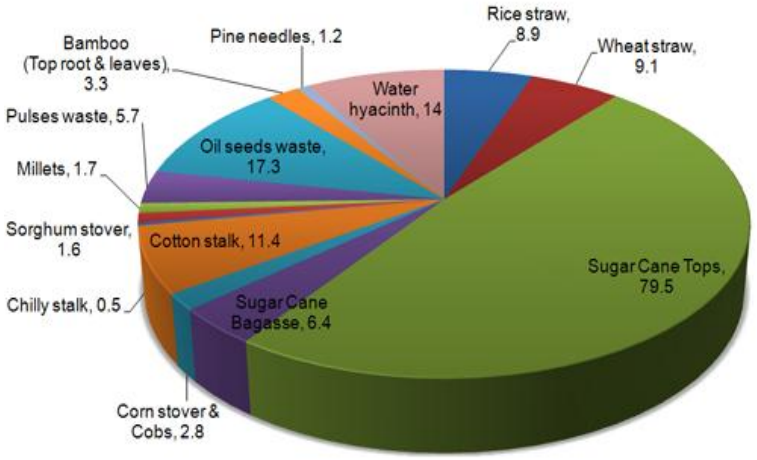
- Identified six Indian biomasses as potential feedstocks for LC bioethanol program.

- Developed enzyme cocktails for de-construction of biomass, with particular emphasis on glucose-tolerant beta glucosidase.

- Developed bioprocesses for C-5 utilization for producing amino acids and biopolymers.

- Established a multi-feed stocks based pilot plant for biomass-based biorefinery.

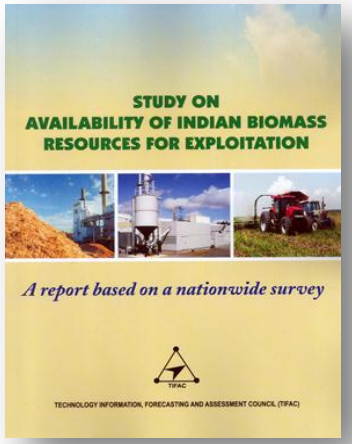
Identification of feedstock to work-on



Annual surplus availability of biomass residues in India (MMT)

- **More than 90% of the cereal crop residues are used domestically !**
- **Surplus residues are sufficient to support projected demand for 2020 even with the most pessimistic conversion figures (Projected Demand for 2017 at 10% Blending = 2.2 Billion L)**

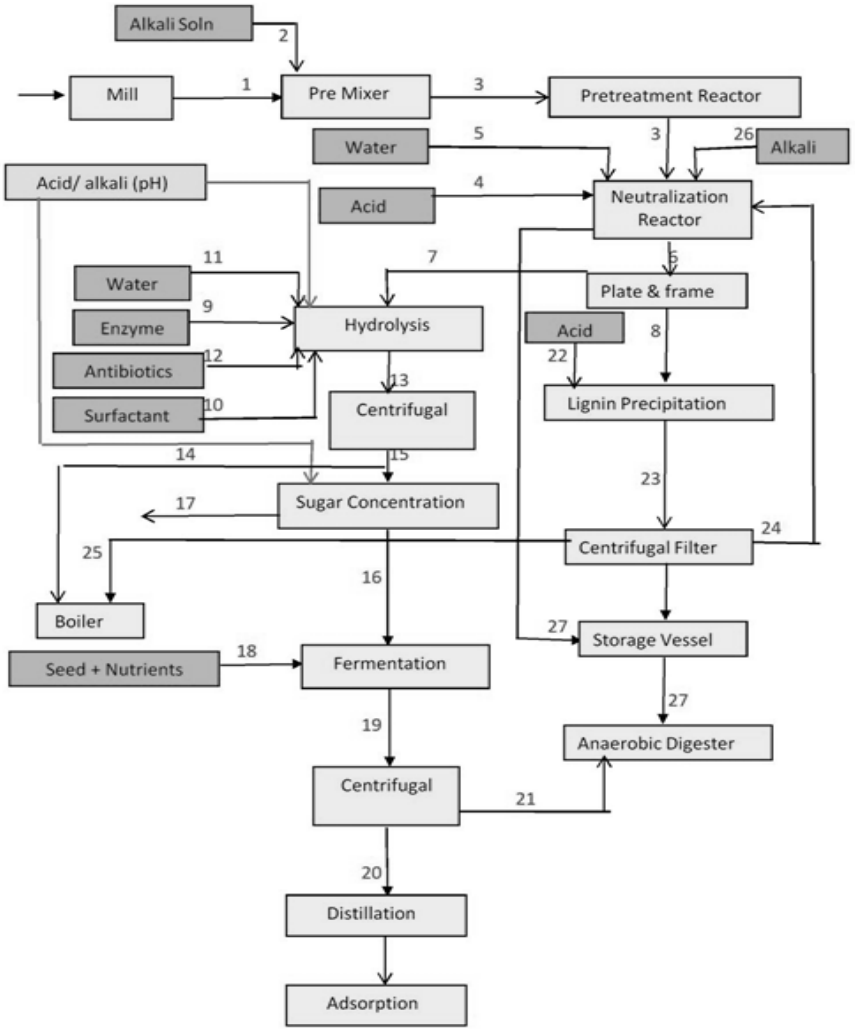
Agro residue	Annual Availability (MMT)	Cellulose (%)	Alcohol - Theoretical Max (Billion L)	Alcohol - Estimated @35% efficiency (Billion L)
Rice Straw	8.9	33	2.11	0.737
Wheat Straw*	9.1	33	2.15	0.754
Bagasse	6.4	40	1.84	0.643
Corn Stover*	1.1	35	0.28	0.097
Sugar Cane Tops	79.5	35	19.96	6.985
Chili PHR	0.5	47	0.17	0.059
Cotton PHR	11.4	31	2.53	0.887
Bamboo	3.3	42	0.99	0.348
TOTAL			**30.03**	**10.51**



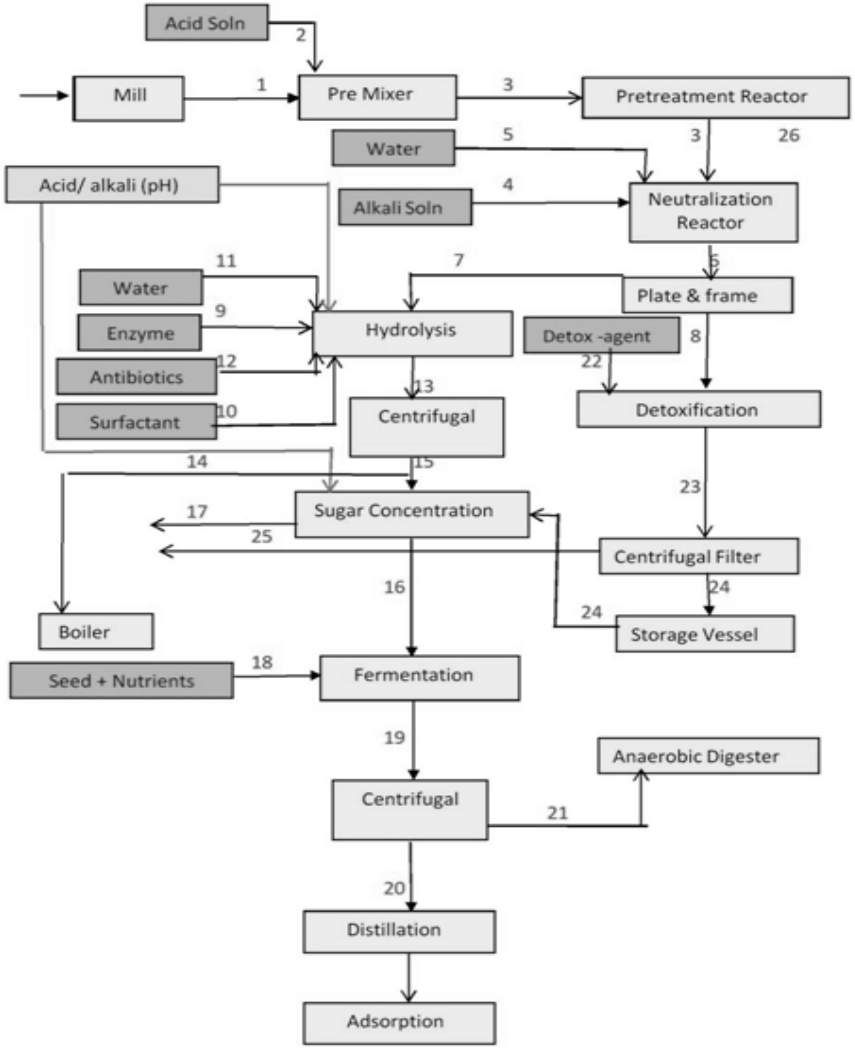
NIIST-TIFAC survey report, 2009

Lab to plant: Design of process-flows and volumes

Alkali pretreatment scheme



Acid pretreatment scheme



Centre for Biofuels






Pilot plant

Bio-economy: Major strengths of India

- **Availability of skilled manpower**

India has the largest English speaking population after US , sciences and engineering streams produce 3 million graduated, 700,000 postgraduates and 1500 PhDs every year. Manpower costs much lower as compared to other nation

- **Highest quality standards in manufacturing**

Outside the US, india has the highest number of FDA approvals in the world-class facilities for manufacturing that comply with glps, cgmps and gcp standards well recognized for low-cost fermentation technology and generics biologicals

- **Genetic profile of Indian population**

Clinical trials can be outsourced to India as the Indian population has the similar genetic profile as the US and European population due to joint Aryan descent.

Indian Bio-industry - Looking forward…

- **Industrial biotechnology has not only gained the recognition it deserves in India, but the years ahead will see more acknowledgement of its strength.**

- **The future major thrust will continue on food security, energy security and healthcare.**

- **An important development occurring is the replacing of hydrocarbon-based materials with bio-based resources. These resources are based on both plant and microbes.**

Indian Bio-industry - Looking forward…

NEW BUSINESS MODELS

COLABORATIVE R&D: **Indian companies partnering with foreign players to enter into collaborative R&D efforts as an initial step towards focusing on R&D.**

NEW REVENUE STREAMS: **Revenues from patent licensing and litigation can redefine existing business models completely and shift them to a higher value generation plan.**

EMERGING BUSINESS OPPORTUNITIES: **India will become a highly lucrative option for contract research once stronger IP protection legislation.**

CAPTURING THE INDIAN: **Indian companies can capture the Indian market by using IP to protect their own innovations.**

Growth of Indian Bio-economy: Needs in Nutshell

- **Industry – Academia- Govt - an effective trihelix for robust bio-economy**
- Industry – Academia interaction to sustainable business – only way to make trihelix a workable proposition
- **Need for both Industry – Academia to change their perceptions of each other**
- Need to create a high interfacial domains to interact and understand intrinsic power and limitations
- **Need for forward looking government policies and science management for national interests**
- Science with passion and realism, not by emotion or for fun

Acknowledgements

- The EU
- SAHYOG Team
- Dr PM Sarma

Questions?