Access and Benefit Sharing

Key Points for Policy-Makers

INDUSTRIAL BIOTECHNOLOGY

THE ABS CAPACITY DEVELOPMENT INITIATIVE

People and Plants international

University of Cape Town · iYunivesithi yaseKapa · Universiteit van Kaapstad

Sarah A. Laird

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SUMMARY OF KEY POINTS

WHAT IS BIOTECHNOLOGY?

- Biotechnology includes a wide range of constantly evolving technologies and activities and is found within almost every commercial sector today. It is divided into three main areas: healthcare, agriculture, and industrial biotechnology.
- Industrial biotech is growing rapidly due to advances in science and technology, concerns over climate change and energy security, and growing interest in more efficient manufacturing processes that use less energy, produce less waste, and result in purer products.

MARKETS, COMPANIES, AND PRODUCTS

- Industrial biotech is employed in virtually every industry today, and yet is largely invisible to the average consumer. Industry sectors include chemicals, plastics, food and feed, detergents, pulp and paper, electronics, automotive, packaging, household products, cosmetics and personal care, textiles, bioprocessing catalysts, and bioenergy.
- Industrial biotech products range from high volume, low value products like biofuels, through to chemical intermediates, bio-plastics, cosmetics and fragrances, up to high value pharmaceuticals and fine chemicals.
- Most industrial biotech products take 2-5 years to reach the market, much shorter than a pharmaceutical which takes 10-15 years. They also cost less to develop, and require less testing for safety and efficacy. Industrial biotech products generate smaller revenues of, on average, between $10-200 million, but companies may market hundreds of products.
- Industrial biotech has received strong government support and incentives around the world, including in the US, Europe, Canada, China, India, Japan, Brazil, and Malaysia. Private investment in much of this sector has also sharply increased in recent years.
- Industrial biotech companies are part of complex, global webs of partnership, investment, and collaboration. These include companies of all sizes and from a wide range of sectors, as well as research institutions and government agencies.

RESEARCH AND DEVELOPMENT

- Most companies access material through internal or external collections, the thousands of genetic sequences in the public domain, or collections in their ‘backyards’. Few undertake collections outside their borders.
- Overseas collections tend to focus on areas with high species diversity, extreme environments, and unique ecological niches. Companies look for organisms that can withstand conditions similar to those of industrial processing.
- Industrial biotech turns microorganisms into biological, or microbial, ‘factories’. The microorganisms are genetically engineered but the final products themselves are not.
- Research and development budgets across biotechnology have increased significantly, with an average of 20% growth per year.
- Advances in science and technology have drastically reduced the time and cost it takes to sequence a gene. The challenge today has moved from data generation (sequencing) to data interpretation (bioinformatics and database technologies).

INDUSTRY AND ABS

- The advanced and complex nature of the science and technology employed has outstripped the ability of many governments to keep pace and effectively regulate industrial biotech. This includes through the Convention on Biological Diversity (CBD) and Nagoya Protocol policy processes.
- Biotechnology creates unique challenges for Nagoya Protocol implementation. In addition to the rapidly changing and sophisticated nature of the science and technologies employed, digital transmission of genetic information and the blending of genetic material obtained from many different countries within a single engineered organism is increasingly common.
- Awareness of the CBD within industrial biotech companies is limited, but growing slowly. Most companies are aware of ‘sustainability’ issues central to their marketing and business model, but do not think ABS applies to them. Some industry groups, however, are developing ABS standards for best practice, hold informational workshops, and provide guidance to their members on ABS and related topics.

WHAT IS BIOTECHNOLOGY?

What is Biotechnology?

The Convention on Biological Diversity defines biotechnology as *any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.*

Bios *Technikos*

Biotechnology includes a wide range of constantly evolving technologies and activities and is found within almost every commercial sector today. It is divided into three main areas: healthcare, agriculture, and industrial biotech.

Healthcare biotechnology

Medicines, diagnostic products, or vaccines that consist of, or have been produced in, living organisms and may be manufactured by recombinant technology.

Agriculture biotechnology

A range of modern plant breeding techniques that include genetic modification.

Industrial biotechnology

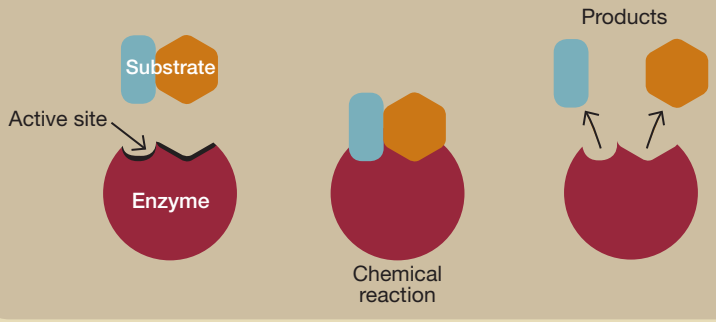
Production of bio-based products from biomass using microorganisms and enzymes.

Industrial biotech has come of age in the last ten years, and is growing rapidly. This is due to advances in science and technology, concerns over climate change and energy security, and growing interest in more efficient manufacturing processes that use less energy, produce less waste, and result in purer products.

Industrial biotech is a migration from traditional petroleum-based processes to engineered fermentation-based manufacturing processes. These are often faster, cheaper, and use fewer resources and less energy than processes dependent upon petroleum.

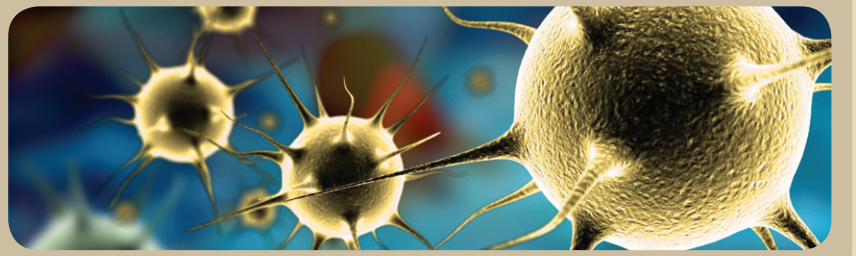
What are enzymes?

Enzymes are proteins produced by a living organism that act as a catalyst for specific chemical reactions. Enzymes are the 'tools of nature', cutting and pasting products, and facilitating and speeding up complex biological processes.



What are microorganisms?

Microorganisms are microscopic single-celled organisms such as bacteria that play a vital role in supporting and maintaining nature and life. They are the most abundant and least understood organisms on the planet. In recent years, advances in science and technology have made it possible to study the 99% of microorganisms previously inaccessible to researchers.



MARKETS, COMPANIES, AND PRODUCTS

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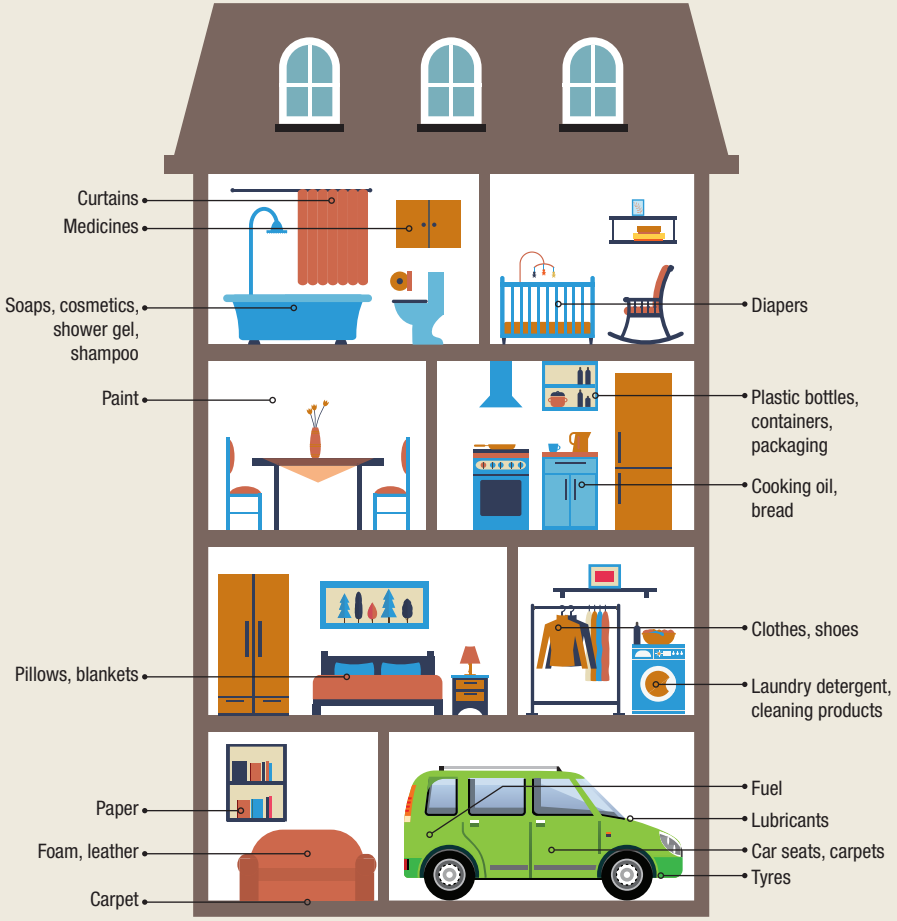
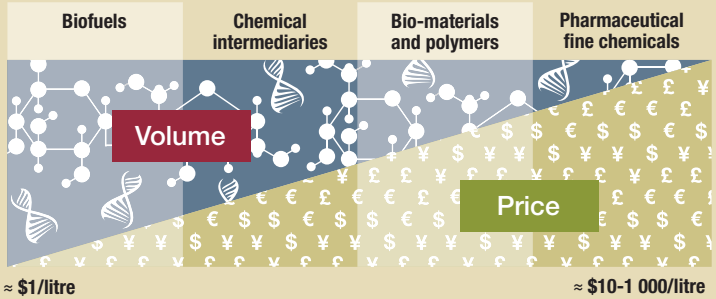
A snapshot of industrial biotechnology in the home



The average developed country home today is filled with products containing biotechnology ingredients, or produced through biotechnology processes.

Industrial biotech products range from high volume, low value products like biofuels, through to chemical intermediates, bio-plastics, cosmetics and fragrances, up to high value pharmaceuticals and fine chemicals.



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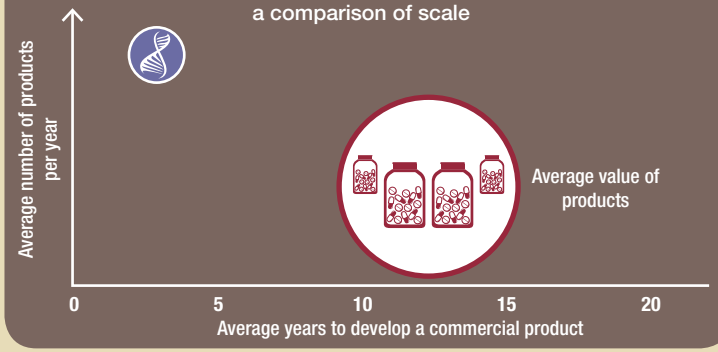
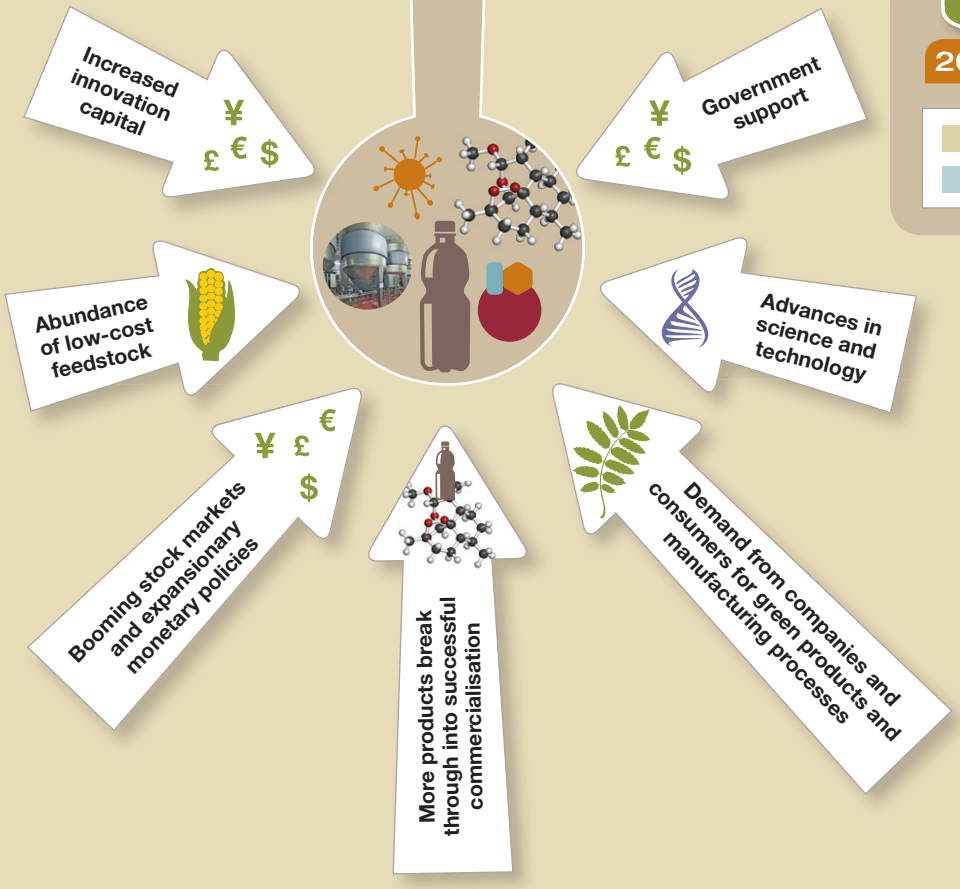
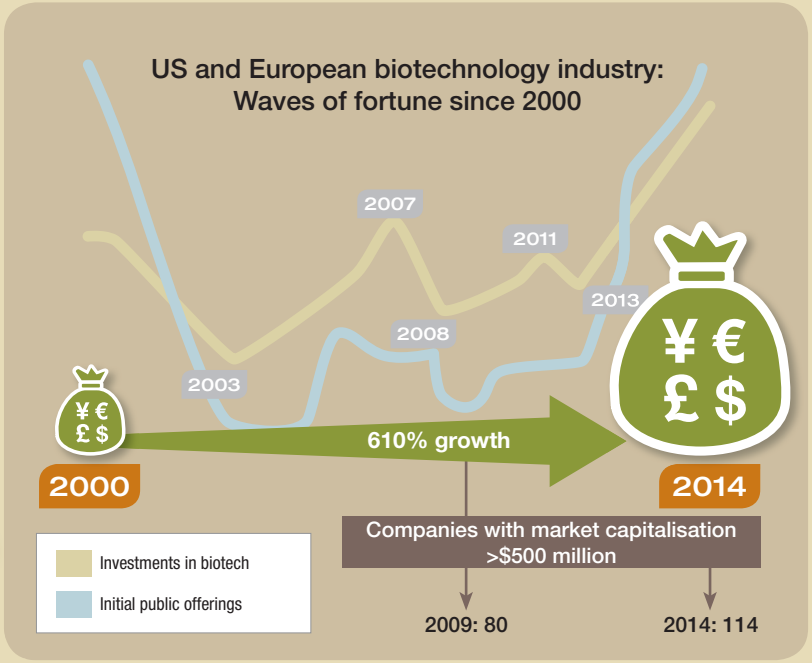
Industrial biotechnology and pharmaceuticals:
a comparison of scale



Drivers of the industrial biotech take-off

In recent years, the fortunes of the biotechnology industry, including industrial biotech, have transformed. Revenues, profitability, capital-raised, and initial public offerings (IPOs) are at an all time high.





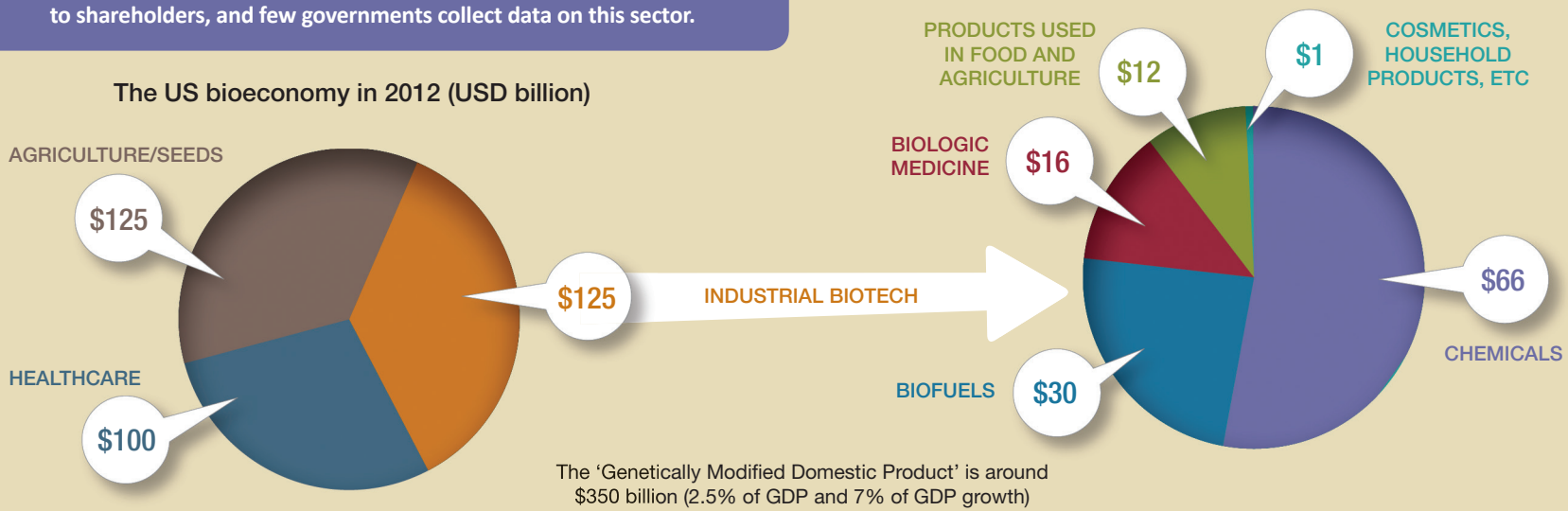
Industrial biotech has received strong government support and incentives around the world, including in the US, Europe, Canada, China, India, Japan, Brazil, and Malaysia. Private investment in much of this sector has sharply increased in recent years. Biofuel was once the primary focus of government and private sector attention, but in recent years biochemicals and biopolymers have also become major areas of public and private investment.

> *…about two thirds of [petroleum derived organic chemicals] can be generated from renewable raw materials, rather than from oil. If so, sustainable chemistry potentially has a market size of about $1 trillion. Less than 7% of organic chemicals are currently produced from renewable materials, thus there is an opportunity for long-term growth.*
>
> – Frederick Frank, Vice Chairman, Peter J Solomon Company

Industrial biotech is extremely difficult to value because industrial biotech processes and products are often neither sold nor patented, and are frequently used internally or sold between companies. Additionally, many companies are privately owned and so do not disclose information to shareholders, and few governments collect data on this sector.

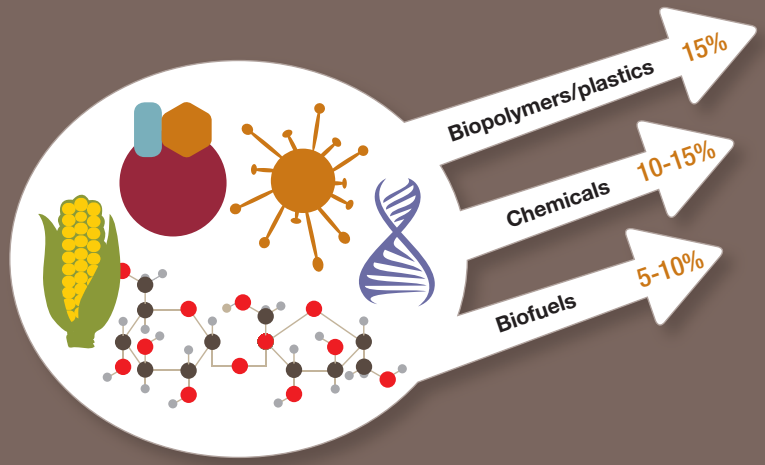
The industrial biotech industry in the US was estimated to be worth roughly $125 billion in 2012, part of a $350 billion bioeconomy.

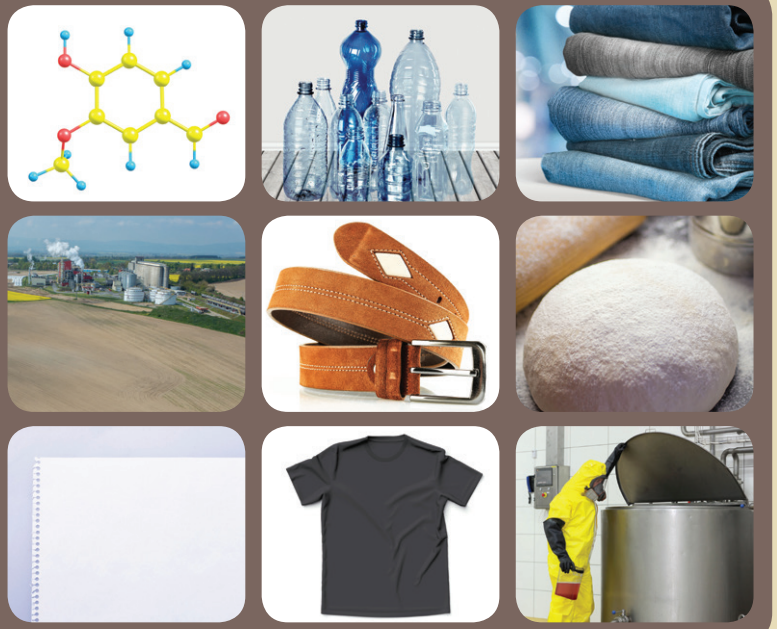
The US bioeconomy in 2012 (USD billion)



The 'Genetically Modified Domestic Product' is around $350 billion (2.5% of GDP and 7% of GDP growth)

Projected growth in industrial biotech 2013 – 2018





Industrial biotech companies are part of complex, global webs of partnership, investment, and collaboration. These include companies of all sizes and from a wide range of sectors, as well as research institutions and government agencies.

Many biofuel companies have realised that they can use existing production processes to enter bio-based chemicals markets that have lower costs and higher yields. The result is that many companies today produce a wide and diverse range of products.

The 15 'hottest' companies 2014-2015 and examples of their diverse products, partnerships, and global reach

genomatica

Some partnerships:

BASF: Germany
– bio-based chemicals

Novamont: Italy
– bio-plastics

Versales: Italy
– bio-based butadiene

Braskem: Brazil
– green plastic

novozymes

Rethink Tomorrow

2014 sales by region:

Europe/MEA	38%
North America	34%
Asia Pacific	17%
Latin America	11%

2014 sales by industry:

Household care	35%
Food and beverage	26%
Bioenergy	18%
Agriculture and feed	14%
Technical and pharma	7%

RANK	BIOBASED CHEMICALS AND MATERIALS	COUNTRY	BIOENERGY	COUNTRY
1	genomatica	US	LanzaTech	US
2	solazyme	US	GranBio	Brazil
3	AMYRIS	US	ALGENOL	US
4	BASF We create chemistry	Germany	novozymes Rethink Tomorrow	Denmark
5	LanzaTech	US	solazyme	US
6	DSM	Netherlands	DUPONT	US
7	Elevance	US	POET DSM Advanced Biofuels	US
8	DUPONT	US	BETARENEWABLES	Italy
9	bioamber	Canada	DSM	Netherlands
10	VIRENT	US	ABENGOA BIOENERGY	Spain
11	novozymes Rethink Tomorrow	Denmark	AMYRIS	US
12	avantium	Netherlands	BETARENEWABLES	US
13	verdezyne	US	POET	US
14	gevo	US	REG	Canada
15	Myriant	US	Enerkem	Germany

LanzaTech

Number of corporate, academic and government partners by region:

North America	13
Europe	6
Asia	16

AMYRIS

Some partnerships:

TOTAL: France
– biofuel

Cosan: Brazil
– lubricants

Kuraray Group: Japan
– biopolymers

Michelin: France
– isoprene, tyres

Braskem: Brazil
– isoprene, tyres

Firmenich: Switzerland
– flavours and fragrances

IFF: USA
– flavours and fragrances

Givaudan: France
– flavours and fragrances

RESEARCH AND DEVELOPMENT

In order to find novel compounds and enzymes, researchers collect microorganisms from soil, water, or other natural environments, as well as ex-situ collections. Most companies access material through internal or external collections, the thousands of genetic sequences in the public domain, and collections in their 'backyards'. A few undertake collections outside their borders.

Overseas collections tend to focus on areas with high species diversity, extreme environments, and unique ecological niches. Companies look for organisms that can withstand conditions similar to those of industrial processing.

Extreme or diverse environments

DEMAND FOR ACCESS

Collections of microorganisms:
- existing collections
- backyard
- sequences on internet
- overseas collections

ABS AGREEMENTS

Screen for interesting leads

Sequence genome

Time Cost

Identify gene that codes for the useful enzyme or compound

Bioinformatics and databases

GTCAT
GAC

Code new DNA instructions

> *Biology is not just a science, it is a material.*
> – Drew Endy, Stanford University

Transfer gene using genetic engineering

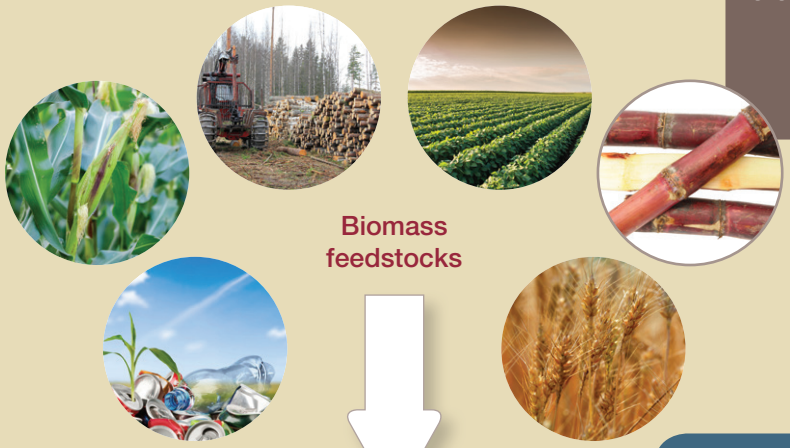
Micro-organism 'host' (usually *E. coli* or yeast)

Product gene

> *Deinococci are extremely robust organisms, which is exactly what you want in an industrial microorganism ….[they] can naturally endure physical and chemical stress experienced from an industrial environment...*
> – Deinove, 2015

Industrial biotech turns microorganisms into biological, or microbial, 'factories'. The microorganisms are genetically engineered but the final products themselves are not.

> *While we can use any fermentable sugar in our process, we are focused on Brazil sugar cane because of cost, availability, and the local industry's ability to meet international sustainability standards.*
> – Amyris, 2015



Biomass feedstocks

Starch
Hemicellulose
Cellulose
Lignin oil

FEEDSTOCK CONCERNS

Sustainability
- forest clearing
- chemical inputs
- biodiversity impacts
- not enough

Displacing crops

Labour
- poor conditions and pay

> *Sugar will be the oil of the 21st century.*

THE BIOLOGICAL FACTORY

Potential benefits:
- faster, cheaper
- better products
- smaller environmental footprint

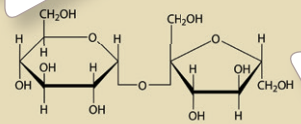
Concerns:
- escaped organisms
- poor regulations and oversight
- feedstock not truly sustainable
- small farmers lose markets

Products

PATENTED ORGANISM

Biobased syngas

Sugars

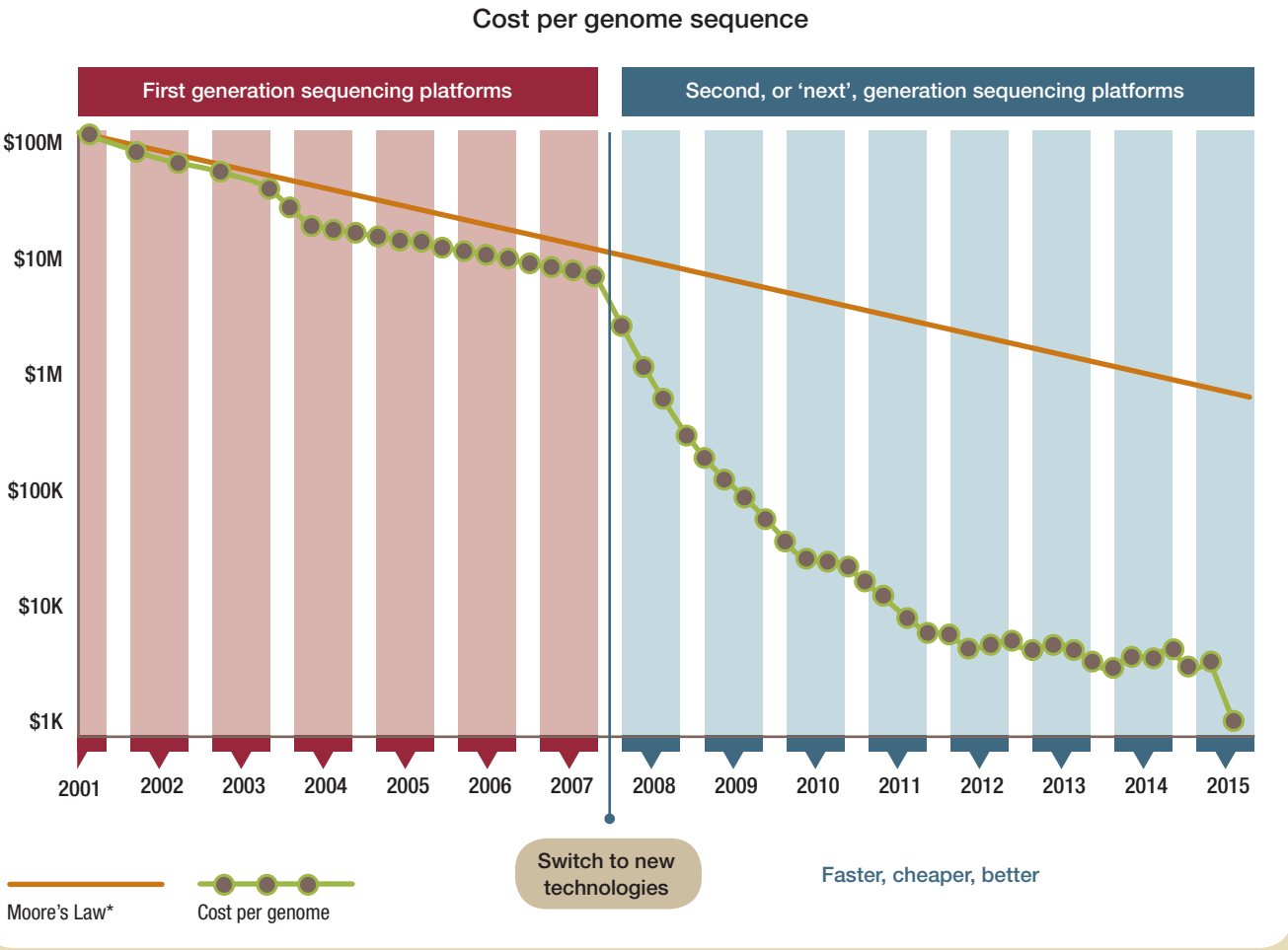


Building blocks

Secondary chemicals

Intermediate and base chemicals

Advances in science and technology have drastically reduced the time and cost it takes to sequence a gene. The challenge today has moved from data generation (sequencing) to data interpretation (bioinformatics and database technologies). Ten years ago the sequence of a single gene required 3 years; today, all 5,000 genes in a typical bacteria can be sequenced in a week.



Recent attention, including within the Convention on Biological Diversity policy process, has focused on synthetic biology, which falls within the scope of biotechnology, and is at times used interchangeably with industrial biotechnology.

> *The digitisation of biology is driving massive disruption in the life sciences. Human genome sequencing is the best example of faster, better, cheaper.*
>
> – Raymond McCauley, 2014

INDUSTRY AND ABS

The pace of change, and the complex nature of the science and technology employed, has outstripped the ability of governments to keep pace and effectively regulate industrial biotechnology. This includes through the Convention on Biological Diversity and Nagoya Protocol policy processes. Around the world, a patchwork of laws and policies, often outdated and inconsistent, are in place.

Biotechnology creates unique challenges for Nagoya Protocol implementation. In addition to the rapidly changing and sophisticated nature of the science and technologies employed, these include the increasingly common digital transmission of genetic information which raises questions about the role and functioning of checkpoints, and the blending of genetic material obtained from many different countries within a single engineered organism.

Awareness of the CBD within industrial biotechnology companies is limited, but growing slowly. Most companies are aware of 'sustainability' issues since they are central to their marketing and business model. Many do not think ABS applies to their business, however some industry groups are developing ABS standards for best practice, hold informational workshops, and provide guidance to their members on ABS and related topics.

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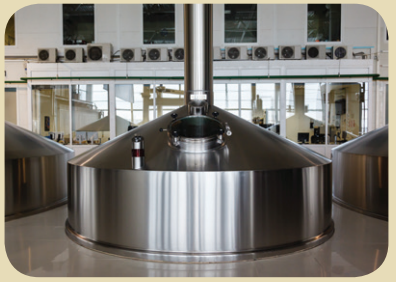
*Moore's Law is a long-term trend in the computer hardware industry that involves the doubling of 'compute power' every 2 years. Technologies that keep up with Moore's Law are widely regarded to be doing exceedingly well.



THE ABS CAPACITY DEVELOPMENT INITIATIVE

www.abs-initiative.info

www.bio-economy.org.za

People and Plants international

www.peopleandplants.org

The Access and Benefit-Sharing Key Points for Policy-Makers series has been produced to provide governments, companies, researchers, communities and others with background information to assist with the development of access and benefit-sharing measures to implement the Nagoya Protocol. The briefs are organised around central, key points on trends and practices in markets, research and development, and ABS. More detailed information on these sectors can be found at: www.bio-economy.org.za; www.abs-initiative.info; www.peopleandplants.org; CBD Bioscience at a Crossroads policy briefs: https://www.cbd.int/abs/policy-brief/default.shtml/; and in the upcoming book: http://www.routledge.com/books/details/9781138779099/

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For further information please contact:
abs-initiative@giz.de