Access and Benefit Sharing in a Time of Scientific, Technological and Market Change

Essential Lessons for Policy-Makers

Sarah A. Laird and Rachel P. Wynberg

March 2017

Biotechnology

Pharmaceutical

Cosmetics

Botanicals

Agriculture

Food and Beverages

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www. peopleandplants.org
www.bio-economy.org.za

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Essential Lessons from 25 Years of ABS:

change and diversity as central themes

Change and diversity characterise the sectors engaged in biodiscovery and the use of genetic and biological resources. This includes astonishing new developments in science and technology, fluctuating markets, and changes in business and intellectual property models, as well as dramatic diversity in company size, culture and research and development (R&D) strategy. These in turn significantly impact demand for access to genetic resources, benefit sharing and implementation of the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (Nagoya Protocol)*.

The research and commercial landscape that was encountered by negotiators to the Convention on Biological Diversity (CBD) in 1992 has transformed. Not only has our understanding of the natural world changed dramatically, but the ways in which researchers demand, study and use genetic resources do not resemble those of 25 years ago. Understanding these changed realities is critical for effective implementation of the Nagoya Protocol, and the development of effective access and benefit-sharing (ABS) policy.

The 'Essential Lessons' gathered here are the fruits of many years' work on emerging technologies, the commercial use of genetic and biological resources, and engagement in ABS policy processes. The lessons are presented simply, with visual images and minimal explanatory text. Analysis, explanation, and complete references can be found in other, complementary work by the authors (see page 24). The purpose of this document is to emphasise the importance of these seemingly simple, but often poorly learned, lessons in a way that encourages their incorporation into policy-making. Given the momentum at present to ratify and implement the Nagoya Protocol, it is urgent that all involved arrive at a basic understanding of the sectors and activities these new laws will regulate, and the implications of different policy choices.

1992 Convention on Biological Diversity adopted

1995 First gene sequenced

2002 Bonn Guidelines adopted
Human genome sequenced

2007 Second-generation gene sequencing platforms
↓
cost of reading DNA drops

2010 Nagoya Protocol adopted
Craig Venter announced creation of first synthetic life form

2012 CRISPR first used as a genome editing and engineering tool

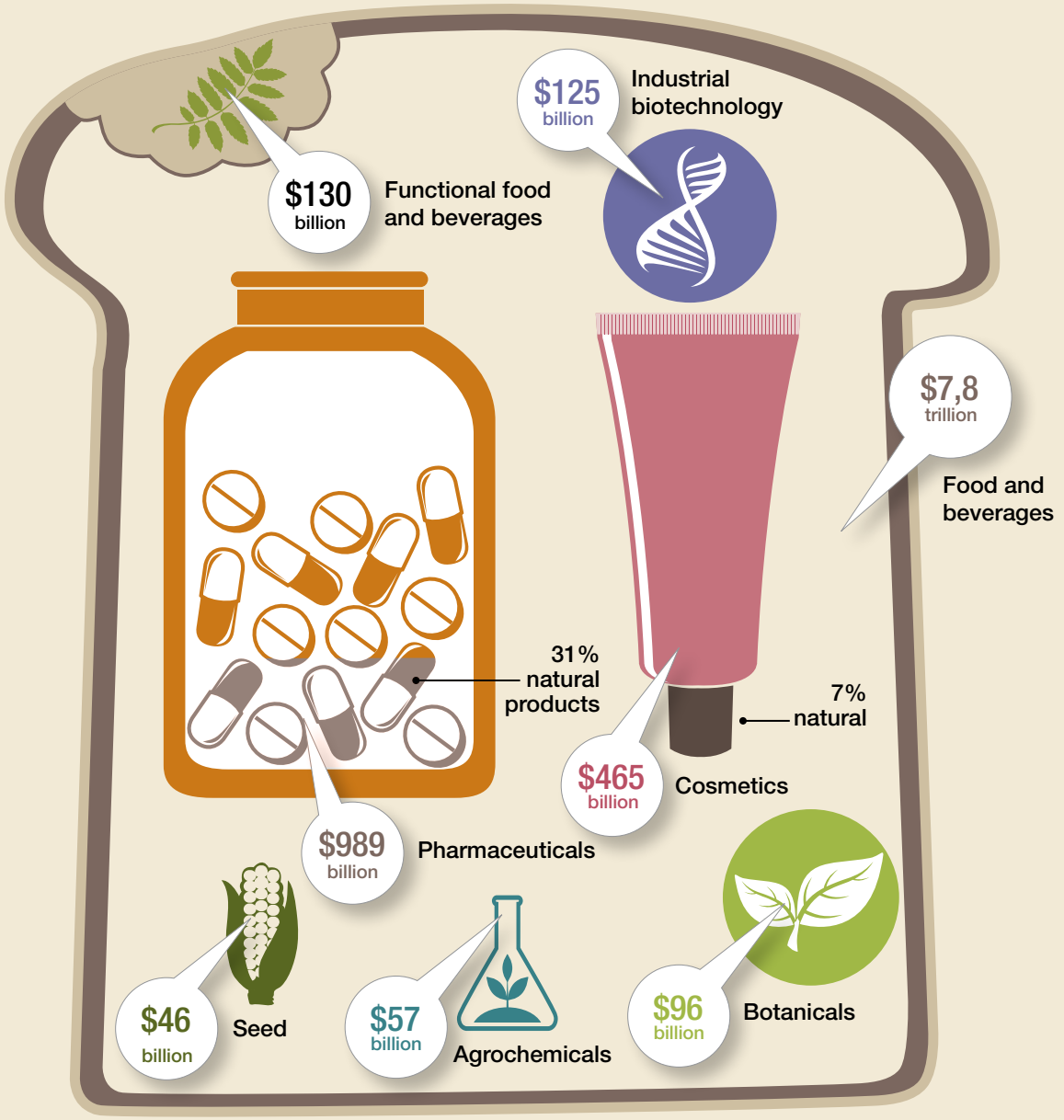
2014 Nagoya Protocol entered into force

2016 The average industrialised country home is filled with products containing biotech ingredients or produced through biotech processes

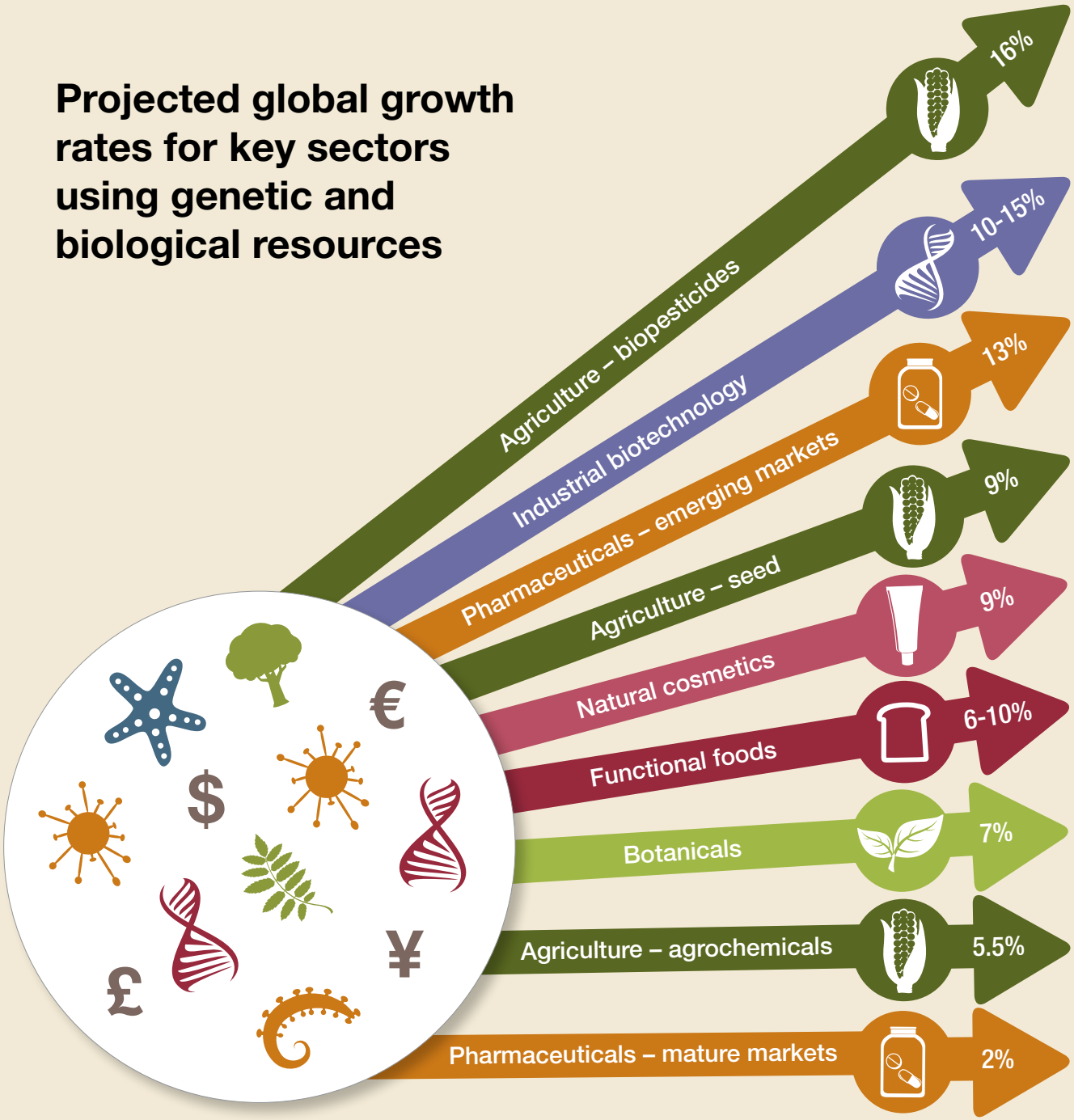
Science and Technology faster, cheaper, transformative

Markets for sectors using genetic and biological resources vary enormously in scale and scope, and this has significant implications for the ways in which the Nagoya Protocol is implemented. Within most sectors, only a portion of products or commercial activities depend upon access to genetic resources.

Global markets for key sectors
(2013/2014)

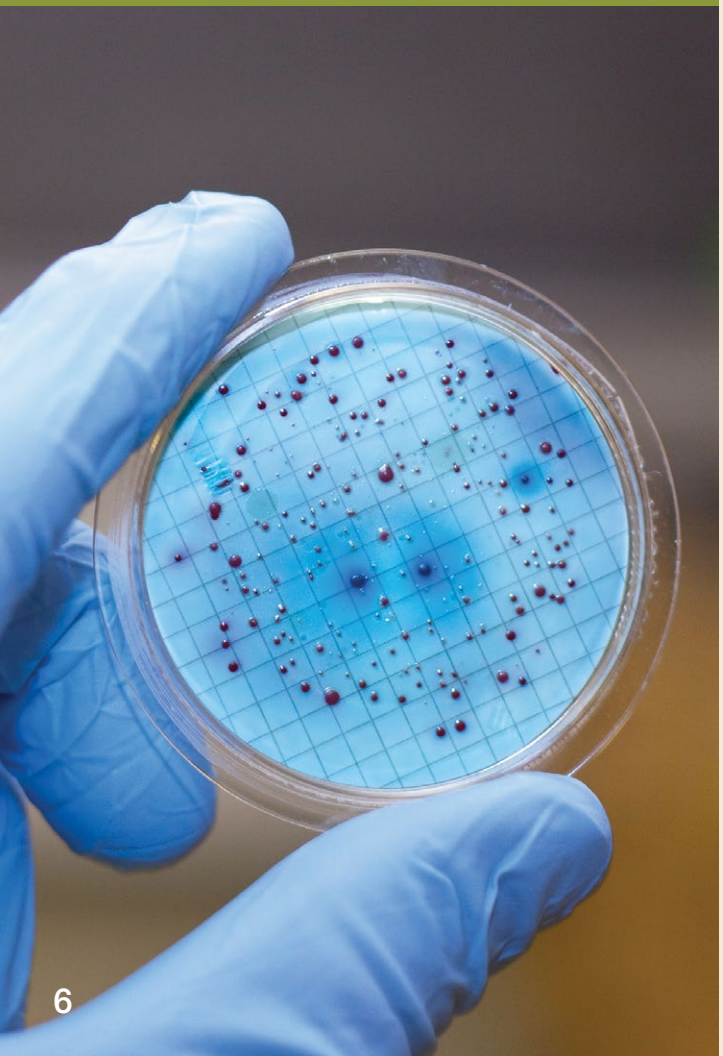


Projected global growth rates for key sectors using genetic and biological resources

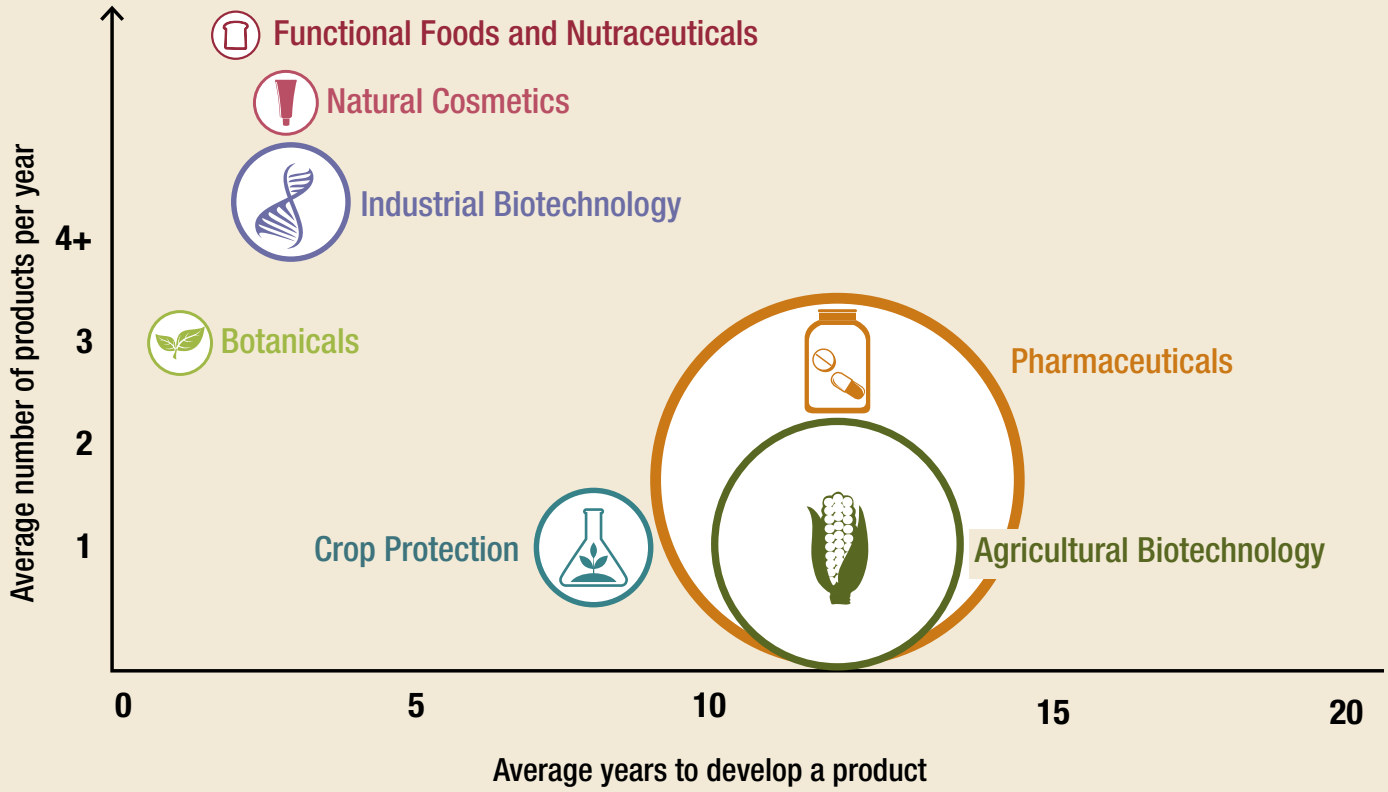


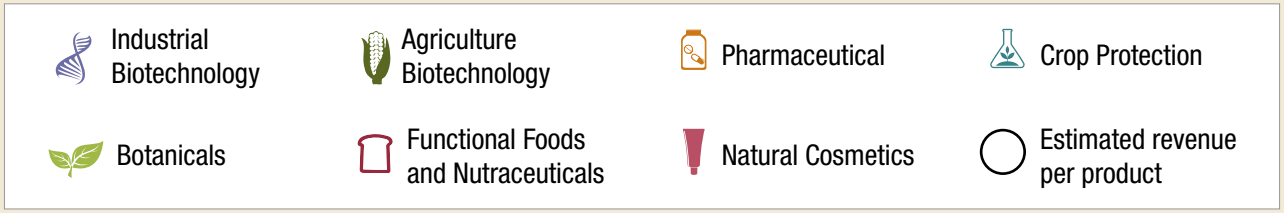
Across the board, sectors that utilise genetic and biological resources are undergoing rapid growth, most significantly in industrial biotechnology and biopesticides. This is due to growth in emerging markets such as Brazil, China and India, as well as advances in science and technology that are producing new, highly efficient, and innovative processes and products. In other sectors, like botanicals, functional foods, and cosmetics, rapid growth is the result of increasing consumer demand for 'natural' products.

There are dramatic differences across sectors in the value of final products, the cost and number of years it takes to produce a commercial product, and the number of products produced by a company each year.

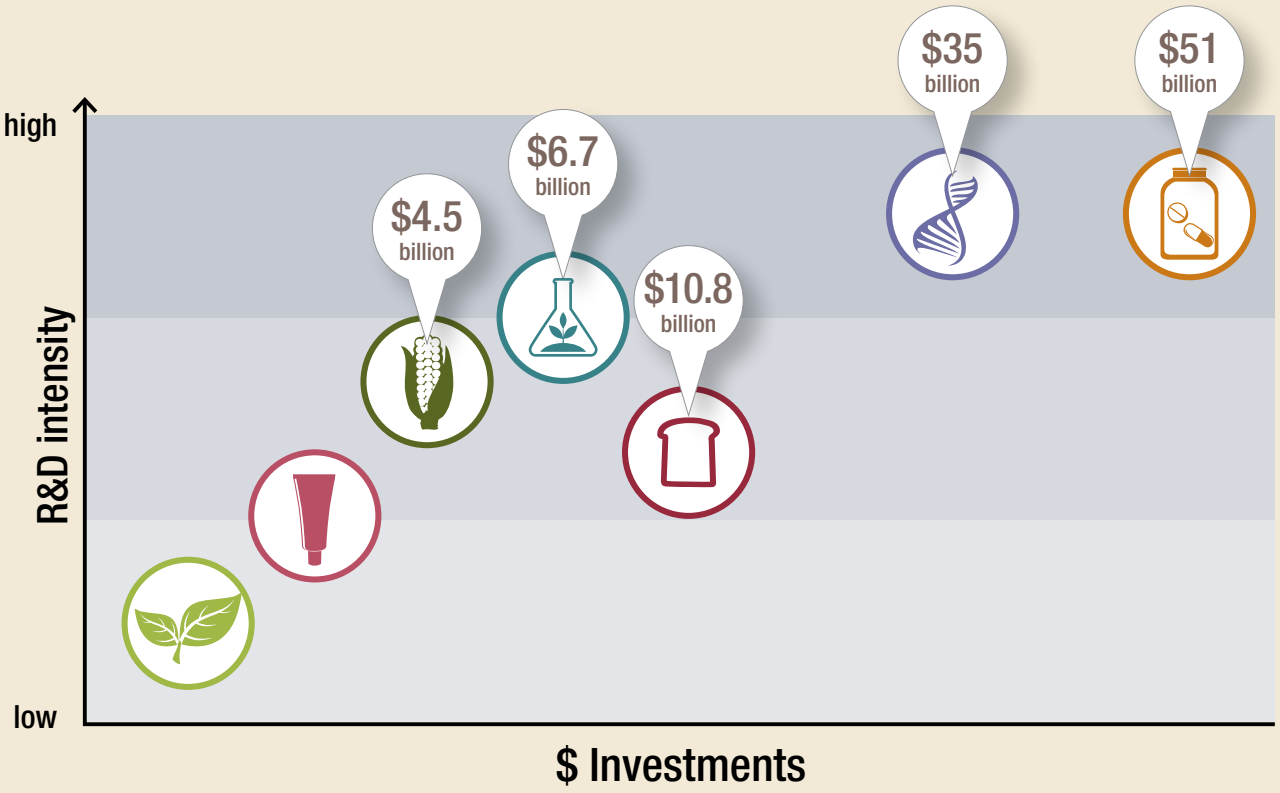


A comparison of estimated time, number and return on products





Estimated R&D expenditures, 2014

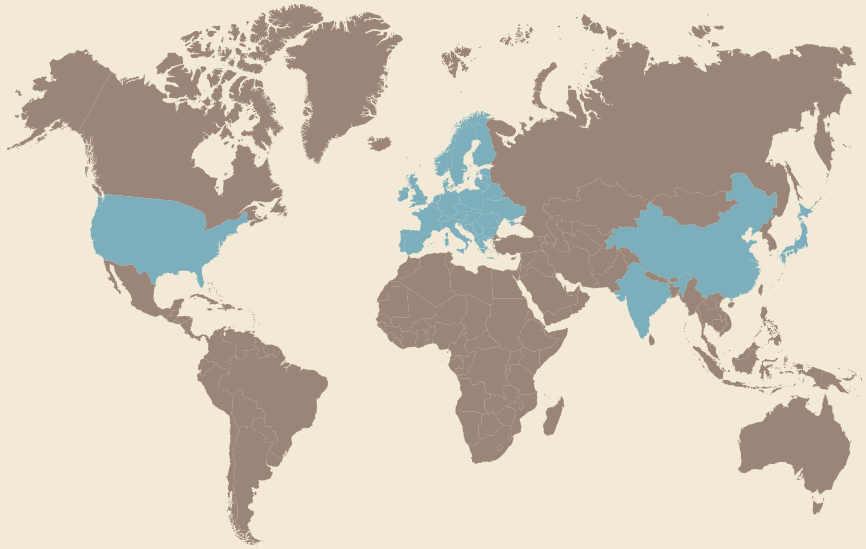


Biotechnology
Seed
Pharmaceutical
Crop Protection
Botanicals
Food and Beverages
Cosmetics

Investments in R&D vary dramatically between sectors, paralleling the levels of technology employed in the discovery and development of products, as well as the approval and regulatory costs incurred. The scale, level of technology and research intensity of R&D programmes have enormous implications for demand for access, benefit sharing, and Nagoya Protocol implementation.

North America, Europe and Asia (primarily China and Japan) are home to the world's largest companies. These regions dominate global markets, and undertake the vast majority of R&D. However, investments in new technologies and the global expansion of markets mean the role of other countries and regions is likely to expand in the future.

Regions with largest companies and markets, and undertaking the bulk of R&D



TOP 10 COSMETIC COMPANIES

RANK	COMPANY	COUNTRY	2014 REVENUES (USD million)
1	L'ORÉAL PARIS		$31
2	Unilever		$21
3	P&G		$20
4	ESTÉE LAUDER		$10
5	SHISEIDO		$8
6	AVON		$7
7	BDF Beiersdorf		$6
8	Johnson&Johnson		$6
9	CHANEL		$6
10	KAO		$6

TOP 10 PHARMACEUTICAL COMPANIES

RANK	COMPANY	COUNTRY	2014 REVENUES (USD million)
1	NOVARTIS		$46
2	Pfizer		$45
3	Roche		$39
4	SANOFI		$38
5	MERCK & CO., INC.		$37
6	gsk GlaxoSmithKline		$33
7	Johnson&Johnson		$26
8	AstraZeneca		$25
9	Lilly		$20
10	abbvie		$19

TOP 10 FOOD AND BEVERAGE COMPANIES

RANK	COMPANY	COUNTRY	2014 REVENUES (USD million)
1	Nestlé		$78
2	pepsi		$66
3	Coca-Cola		$47
4	JBS		$45
5	ADM		$43
6	ABInBev		$43
7	Mondelēz International		$35
8	Tyson		$34
9	SAB MILLER		$34
10	Cargill		$34

TOP 10 AGROCHEMICAL COMPANIES

RANK	COMPANY	COUNTRY	2014 REVENUES (USD million)
1	syngenta		$11
2	Bayer		$11
3	BASF We create chemistry		$7
4	DOW		$6
5	MONSANTO		$5
6	DUPONT		$4
7	ADAMA		$3
8	Nufarm		$2
9	FMC		$2
10	SUMITOMO CHEMICAL		$2

TOP 10 SEED COMPANIES

RANK	COMPANY	COUNTRY	2014 REVENUES (USD million)
1	MONSANTO		$11
2	DUPONT PIONEER		$8
3	syngenta		$3
4	Vilmorin		$2
5	DOW		$2
6	KWS		$2
7	Bayer		$1
8	DLF SEEDS		$0.5
9	SAKATA SEED		$0.4
10	TAKII		$0.3

TOP 10 BIOCHEMICAL COMPANIES

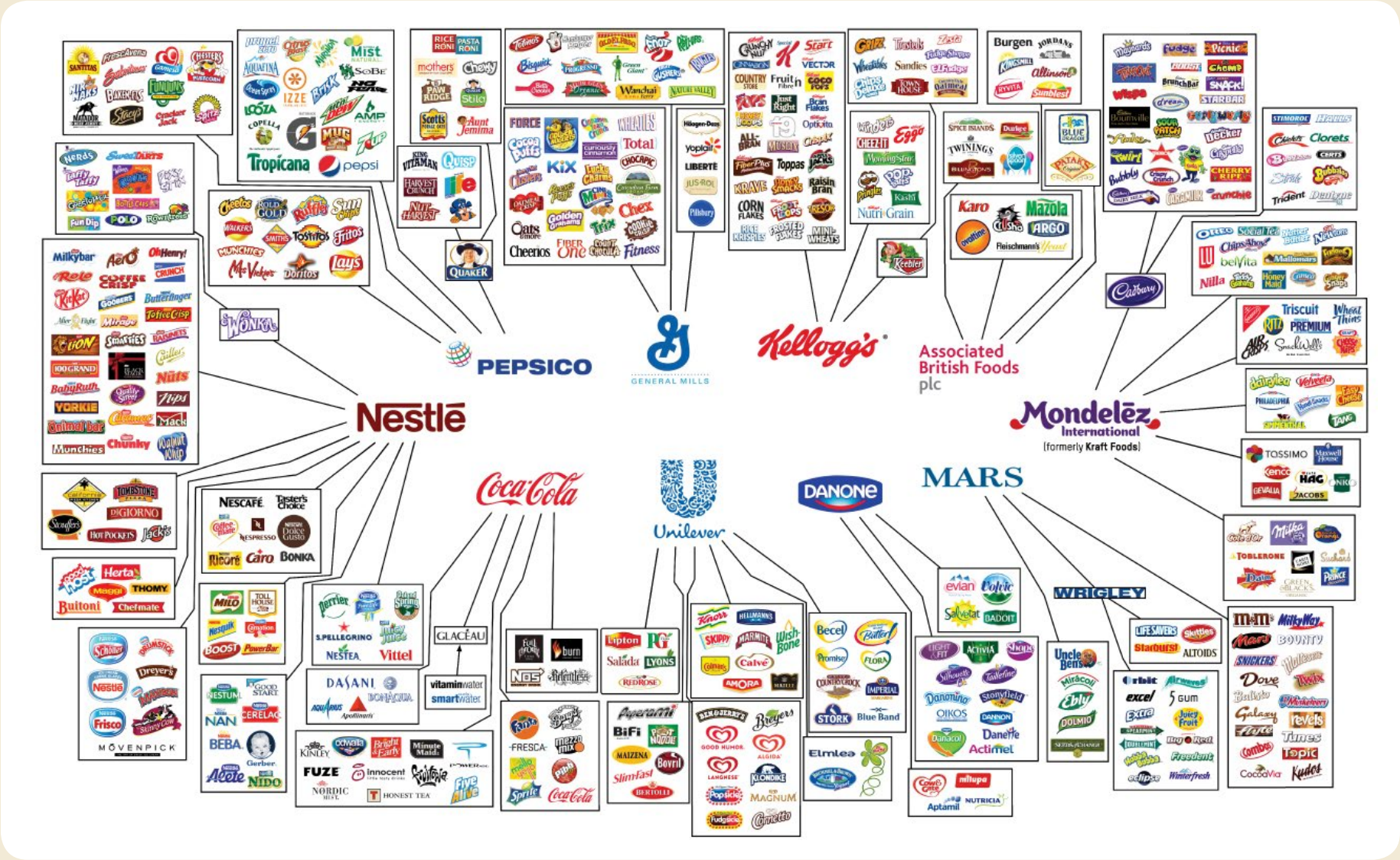
RANK	COMPANY	COUNTRY
1	genomatica	
2	solazyme	
3	AMYRIS	
4	BASF We create chemistry	
5	LanzaTech	
6	DSM	
7	Elevance	
8	DUPONT	
9	bioamber	
10	VIRENT	

TOP 10 BIOFUEL COMPANIES

RANK	COMPANY	COUNTRY
1	LanzaTech	
2	GranBio	
3	ALGENOL	
4	novozymes Rethink Tomorrow	
5	solazyme	
6	DUPONT	
7	POET DSM Advanced Biofuels	
8	BETARENEWABLES	
9	DSM	
10	ABENGOA BIOENERGY	

Over the last few decades, and across sectors, a global trend towards consolidation through mergers and acquisitions has resulted in fewer, larger companies that span across different sectors. At the same time, a trend towards outsourcing, licensing, and partnerships has meant that R&D is spread across multiple entities and is often not housed within a single company.

Global trends toward consolidation: the food and beverage sector



Global trends towards consolidation: the pharmaceutical sector (1980-2010)

1980

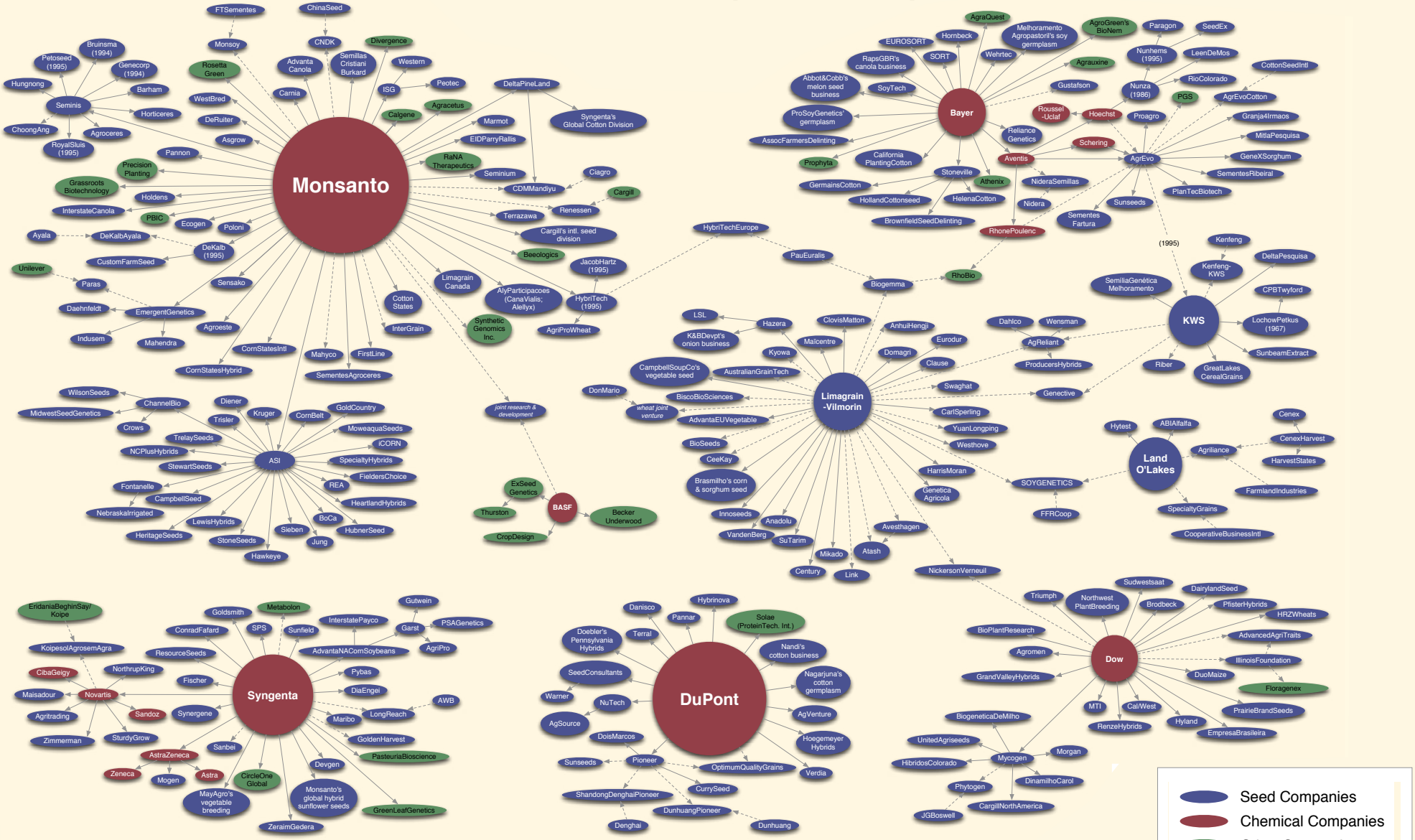
Consolidation has been a continuing process

2010

No. Companies: (including Amgen and Johnson and Johnson) **33** → **9**

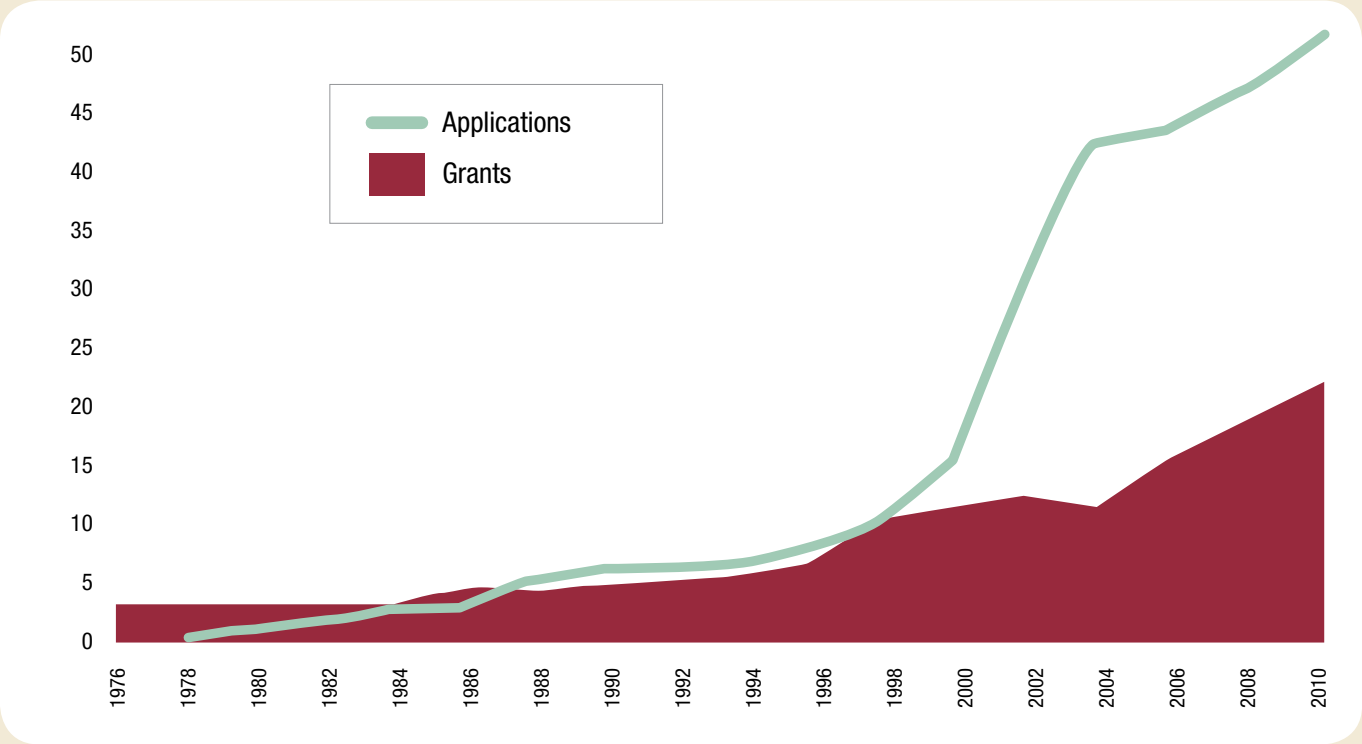
Merck	Hoffman	Hoescht Roussel	Squibb	Sandoz	Glaxo	Pfizer
Schering-Plough	Genentech	Marion Merril Dow	Bristol Myers	Ciba-Geigy	Wellcome	Parke-Davis
Organon		Rhone Poulenc	DuPont Pharma		Burroughs	Warner Lambert
		Sanofi	Merck DuPont		Smith Kline & French	Monsanto
		Synthelabo			Beecham	Searle
						Upjohn
						Pharmacia
						A H Robbins
						Lederle (AHP)
						Wyeth
	H-LaRoche Syntex	Hoescht	Squibb	Sandoz	SmithKline Beecham	Pfizer
	Genentech	Sanofi/ Synthelabo	Bristol Meyers	Ciba-Geigy		Warner Lambert
		RhonePoulenc & Fisons				Monsanto Searle
		Marion Merril Dow				Pharmacia Upjohn
						Lederle (AHP)
						Wyeth
		Hoescht Roussel	Bristol-Meyers Squibb		SmithKline Beecham	Pfizer
		Sanofi/ Synthelabo			Burroughs-Wellcome	Pharmacia
		RhonePoulenc & Fisons			Glaxo	Lederle(AHP)
						Wyeth
Merck	Hoffman LaRoche	Aventis			GlaxoSmith Kline	Wyeth
Schering-Plough		Sanofi/ Synthelabo				Pfizer
Merck	Roche	Sanofi-Aventis	Bristol-Meyers Squibb	Novartis	Glaxo SmithKline	Pfizer

Global trends towards consolidation: the seed sector (1996-2013)



Phil Howard, Associate Professor, Michigan State University
http://www.msu.edu/~howardp

Increasing number of patents on biodiversity



Patents and other forms of intellectual property are increasingly central to industry R&D strategies. The number of applications for patents linked to biodiversity has increased significantly since around 2000.

Examples of plants popular in patents for cosmetic and botanical use

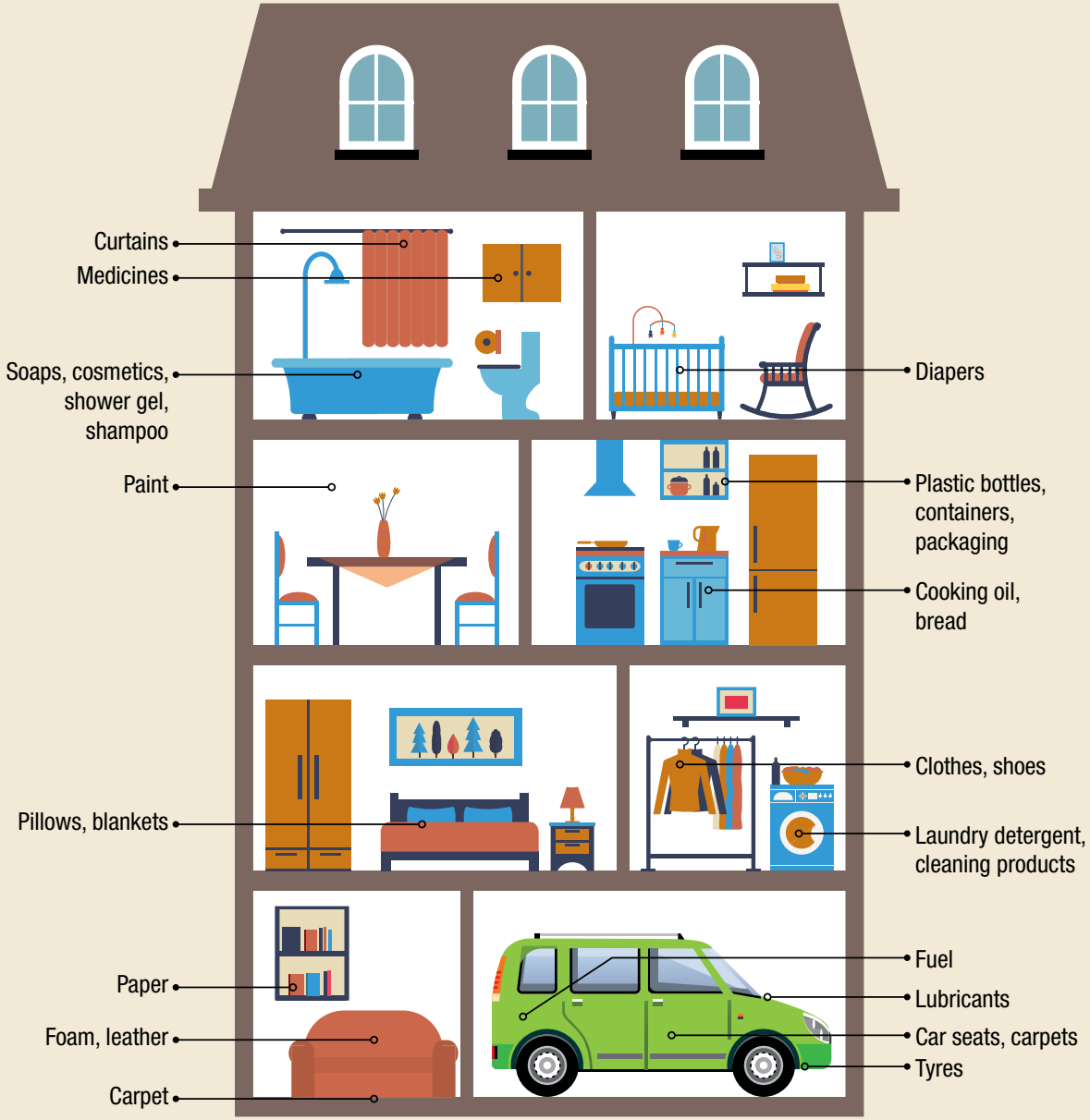
Aloe vera

Glycine max

Centella asiatica

Ginkgo biloba

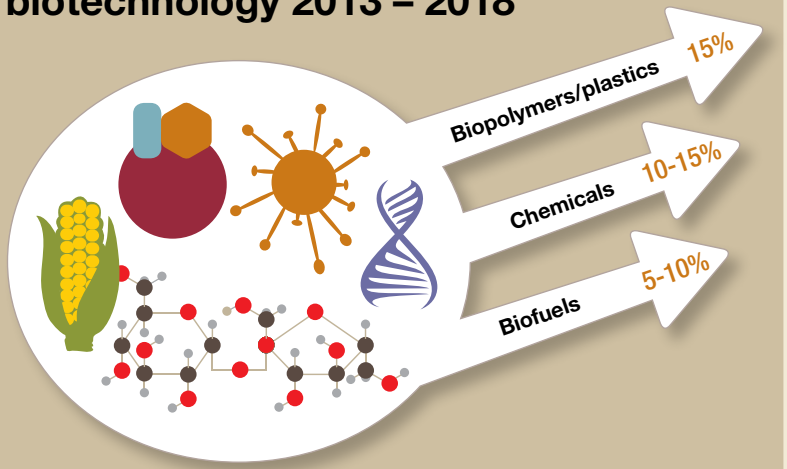
A snapshot of industrial biotechnology in the home



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

Biotechnology is employed in virtually every industry today, and yet is largely invisible to the average consumer. Industry sectors making use of biotechnology include chemicals, plastics, food and feed, detergents, pulp and paper, electronics, automotive, packaging, household products, cosmetics and personal care, textiles, bioprocessing catalysts, and bioenergy.

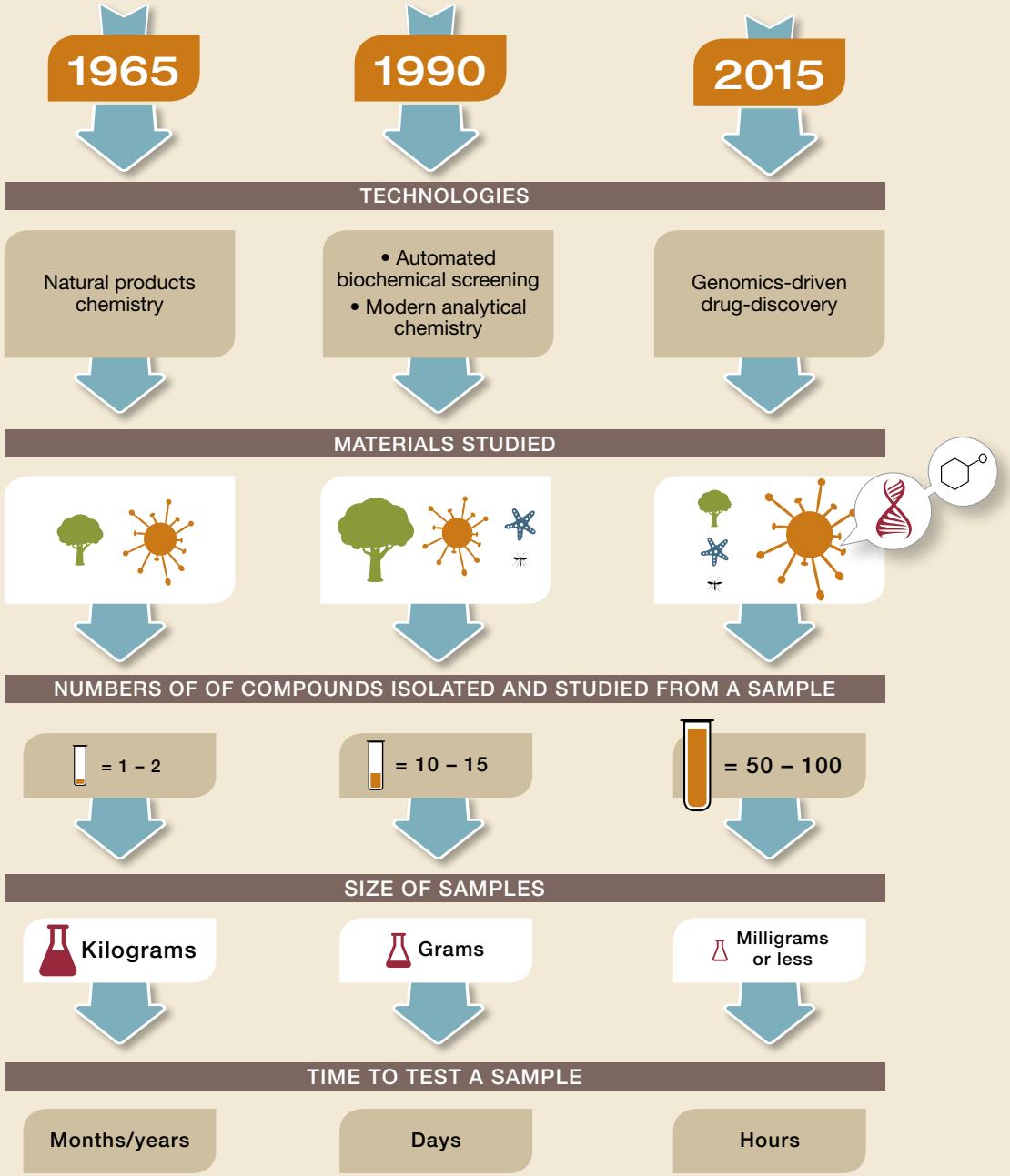
Projected growth in industrial biotechnology 2013 – 2018



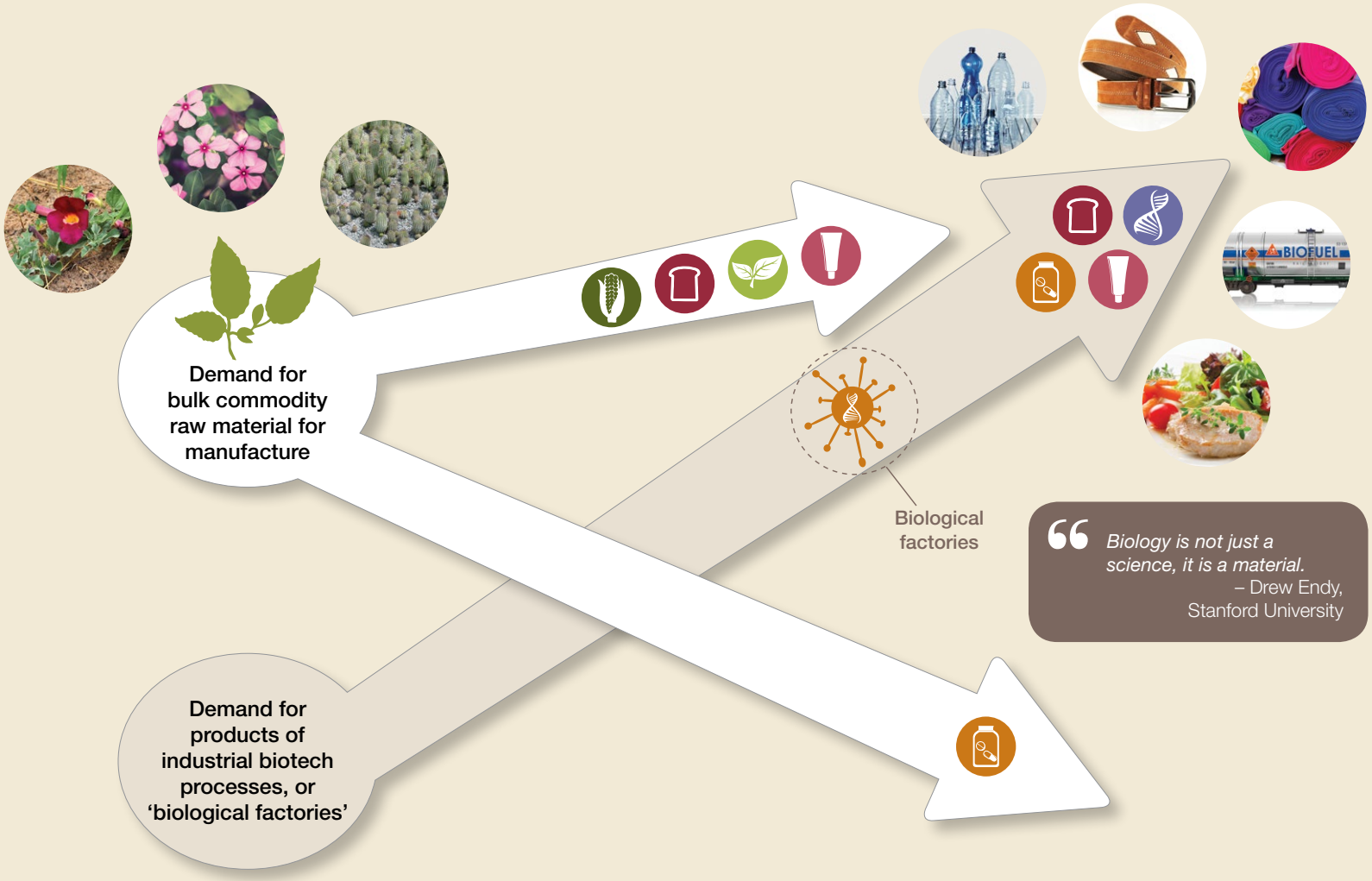
The divergence between research intensive, 'high' technology industries and 'lower' technology users of genetic resources is growing. This is due in part to rapid transformations in science and technology that pull research-intensive industries into ever-higher technologies. At the same time, consumer demand for natural, sustainable, organic and fair trade products has grown significantly, meaning cosmetic, food and beverage, and botanical sectors are pulled in the opposite direction toward traditional knowledge and raw material-based approaches.

Companies today are interested primarily in the genetic material contained within organisms, something that can increasingly be acquired as digital information. When companies do collect physical samples, the sample size is milligrams or less, unlike the grams or more needed in 1992. Within a single sample 50-100 compounds, rather than 10-15 compounds, might be identified, and within hours rather than days.

Trends in natural product research and drug discovery: a time of transformation

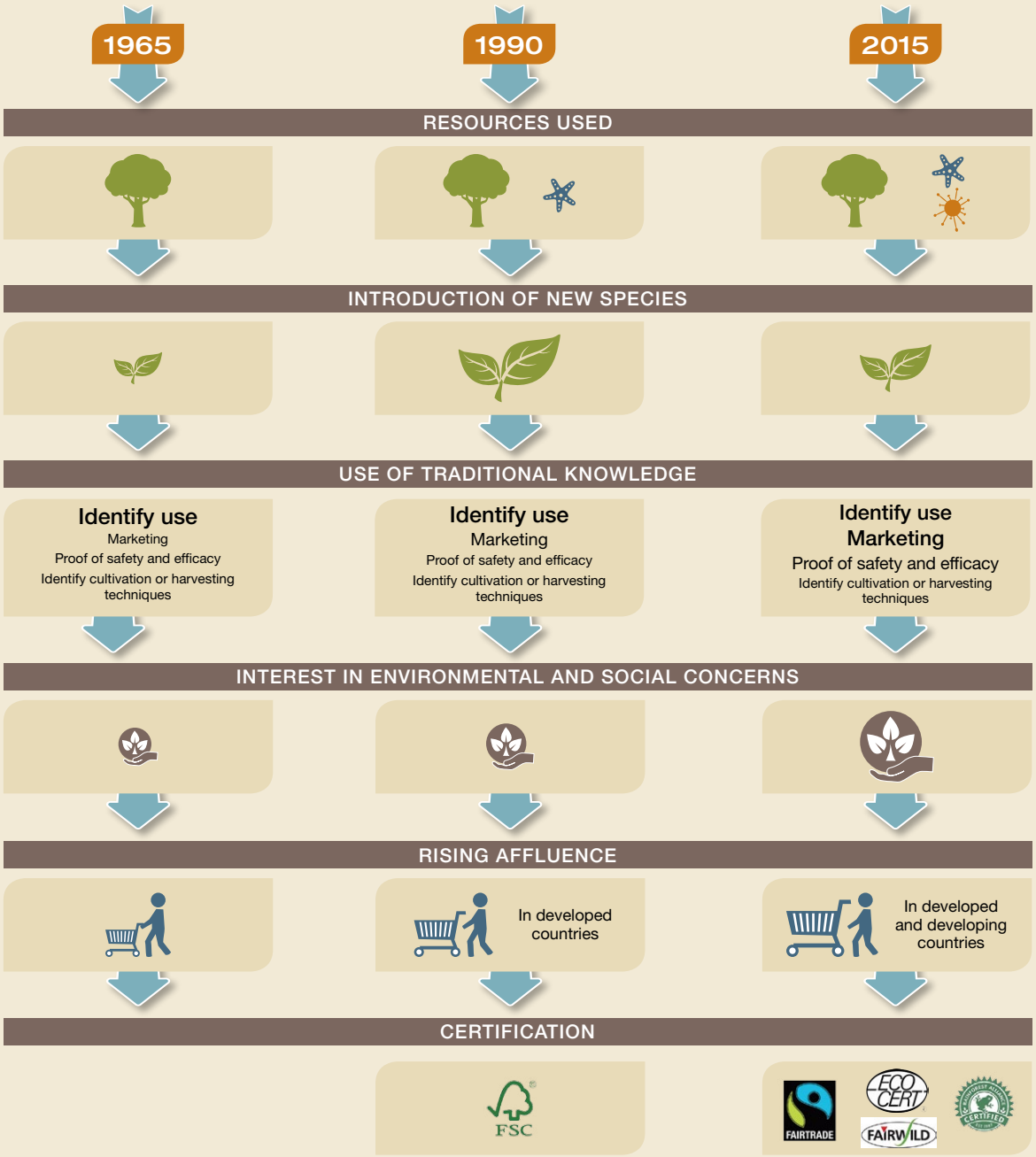


Trends in demand for access to biological resources for product manufacture



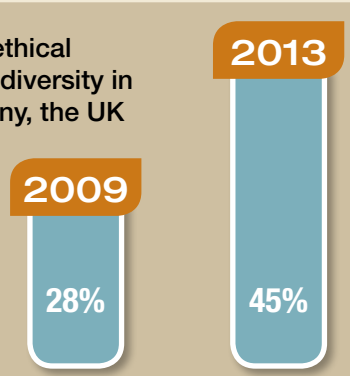
> *Biology is not just a science, it is a material.*
> – Drew Endy, Stanford University

Trends in demand for access: botanicals, natural cosmetics, and functional foods



Over the last few decades, global consumer demand for products that are green and fairly traded has consistently increased. Interest in marketing these products has also increased, along with the number of certifiers and accreditors.

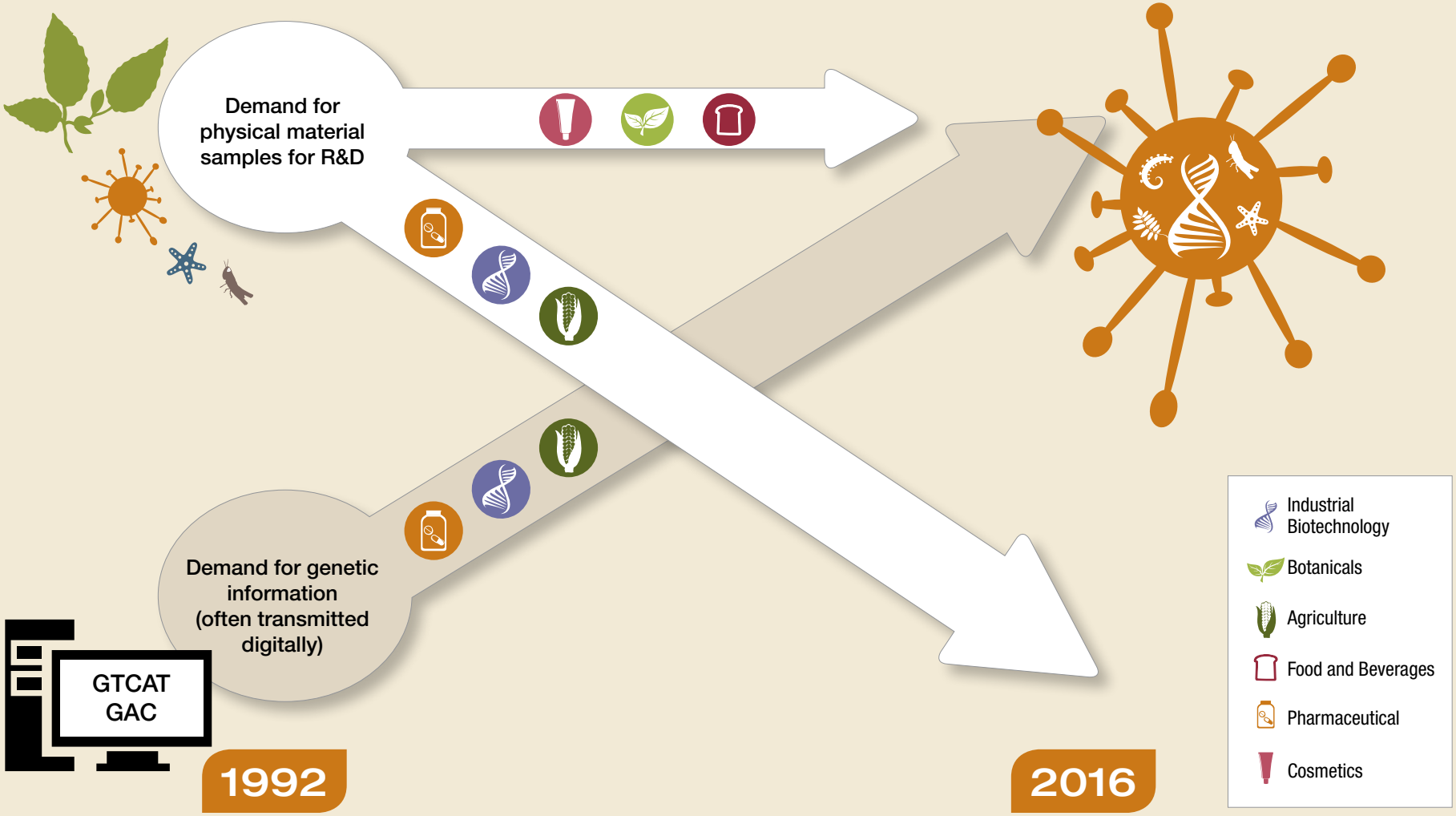
Awareness of ethical sourcing of biodiversity in France, Germany, the UK and USA



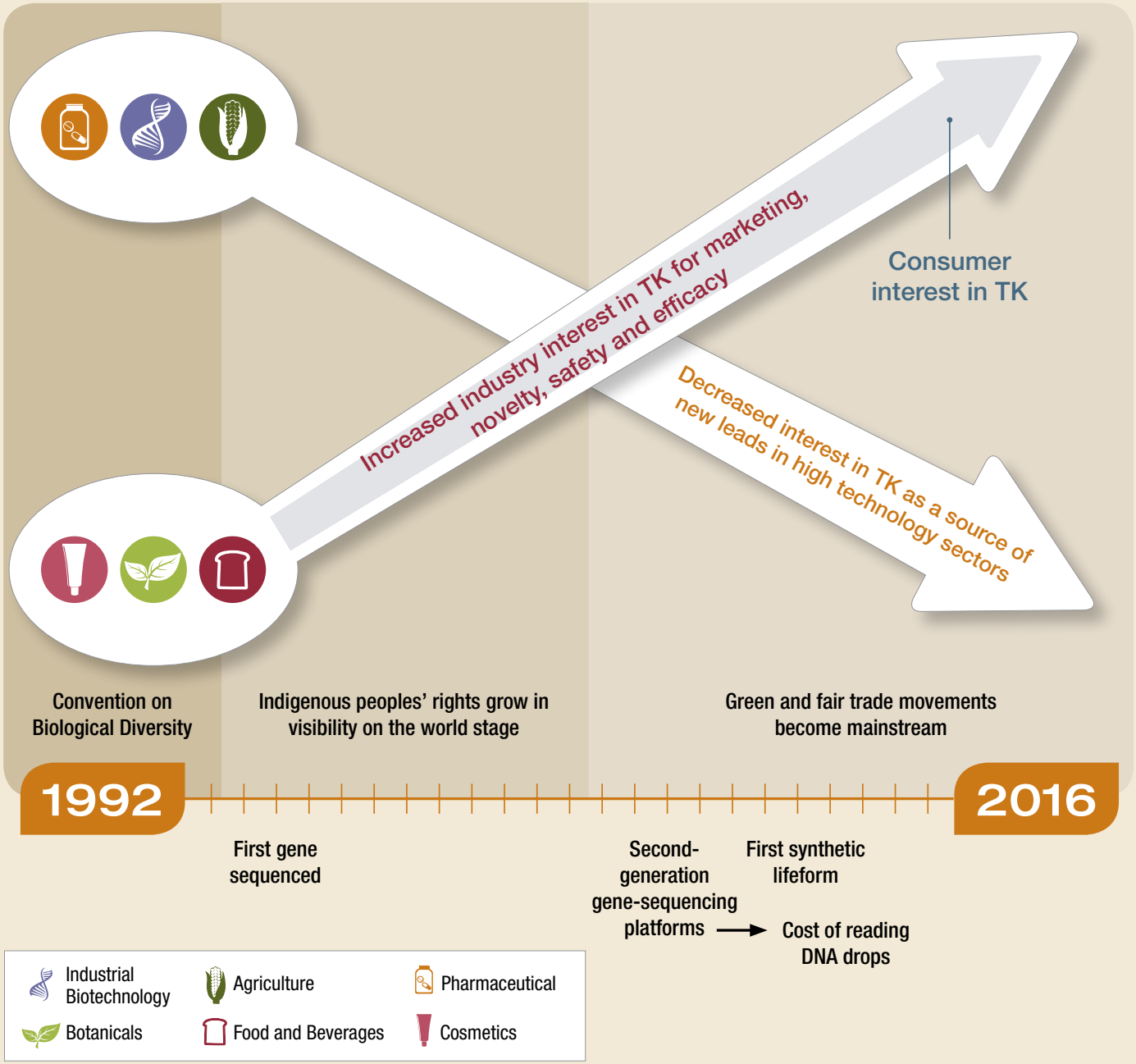
Source: UEBT Biodiversity Barometer 2009-2014

Researchers in high technology sectors are primarily interested in the genetic material of microorganisms. Improved techniques mean that most of the microbial diversity previously unavailable to researchers can now be studied. Companies have sufficient material available to them in existing collections or locally, but some companies continue to have an interest in novel and diverse organisms from other parts of the world. Increasingly, however, physical samples are not shared and instead genetic material is transmitted digitally.

Trends in demand for access to genetic resources for R&D



Trends in demand for traditional knowledge

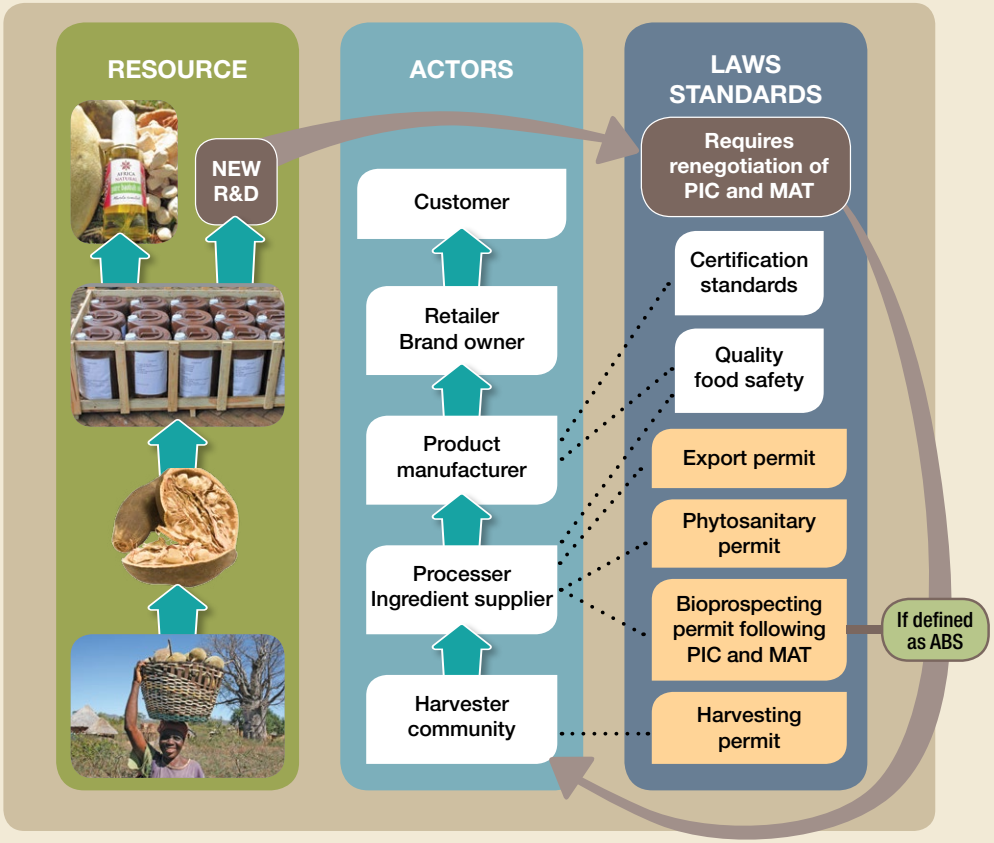


The use of traditional knowledge (TK) varies significantly across sectors. Higher-technology industries very rarely, if at all, use TK in their R&D programmes today. In contrast, those marketing fair trade and sustainable products like natural cosmetics, botanicals and functional foods and beverages, often rely on TK to develop novel products and ingredients, to prove safety and efficacy, and for marketing.

Awareness of obligations for Prior Informed Consent (PIC), equitable partnerships, and benefit sharing with indigenous people and local communities providing TK remains inconsistent across and within sectors.

Local harvesters, producers and traders of biological resources are already burdened by costly and bureaucratic regulations under forestry, agriculture, trade, taxation and other measures. Additional regulation in the form of ABS should clearly benefit, and not penalise, these groups.

ABS as the last straw: regulatory overload with the best intentions



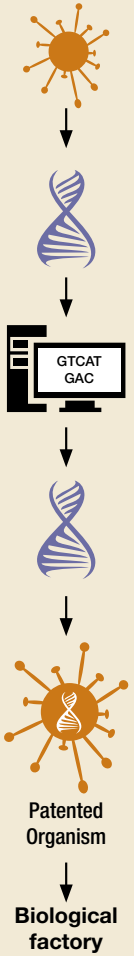
Developing a baobab oil product in South Africa

An already complex regulatory framework for baobab has been made more so due to the view held by the South African government that the use of baobab in food and cosmetic products constitutes bioprospecting. The question of whether or not baobab oil falls into an ABS 'category' revolves largely around its utilisation. Some think it is a commodity, but others believe activity claims attached to the oil gives it 'functional food' or cosmetic status, thus triggering ABS requirements. At present, developing a baobab oil product in South Africa not only needs to meet a variety of measures and standards, but also requires a bioprospecting permit which is issued upon proof of benefit sharing and PIC. Any new R&D on the oil would require a renegotiation of ABS terms. These measures have failed to generate additional benefits for local groups, and instead have resulted in added bureaucracy for local harvesters and traders, as well as companies, some of whom have halted marketing of baobab products due to legal uncertainty. The emerging lesson is that the best intentions for ABS policy-making can undermine rather than enhance local livelihoods if they are based on unrealistic views of harvesting, trade and markets.

Genetic and biological resources: a single regulatory framework?

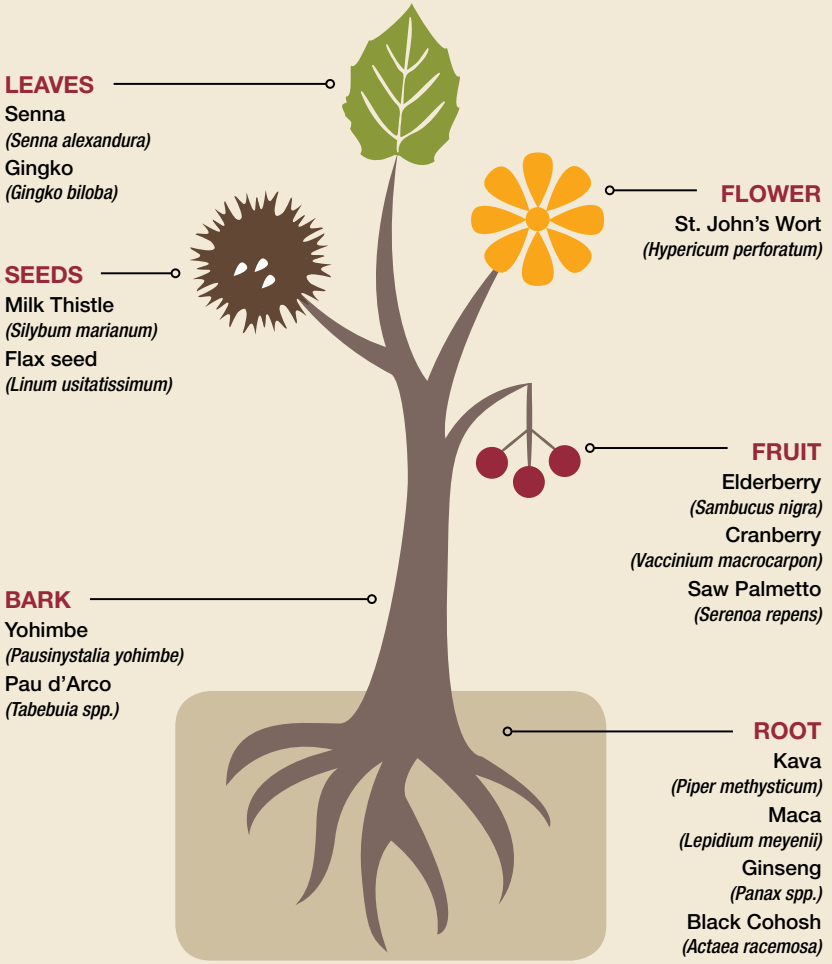
Policy-makers grapple today with the central definitional challenge of what constitutes 'genetic resources' and the scope of ABS. This is particularly true if digital genetic information, rather than physical material, is exchanged. There is also confusion in cases where governments fold biological resources, and the exchange of raw materials known as 'biotrade', into ABS.

Genetic resources



	Genetic resources	Biological resources
CBD definition	Genetic material of actual or potential value. Genetic material is any material of plant, animal, microbial or other origin containing functional units of heredity	Biological resources include genetic resources, organisms or parts thereof, populations and any other biotic component of ecosystems with actual or potential use or value for humanity
Resource aspects of interest	Genetic information contained within genetic material	Qualities associated with whole organism, multiple compounds
Levels of technology	High	Low to medium
Sizes of companies	Small through to very large	Small to medium, some very large
Size of sectors	Very large	Small to medium, some very large
Use of material	R&D to develop new products, ingredients, processes, etc.	Industrial processing and manufacture
Form accessed	Digital transmission of genetic information and some physical material	Bulk raw material, often a commodity
Use of TK	None to very little	Can be significant

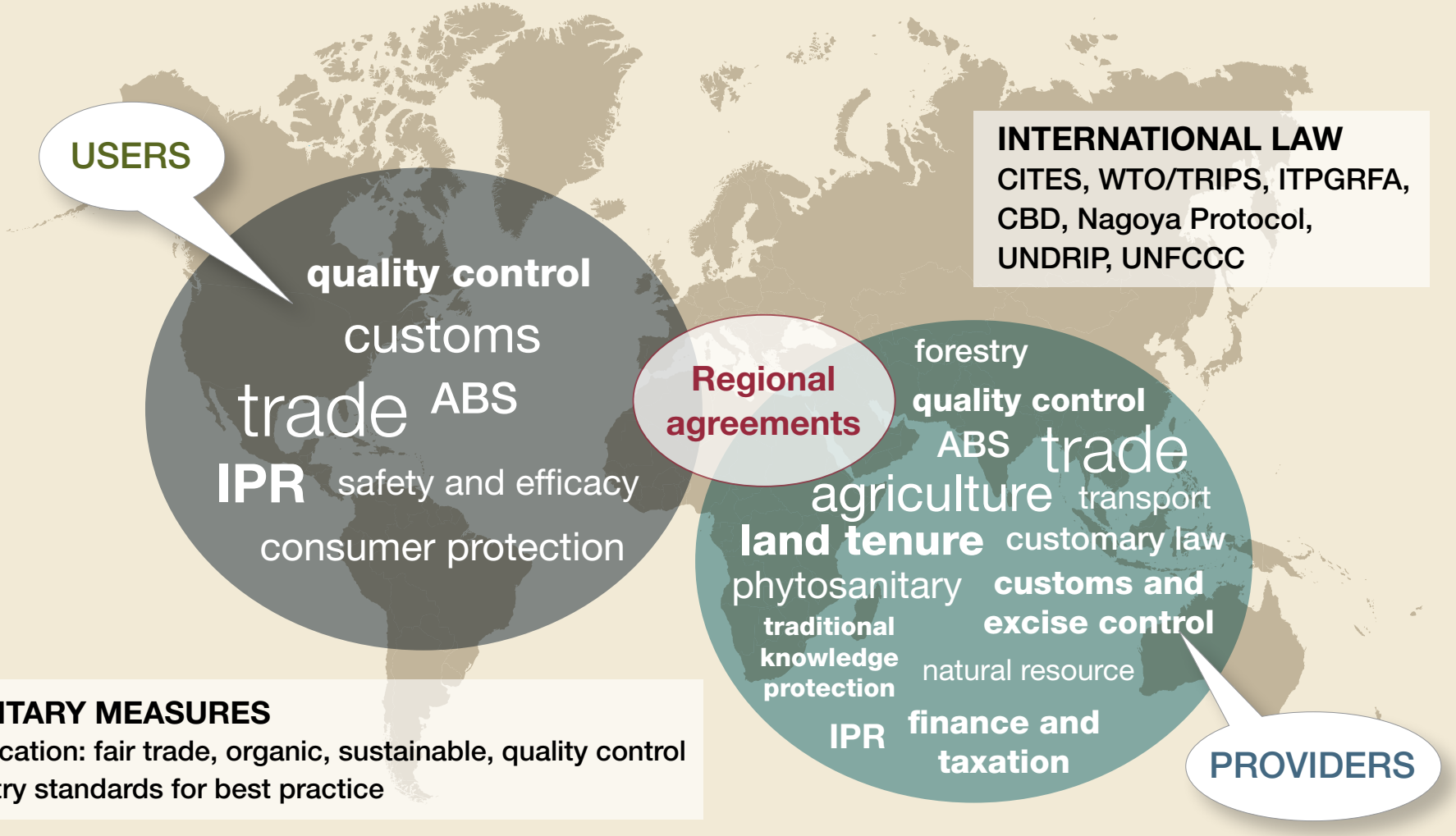
Biological resources



Has ABS become too complex and broad to be effective? Would ABS function better using principles and requirements that are integrated into existing measures, rather than a single regulatory umbrella for extremely different activities?

Companies undertaking biodiscovery engage with a complex web of regulations at the local, national, regional and international level. ABS measures should be streamlined and coordinated with other laws that impact genetic resource use, in order to increase their effectiveness and likely adoption.

The mix of laws and policies for genetic resources

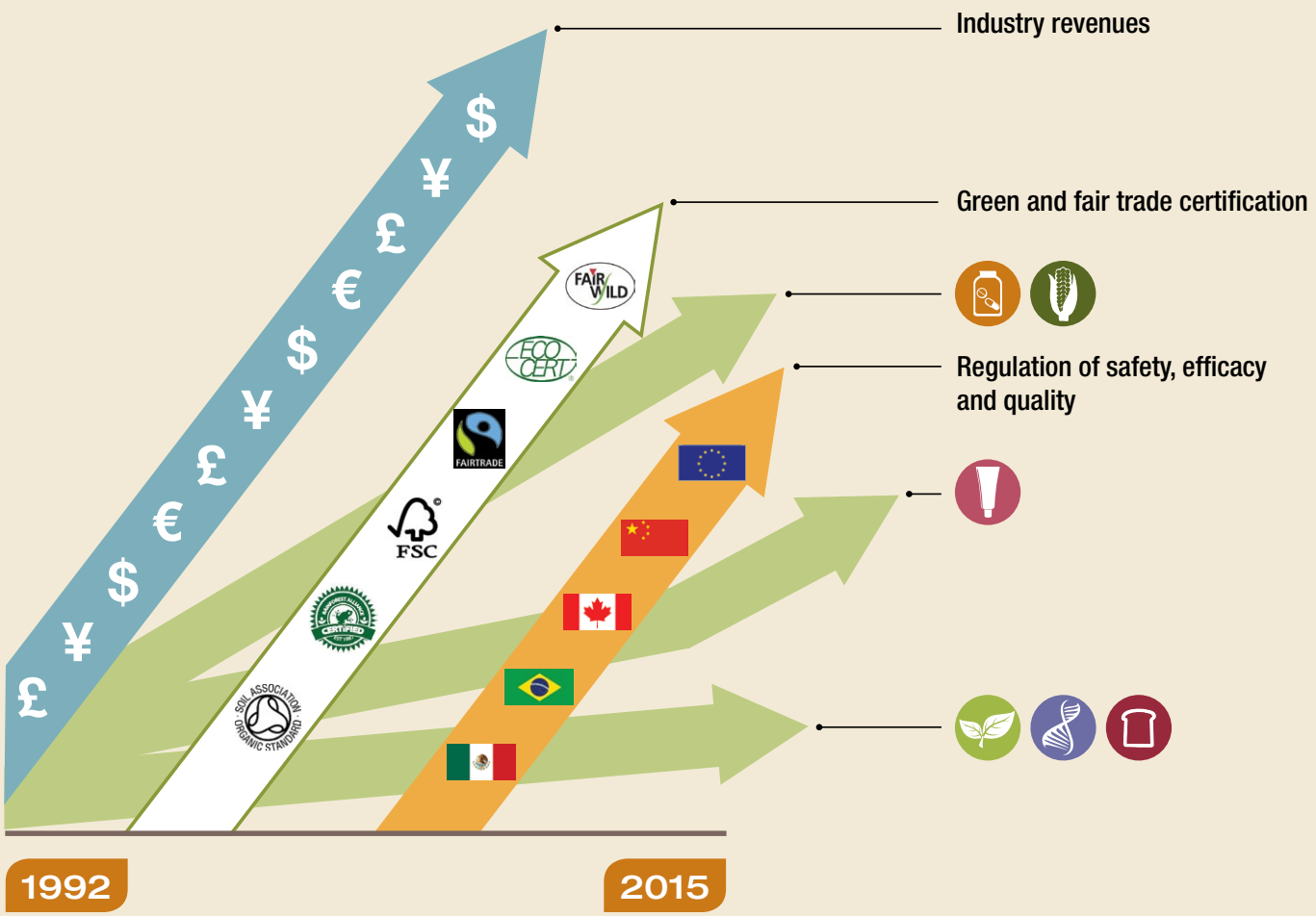


INTERNATIONAL LAW
CITES, WTO/TRIPS, ITPGRFA, CBD, Nagoya Protocol, UNDRIP, UNFCCC

VOLUNTARY MEASURES
- Certification: fair trade, organic, sustainable, quality control
- Industry standards for best practice

ACRONYMS
CITES – Convention on International Trade in Endangered Species of Wild Fauna and Flora
WTO/TRIPS – World Trade Organization/Agreement on Trade-Related Aspects of Intellectual Property Rights
ITPGRFA – International Treaty on Plant Genetic Resources for Food and Agriculture
UNDRIP – United Nations Declaration on the Rights of Indigenous Peoples
UNFCCC – United Nations Framework Convention on Climate Change

Industry and the CBD: growth of awareness 1992-2015



Awareness of ABS and the CBD has grown within and across sectors, but there remain great differences between them. Many governments, international agencies, industry associations, and others, are working to increase industry awareness of these issues and policies, and in some sectors such as cosmetics, this has had a significant impact. Other sectors such as botanicals, food and beverage, and industrial biotechnology, continue to lag in their awareness of the CBD.

Sources

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Carlson, R. 2014. How did the US Bioeconomy Perform in 2012?; IMS Health, 2014. Global Outlook for Medicines through 2018; Nutrition Business Journal, 2014. NBJ's Global Supplement and Nutrition Industry Report. https://www.plunkettresearch.com/industries/food-beverage-grocery-market-research/; Phillips McDougall, 2015. Chemical Crop Protection and GM Seed Industries 2014. http://phillipsmcdougall.co.uk/wp-content/uploads/2015/07/chemical-crop-gm-seeds-infographic_Linked.pdf-Final.pdf; Sloan, E. 2012. Beverage Trends in 2012 and Beyond. Agro Food Industry 23: 8–12; Syngenta, 2014. Our Industry; Szalai, I. 2015. Evolving Habits in Global Beauty. In-Cosmetics, Barcelona. Euromonitor International.

PAGE 5

Carlson, R. 2016. Estimating the Biotech Sector's Contribution to the US economy. Nature Biotechnology 34: 247-255; IMS Health, 2014. Global Outlook for Medicines through 2018; Markets and Markets 2015. Seed Market worth $92.04 billion by 2020; Nutraceuticals World, 2015. Functional Food Ingredients Market worth $2.5 Billion by 2020. Press Release, July 2; Nutrition Business Journal, 2014. NBJ's Global Supplement and Nutrition Industry Report; Parsippany, N.J. 2013. At $29+ billion, the Global Natural Product Care Market is Naturally Strong, say Kline. KlineGroup.com; Stoneman, B. 2015. Biopesticides: Some Industry Perspectives on Research and Demonstration. Biopesticide Industry Alliance.

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Chakma, J., Sun, G.H., Steinberg, J.D., Sammut, S.M. and Jagsi, R. 2014. Asia's Ascent – Global Trends in Biomedical R&D Expenditures. The New England Journal of Medicine 370(1):3-6; CropLife International, 2016. https://croplife.org/crop-protection/stewardship/research-development/; EFPIA, 2014. www.efpia.eu; Ernst and Young, 2015. Beyond Borders, Reaching New Heights: Biotechnology Industry Report 2015; Food Drink Europe, 2014. Data and Trends in the European Food and Drink Industry 2013-2014; Phillips McDougall, 2015. Chemical Crop Protection and GM Seed Industries 2014. http://phillipsmcdougall.co.uk/wp-content/uploads/2015/07/chemical-crop-gm-seeds-infographic_Linked.pdf-Final.pdf; PhRMA, 2015. www.phrma.org.

PAGE 8

Food Engineering Mag, 2014. The World's Top 10 Food and Beverage Companies; Pharmaceutical Executive, 2014. Pharma 50 2014; Women's Wear Daily, 2013. The 2013 Beauty Inc Top 100.

PAGE 9

ETC Group, 2015. Mega-Mergers in the Global Agricultural Inputs Sector: Threats to Food Security and Climate Resilience, October 30; Lane, J. 2014. Genomatics, Solazyme, Amyris, BASF Take Top Slots in the 30 Hottest Companies in Biobased Chemicals and Materials for 2014-2015 and LanzaTech, GranBio, Algenol, and Novozymes take Top Slots in the 50 Hottest Companies in Bioenergy for 2014-2015. The Biofuels Digest, November 2014.; Vilmorin & Cie, 2015. Presentation to Investors, March 9.

PAGE 10

Gauthier, J. for Oxfam 2013. Behind the Brands: Food Justice and the 'Big 10' Food and Beverage Companies. Oxfam Briefing Paper No 166.

PAGE 11

Kearney, P. 2011. What is the Future for the Big Pharma Model? AFG Venture Group Dispatches; Newman, D.J. 2015. US National Cancer Institute, pers. com.

PAGE 13

Oldham, P., Hall, S. and Forero, O. 2013. Biological Diversity in the Patent System. PLoS ONE 8(11): e78737.

PAGE 14

BIO, 2014. Current Uses of Synthetic Biology for Renewable Chemicals, Pharmaceuticals, and Biofuels; Carlson, R. 2016. Estimating the Biotech Sector's Contribution to the US Economy. Nature Biotechnology 34: 247-255; EuropaBio, 2015. Industrial Biotech: Enabling a Competitive, Sustainable and Renewable Bioeconomy; OECD, 2011. Future Prospects for Industrial Biotechnology.

PAGE 20

Wynberg, R. and Laird, S. 2014. Access and Benefit Sharing for Baobab Fruit, Oil and By-products in South Africa. A Briefing Document. PhytoTrade Africa.

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