Sectoral Analysis:

R&D Needs / Requirements / Opportunities in Four User Sectors - Cosmetics, Pharmaceuticals, Biotechnology, and Functional Food

Index

Overall introduction to the report "Economic potential and valorization opportunities of genetic resources under the Nagoya Protocol in Africa"

The Access and Benefit Sharing (ABS) Capacity Development Initiative has executed a regional UNEP/GEF project to support six African countries (i.e., Cameroon, Kenya, Madagascar, Mozambique, Senegal, and South Africa) in implementing the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Its Use (hereinafter NP) . This project aims to inform the development of national ABS frameworks and business initiatives to promote partnerships that will ensure the fair and equitable sharing of benefits. Thereport "Economic potential and valorization opportunities of genetic resources under the Nagoya Protocol in Africa" is based on the following two premises. First, there is generally a limited understanding of how genetic resources (GR) are utilized by different type of actors in innovation and research and development (R&D) processes across various sectors. The use of GR has dramatically changed over the last 20 years: "*It is important for governments to ensure that they are not regulating for activities and scenarios that no longer exist or have substantially transformed*".[1] For instance, the traceability of GR, such as enzymes, is becoming more and more difficult. Second, few countries have a clear picture of the national actors that could potentially be involved in the valorisation of GRand of foreign user institutions in different sectors that may be interested in accessing and utilizing them.

Thus, it may be a challenge for policy makers to develop a national valorisation strategy and ABS frameworks that respond to these actors needs and lead to the establishment of fair and equitable ABS contracts and partnerships.

In this context, this report seeks to provide a clearer picture of the current situation regarding R&D on GR in order to bridge the gap between provider and potential user institutions. The objective is to support the valorisation of GR with a view to increasing the potential benefits arising from their utilisation. The results of this report are presented as follows: :

- **Six studieson the countries' biodiversity in the global patent systems ("Patent Studies)**
- **A sectoral analysis: R&D needs/requirements/opportunities in four user sectors - Functional food, Cosmetics, Pharmaceuticals and Biotechnology**.
- **Six valorization potential assessments** further exploring:
    a. the national actors involved in activities related to the utilisation of GR,
    b. the links between patent documents, values chains and markets, and
    c. country-specific recommendations to inform the development of national ABS frameworks and the valorisation of GR

[1] Laird, S.A. and R.P. Wynberg. 2013. *Bioscience at a Crossroads: Access and Benefit Sharing in a Time of Scientific, Technological and Industry Change.* Secretariat of the Convention on Biological Diversity. www.cbd.int/abs/policy-brief/default.shtml/

- **A synthesis: Economic potential and valorization opportunities for genetic resources in six African countries**

Further information on the rationale and the above-named elements of the report is provided in the introduction to the report "Economic potential and valorization opportunities of genetic resources under the Nagoya Protocol in Africa".

This report is based on a literature review, expert interviews and internet research. Considering its wide scope from a geographical, economic, and regulatory perspective and the challenge of accessing relevant information remotely, the methodology evolved as information and key findings became available. It does not purport to be exhaustive. It is envisaged that this preliminary analysis will contribute to identifying issues requiring further in-depth research and analytical work.

Introduction to the Sectoral Analysis: R&D Needs/Requirements/Opportunities in Four Sectors: Functional Food, Cosmetics, Pharmaceutical and Biotechnology

This sectoral analysispresents the results of the research carried out in four sectors considered as some of the most important user institutions of GR: Functional Food, Cosmetics, Pharmaceuticals and Biotechnology. In order to identify the opportunities to valorise GR that occur at various stages of the R&D and product innovation processes, it is necessary to understand the R&D patterns. For this purpose, the following questions were addressed for each sector:

- What is the R&D dynamic and intensity?
- What are the key drivers of R&D?
- What are the R&D processes?
- What are the users' needs and requirements for using GR and for working with an R&D partner in the providing countries?
- What are the positive features and barriers in ABS agreements for the valorisation of GR?
- What are the main valorisation opportunities for GR?

The chemical industry is briefly analysed as it is the main competitor of biodiversity-based innovation. It delivers artificial solutions that can be used instead of GR/natural derivatives.

Based on the facts compiled, a number of points across the four sectors stood out as potentially relevant for the valorisation of GR.

Section 1 presents the market, R&D and patent trends with a quantitative approach.

Section 2 presents the challenges and the R&D drivers that shape R&D practices.

Section 3 presents the valorisation opportunities for GR across the four sectors with a qualitative approach.

Section 4 presents an overview of what constitutes an R&D process as well as the user institutions' R&D requirements for accessing a GR and establishing a R&D collaboration.

Section 5 presents some challenges to the valorisation of GR in ABS agreements and identifies potential solutions.

Finally, recommendations are provided with a view to informing the development or revision of national ABS frameworks and creating an enabling environment for the valorisation of GR

Scope of the Research, Methodology and Definitions

The analysis focused on the research and pilot phases of the R&D process. They provide the most appropriate fit for the majority of the domestic R&D actors, across the six countries covered by this report , to valorise GR.

While all four sectors were analysed, the cosmetics and the functional food sectors were emphasised. This was based on the assumptions that:

- The R&D capacity gap between user and provider institutions is generally closer as the level of science and technology is less advanced than in pharmaceutical and biotechnology.
- There is a higher interest on natural ingredients.
- The length of the R&D process (i.e., the time to market) is shorter than in the pharmaceutical and biotechnology sectors, potentially allowing a faster realisation of economic gain and benefits.
- When R&D succeeds, there is generally a need to produce the raw material for the production of final products, whereas in the other two sectors, the molecules tend to be synthesised.

However, this situation is quickly changing with rapid scientific and technological developments currently underway.

The focus on the functional food sector is complementary to the current work of the Food and Agricultural Organisation (FAO) on the issues of Genetic Resources for Food and Agriculture (GRFA).[2] The FAO conducts a cross-sector analysis to understand the extent to which GRFA displays common characteristics across various sectors. It aims to discuss the implications for the design of ABS measures for the food and agriculture sector.[3]

Methodology

The overall methodological approach was based on the following steps:

1. Map current sectors R&D practices and activities related to GR
2. Identify high level challenges and drivers to innovation
3. Identify opportunities, barriers, and gaps.

These steps involved a literature review of previous studies in this area and participation in conferences and interviews with representatives from industry, universities, research and technology institutes, trade associations, and other bodies to understand levels of current activity. The third step focused on prioritising key opportunities and challenges (those which are important today and are

[2] http://www.fao.org/nr/cgrfa/cgrfa-home/en/
[3] Schloen et al. 2014, Access and Benefit-Sharing for Genetic Resources for Food and Agriculture – Current Use and Exchange Practices, Commonalities, Differences and User Community Needs - Report from a Multi-Stakeholder Expert Dialogue. FAO, Background study paper Nb 59

likely to remain important in the future). An interim report was then prepared and used as a support for selected interviews with R&D experts.

Definitions

For the purpose of this report the following definitions are used:

User: public institution with responsibility for ABS

User institution: public, non-governmental or private organisation utilising or doing R&D on GR

Provider: public institution with responsibility for ABS

Provider institution: public, non-governmental or private institution carrying R&D on GR or that can provide access to GR

Actors: any kind of institutions

Valorisation opportunity: potential for creating an economic value within a R&D process or an innovation value chain

Product innovation: innovation that encompasses new or significantly improved goods or services[4]

Compound Annual Growth Rate (CAGR) is the mean annual growth rate of an investment over a specified period of time longer than one year

R&D intensity: the ratio between R&D invested and net sales

Pharmaceutical: a drug used to diagnose, cure, treat, or prevent disease[5 6 7]. The pharmaceutical sector relates to the research, development, and commercialisation of pharmaceutical drugs.

Cosmetics: "any substance or mixture intended to be placed in contact with the various external parts of the human body or with the teeth and the mucous membranes of the oral cavity with a view to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours"[8].

Functional food: foods and food components that provide a health benefit beyond basic nutrition. Examples of functional foods include foods that contain specific minerals, vitamins, fatty acids or dietary fibre. It has not yet been defined by legislation (e.g. Europe, USA).

Biotechnology: the application of science and technology to living organisms in order to produce new products and services. This large scope encompasses biological production processes and chemical production derived from a biological entity or extract. Three subsectors can be identified[9]:

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[4] http://ec.europa.eu/eurostat/statistics-explained/index.php/Innovation_statistics

5 Definition and classification of Drug or Pharmaceutical Regulatory aspects of drug approval Accessed 30 December 2013.

6 US Federal Food, Drug, and Cosmetic Act, SEC. 210., (g)(1)(B)

7 Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.

[8] Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products, 30 November 2009.

[9] Laird, S. and Wynberg, R. 2013. Bioscience at a crossroads: Access and benefit sharing in a time of scientific, technological and industry change: the biotechnology sector. Secretariat of the Convention on Biological Diversity, Montreal.

- Healthcare or red biotechnology: medicinal or diagnostic product that consists of, or has been produced in living organisms
- Agricultural or green biotechnology: modern plant breeding techniques including genetic modification
- Industrial or white biotechnology: uses the tools of nature (e.g., micro-organisms and enzymes) and the genetic information to create the product from agricultural feedstock and other biomass. Industrial biotech is employed in a wide range of industries, including chemicals, plastics, food and feed, detergents, pulp and paper, electronics, automotive, textiles, bioprocessing catalysts, and biofuels. It has well-established products such as biochemicals, biofuels, and biomaterials.

1. Markets, R&D, and Patent Documents Trends (Quantitative Analysis)

Methodology

Opportunities to valorise GR are complex to measure. The typical objective of R&D is to produce new knowledge and to market innovative product and services in response to a challenge or a need.[10] However, the nature of innovation is changing as it is no longer mainly about science and technology. Firms develop new R&D models as environmental and social challenges increasingly drive innovation.[11] Furthermore, innovation remains a blurred concept. When an enterprise describes itself as innovative, it is often unclear "how much" it has innovated and "how many" resources it has allocated.[12]

There are a range of challenges in providing such measures. First, R&D and innovation means different things to different players in the industries. The large companies mostly identify innovation with new product or service development, often based on the identification of an active principle, whereas for small to medium enterprises (SMEs), which participate in the broader R&D process, innovation is any activity that results in increase of value.[13] This raises issues such as relevance and of comprehensiveness (measuring what, for whom?) and the availability of credible data (how to efficiently measure the diversity of R&D activities?).

The input/output framework[14] is used to evaluate R&D dynamic and intensity. Historically, the measurement of scientific and technical (S&T) activity has developed around two types of indicators: resources allocated to R&D and patent counting. R&D expenditures (input) account for resources allocated by business and government to increase science and technology (S&T) knowledge. However, this framework does not cover the results (output) of these activities, or innovation activities. By contrast, patent documents counts are a measure of the results of innovation activity. However, not all inventions are patented, or patentable. Therefore, there is a need for qualitative indicators too[15]. There is a dynamic debate underway on measuring innovation.[16] Further information is available at the Global Innovation Index.[17]

Hence, macro level indicators across sectors and micro level indicators are analysed (Table 1). The micro indicators focus on companies in the cosmetics and functional food sectors to illustrate R&D dynamics and intensity at the individual company or R&D project level. A few other criteria were used to clarify the context for R&D and to gain further insights. The macro criteria were gathered from publicly available information (e.g., public statistics, market research agencies, industry literature). These methodologies vary and the figures provided are only indicative. For instance, biotechnology is

[10] Creating an R&D Strategy, G. Pisano 2012. www.hbs.edu/faculty/Publication%20Files/12-095_fb1bdf97-e0ec-4a82-b7c0-42279dd4d00e.pdf
[11] Fostering Innovation to Address Social Challenges, OECD, 2011 http://www.oecd.org/sti/inno/47861327.pdf
[12] Insee: measuring innovation? http://www.insee.fr/fr/ppp/sommaire/imet105h.pdf
[13] InnovatIon and knowledge framework for SME competitivenes. Case study of SMEs in a Pharmaceutical industry cluster. Techmonitor. 2011. http://www.techmonitor.net/tm/images/b/b4/10sep_oct_sf3.pdf
[14] This is an accounting framework based on the anticipated economic benefits of science. http://www.csiic.ca/PDF/Godin_31.pdf
[15] InnovatIon and knowledge framework for SME competitivenes. Case study of SMEs in a Pharmaceutical industry cluster. Techmonitor. 2011 (accessed 4 3 2016). http://www.techmonitor.net/tm/images/b/b4/10sep_oct_sf3.pdf
[16] http://www.oecd.org/fr/sites/strategiedelocdepourlinnovation/mesurerlinnovationunnouveauregard-versionenligne.htm (accessed 4 march 2016).
[17] http://www.globalinnovationindex.org/content.aspx?page=framework (accessed 4 march 2016).

sometimes included within the sectors it serves (e.g. pharmaceuticals) or presented separately. The micro indicators were collected through interviews with R&D experts.[18]

	Macro	Micro
Input	- Size of the industry (turnover and Compound Annual Growth Rate) and growth rate - R&D budget and growth rate (based on IRI's top 2500 R&D investment scoreboard 2014[19])	- R&D budget - Average R&D budget for a project - Average number of external actors involved in a standard R&D project
Output	- Number of innovative products/services introduced on the market - Number of patent documents applications and grants for the sector[20]	- Average success rate of R&D projects - Average number of innovative products or services introduced on the market
Other criteria		- Type of measure for the Return On Investment (ROI) for a new product/service - Average quantity of raw material required for production, when an ingredient is commercialised

Table 1. Overview of the indicators for measuring markets and R&D trends

1.1. Macro Analysis across Sectors

1.1.1. Overview of the Sectors

There is an aggregated product market size of US $1846 bn. The four sectors are expected to grow annually to 2020 by 3.7% to 12.3% depending on the sector. Furthermore, across the four sectors examined, an aggregate of US $124.4 bn was spent on R&D in 2013 by over 400 large companies. This represented an output of 87169 patent grants in 2013 and the number of patents is also on the rise. An overview of these figures is presented in Table 2.

The top 2500 companies investing in R&D invested €607.2 bn in R&D in 2014. This represents about 90% of the total expenditure on R&D by business worldwide. They continued to increase their investment in R&D (4.9% of turnover) above their growth in net sales (2.7%). Between 2006 and 2014, R&D investments at the company level grew in all geographical areas, totalling a world increase of 50.9%[21]. Detailed figures are provided for each sector in Annex 1.

[18] Antoine Billy, Director R&D, Naturex. Patrice André, Director Cosm'ethic (former Director of Botanical Innovation, LVMH). Francesco Gattesco, Senior R&D scientist, Indena. Cyril Lombard, CEO, Phytotrade Africa. Oriane Lafon, Expert in agro-industry strategy, independent. Xavier Brochet, Director of natural innovation, Firmenich. Chloé Ambroset, ingénieure de recherche en biologie Anses laboratoires de Lyon.
19 The "EU Industrial R&D Investment Scoreboard" uses the latest available accounts of the world's top 2,500 R&D investing companies. It comprises 608 companies based in the EU, 829 companies based in the US, 360 in Japan and 703 from the rest of the world. It is based on company data extracted directly from each company's Annual Report. http://iri.jrc.ec.europa.eu/scoreboard14.html
[20] WIPO patents statistics database spring 2014 http://www.wipo.int/ipstats/en/statistics/patents/
[21] https://ec.europa.eu/jrc/sites/default/files/minisites/eu-scoreboard-2015/ (accessed 4 march 2016)

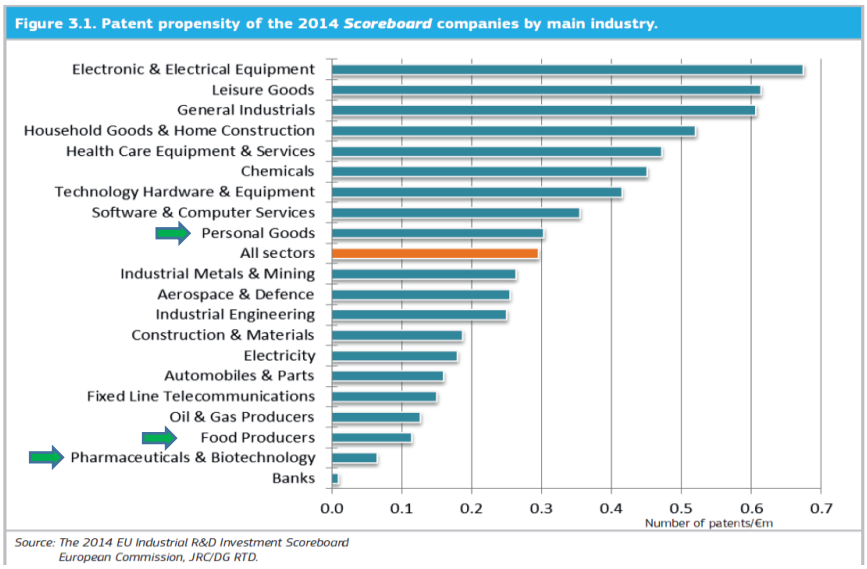
Table 2: Sectors global market, R&D and patents documents sizes and trends. (All data was last accessed on 4 march 2016).

	Market size	Market growth	Expected growth	R&D intensity 2013 (% of turnover)[22]	R&D investment 2013[23]	Evolution R&D CAGR 2010 / 2013[24]	Patent grants 2013[25]	Patent evolution[26]
Functional Food	US$168 bn[27]	+5.38% (CAGR 2009 - 2013)[28]	+8.5% (CAGR 2013-2020) US$305.4 bn by 2020[29]	1.2% (Food sector, 73 companies)	US$8 bn (Food sector, 73 companies)	+2,7%	19 030 (Food chemistry)	8,2% (Food chemistry)
Cosmetics	US$460 bn[30]	+3.8% (CAGR 2005 - 2015)[31]	From +3.7%[32] to +6.4%[33] (CAGR 2015 – 2020) Forecast of 100% in the next 10 to 15 years[34]	2.2% (Personal care, 47 companies)	US$3.7 bn (Personal care, 47 companies)	+6,7%	14 918 (Personal care)	2,8% (Personal care)
Pharmaceutical	US$1.057 tn[35]	+5.4% (CAGR 2009 – 2014)[36]	+3.8% (CAGR 2015-2018)[37] From $1.2 tn by 2018[38] to US$1.6 tn by 2020[39]	14% (293 companies)	US$96 bn (293 companies)	+3,1%	33 132	6,30%
Biotechnology	US$129,6 bn (excl. Pharmaceutical)[40]	+5.6% (CAGR 2010-2013) [41]	+12.3% (CAGR 2013 – 2020)[42]	20.55% (for US and EU)	US$16.7 bn (for US and EU)	Not available.	20 116	6,90%

[22] EU Industrial R&D Investment Scoreboard, EU, 2014. http://iri.jrc.ec.europa.eu/scoreboard14.html
[23] Ibid.
[24] Ibid.
[25] WIPO patents statistics database spring 2014 http://www.wipo.int/ipstats/en/statistics/patents/
[26] Ibid.
[27] Functional Food and Nutraceuticals Market (2014 - 2020), Research & Markets, 2014. http://www.researchandmarkets.com/research/m9qvsw/global_functional
[28] Future Directions for the Global Functional Foods Market; Leatherhead Food Research, 2014. https://www.leatherheadfood.com/sites/default/files/Future-Directions-for-the-Global-Functional-Foods-Market.pdf
[29] Functional Food and Nutraceuticals Market (2014 - 2020), Research & Markets, 2014. http://www.researchandmarkets.com/research/m9qvsw/global_functional
[30] Global Cosmetics Market, Research & Markets, 2015. www.researchandmarkets.com/research/f2lvdg/global_cosmetics
[31] YE, Luxury and Cosmetic financial Factbook 2015 http://www.ey.com/Publication/vwLUAssets/EY_Factbook_2015/$FILE/EY-Factbook-2015.PDF
[32] World Cosmetics Market - Opportunities and Forecasts, 2014 – 2020, Allied Market Reseach. 2014. https://www.alliedmarketresearch.com/cosmetics-market
[33] YE, Luxury and Cosmetic financial Factbook 2015 http://www.ey.com/Publication/vwLUAssets/EY_Factbook_2015/$FILE/EY-Factbook-2015.PDF
[34] Ibid.
[35] IMSHealth, 2014. www.imshealth.com/files/web/Corporate/News/Top-Line%20Market%20Data/Global%20Prescription%20Sales%20Information5%20World%20figures%20by%20Region%202015-2019.pdf
[36] Ibid.
[37] Projected revenue growth rates of the global pharmaceutical industry from 2015 to 2018, Statista, 2015. http://www.statista.com/statistics/398223/prediction-of-pharmaceutical-industry-cagr-worldwide-by-region/
[38] Global Pharmaceutical Industry 2013-2018: Trend, Profit, and Forecast Analysis, Research and markets, 2013 www.researchandmarkets.com/reports/2634732/global_pharmaceutical_industry_20132018_trend
[39] Pharma 2020, PWC, 2012. www.pwc.com/gx/en/industries/pharmaceuticals-life-sciences/pharma-2020/market-opportunities-outlook.html
[40] Biotechnology Market - Global Industry Analysis, Size, Share, Growth, Trends and Forecast, 2010 – 2017, Research & Markets, 2013 www.researchandmarkets.com/research/lx22np/biotechnology
[41] Global Biotechnology: Market Research Report, IBISworld, 2016. http://www.ibisworld.com/industry/global/global-biotechnology.html
[42] Biotechnology Market Analysis and forecast, Grandview research, 2015. www.grandviewresearch.com/industry-analysis/biotechnology-market

The evolution of patent applications and grants between 2003-2013 shows an average growth of patent grants of 5.7%. North America, Japan, and Europe are leading in volume but Latin America and Asian developing countries are catching up. Africa has the lowest number of patent applications and grants, and these figures are decreasing. Details are available in Annex 2.

There is a reduction of the number of patent applications, whereas the proportion of grants is increasing. This indicates a more efficient pattern throughout industry. The average patent application efficiency is of 49% (ranging from in personal care 39% to chemistry 53%). Information available on patent propensity[43] for Europe indicates an average of 0.29 per million Euros with the sectors ranking as shown in the graph below. Thus patent grants in the pharmaceuticals, biotechnology, and food sectors are more expensive than in personal goods (Graphic 1).



Graphic 1: Patent propensity across sectors in Europe.
Source: The 2014 EU industrial R&D investment scoreboard. European commission.

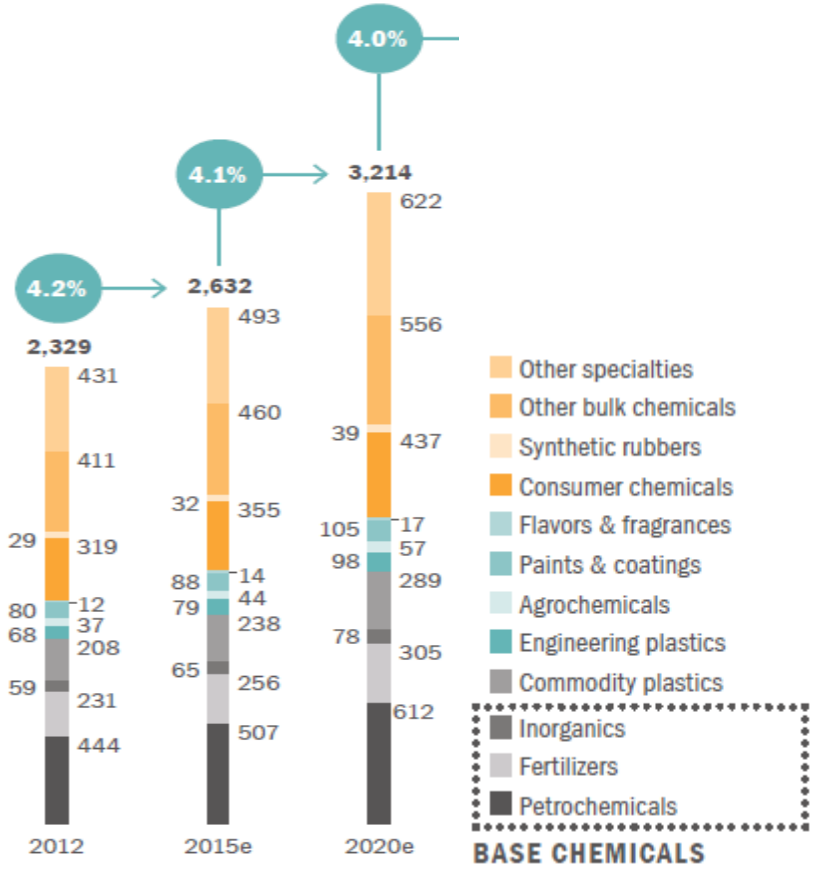
Overall, there is tremendous progress, with double digit growth over ten years, of R&D in Asia (Japan, but also Korea, China, Hong Kong, Thailand). For instance, the FOODPOLIS initiative in South Korea is one of the biggest food R&D investment projects in the world.[44] It aims to offer multinational food companies and research institutes growth potential in the key Asian markets, which are responsible for approximately 32% of global food consumption. There is a plan to attract over 150 local and international food companies and ten research centres, churning out US $15 bn output annually and generating 22,000 new jobs in the process.

In this context, it is pertinent to consider the chemical industry as a direct competitor to natural species utilisation (Graphic 2). This sector has a global market size of US $2.85 trillion (tn) with growth of +4.2% (CAGR 2012-2015). It has a relatively low R&D intensity (0.8 patents per million Euros), but it is on the

[43] Patent propensity informs about the cost of developing a patent. It is the ratio between the number of patents and R&D investments. The highest the ratio, the "cheapest" the patent comes in terms of research.
[44] http://eng.foodpolis.kr/ (accessed 4 march 2016)

rise to 6.8, (CAGR 2013-2013). It has one of the highest volumes of patent grants (74,969 in 2013), across all industries, with a growth rate of 5.3%.[45]

Currently, most of the product solutions natural resources can bring are more expensive than their synthesized or extracted (from fossil sources) counterparts. This situation is likely to remain, as long as the bio-based feedstock activities are not cost-effective enough for a large-scale application. Currently Asian supply and demand is fuelling the market growth.[46] The emergence of new sustainable development goals[47] and the fight against climate change may, however, accelerate such transition.



Graphic 2: Total Chemical real value forecast
Source: Roland Berger, 2015 Chemicals report

[45] Roland Berger, 2015 Chemicals report www.rolandberger.com/media/pdf/Roland_Berger_TAB_Chemicals_2035_20150521.pdf (accessed 4 march 2016)
[46] Ibid
[47] https://sustainabledevelopment.un.org/?menu=1300 (accessed 4 march 2016)

1.1.2. Functional Food

The main markets are USA, Japan, and Europe to a lesser extent (Graphic 3). There is limited information on R&D budgets allocated specifically in this sector.[48] As a major factor contributing to the growth of the functional market is the growing food and beverages industry, this wider sector is used as a proxy indicator.

The food sector is typically a mass market with low profit margins and R&D budgets[49]. However, there is likely higher R&D investment in the functional food sector.[50] [51] A study focusing on the UK sector tends to confirm this: "*in terms both of turnover and staff, SMEs tend to be around twice as R&D-intensive as large businesses, spending around 1.2% of their turnover on R&D and innovation compared with 0.5% for large businesses*".[52] Industry experts confirm that in other countries many SMEs have a relative higher focus on R&D and innovation than their larger counterparts.[53]

Most businesses concentrate on well-known processes and existing ingredients. In the USA, 5000 of the 21,000 "new" products recorded worldwide each year[54] can be attributed to Functional Products[55] (Graphic 4). However, over 90% of new food and beverage products are not innovative.[56] These "new" products typically involve variations such as new flavors, package sizes, or brand names. This practice suggests that food firms use new-product introductions as a differentiation strategy to present a fresh image to consumers, rather than providing truly novel or innovative products. The high failure rates for new products, exceeding 90% for some categories, can partly explain this trend.[57]

Hence, it is the sub-sector for food ingredients/additives that does most of the "real" innovation.[58] The market for functional food ingredients is expected to grow from US $1.83 bn in 2015 to around US $2.5 bn by 2020. This represents a 6% annual growth from 2015 to 2020 (CAGR); higher than the rest of the sector. In 2014, North America was the largest market and Asia-Pacific is projected to be the fastest-growing market.[59]

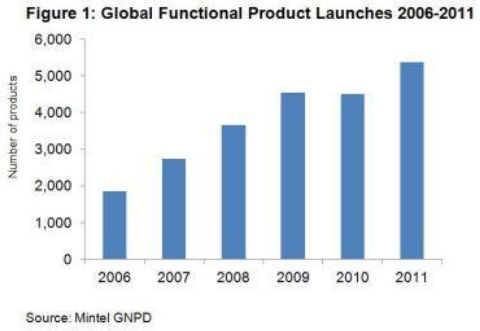
In this context, the share of "functional" claims in new products has increased in the last decade. While health claims are declining, natural claims and ethical source or use claims are on the rise (Graphic 5

[48]Food and health: A report on research and development activity in the United States, European Commission and the United Kingdom. Cooper et al. 2011
[49] Food and Beverages sector, 2016. Transparency market research www.transparencymarketresearch.com/food-beverages-market-reports-4.html (accessed 4 march 2016)
[50] http://www.pwc.com/us/en/view/issue-12/investing-in-functional-foods.html (accessed 4 march 2016)
[51] Food Additives Market: Global Industry Analysis, 2012 – 2018. Transparency market research. http://sbdi.co.kr/cart/data/info/Transparency_Food_Additives_Market_Sample.pdf?ckattempt=1 (accessed 4 march 2016)
[52] Mapping current innovation and emerging R&D needs in the food and drink industry required for sustainable economic growth. Arthur D Little. 2013.
[53] C. Lombard, CEO Phytotrade. 2014. Pers. Comm.
[54] New food product introduction. USDA, 2010. www.ers.usda.gov/topics/food-markets-prices/processing-marketing/new-products.aspx (accessed 4 march 2016)
[55] Mintel GNPD, 2011.
[56] Datamonitor, 2007 www.highbeam.com/doc/1G1-172832585.html (accessed 4 march 2016)
[57] O. Lafon, Expert in food marketing strategy, 2015. Pers. Comm.
[58] Food Additives Market report, Transparency Market Research, 2015. www.transparencymarketresearch.com/food-additives.html (accessed 4 march 2016)
[59] Functional Food Ingredients Market by Type, Application, Health Benefit, & by Region - Global Forecast to 2020. Markets and markets. www.marketsandmarkets.com/PressReleases/functional-food-ingredients.asp (accessed 4 march 2016)

and Table 3). Other trends like high vitamins/minerals and low fat are also firming. The increase of private label products[60] indicates higher vertical integration of R&D in the business-2-business sector.

Eventually, a surge in patent deposits and grants might be expected from 2015 in Europe. The European Patent Office Board of Appeal has allowed plant products arising from conventional breeding to be patented.[61] [62] NGOs estimate that this decision will be used to bypass the current legislation in Europe, according to which conventional selection processes on plant and animals cannot be patented. The analysis of the consequences of this decision on R&D on GR was not in the scope of this report.

Graphic 3: Global functional foods market by region, 2013
Source: Leatherhead Food research



Graphic 4: Global functional product launches 2006 – 2011

[60] Private-label products or services are typically those manufactured or provided by one company for offer under another company's brand.

[61] Intellectual Property Watch, april 2015 www.ip-watch.org/2015/04/01/epo-backs-patents-on-conventional-plants-broccoli-tomato-cases-decided/ (accessed 4 march 2016)

[62] In the US, patents on the living have been issued since 1930, and definitively validated by the US Patent and Trademark Office in 1985 (The Patent and Trademark Office now considers non-naturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101 : "include anything under the sun that is made by man". www.uspto.gov/web/patents/patog/week53/OG/TOCCN/item-137.htm www.infogm.org/-OGM-et-brevet-sur-le-vivant- (accessed 4 march 2016).
In 2013 the US Supreme Court has put a constraint on the application patents to naturally ocurring DNA by determining that DNA found in nature is not 'patentable subject matter' (the BRCA1 Gene CASE –AMP Vs Myriad Genetics). Partial gene DNA (cDNA) can be patented in the US but is liable to fail the 'non obviousness test' (i.e., not really very inventive). The US decision is influencing other patent markets (e.g., the Australian High court has come down with a similar ruling (http://www.hcourt.gov.au/cases/case_s28-2015).
Policy in this area is still evolving. In any conflict between sovereign national law and administrative decisions made by a supranational patent body the national law would prevail unless national law provides otherwise. (See the Hague Convention and agreed EU Law interpreting it for the purposes of the operation of the EU.)

Source: Mintel GNPD

Graphic 5: Percentage of world's new food products in last 12 months (main claim), 2007 – 2013.
Source: CFIA 2014 / Nutrimarketing

Total new product claims	16,374	17,629	19,261	20,459	26,263	25,012	22,483	25,640

Percent of new product introductions in the top 10 product claim categories for 2003-10*

Tag or claim**	2003	2004	2005	2006	2007	2008	2009	2010
Natural	8.4	7.6	8.3	8.1	8.9	8.5	8.4	8.4
Premium	9.7	8.8	10.8	12.9	13.5	13.4	10.4	7.0
Private label	2.6	1.6	1.5	2.0	2.8	3.0	3.6	6.2
Single serving	6.9	6.2	6.6	6.8	5.9	6.1	6.0	5.7
High-vitamins/minerals	4.2	4.0	3.9	3.9	3.5	4.0	3.4	3.8
No gluten	1.0	1.0	1.2	1.2	1.5	1.9	2.5	3.4
No preservatives	3.5	3.1	2.8	2.9	3.2	3.2	3.4	3.4
Organic	3.4	3.0	3.5	3.6	4.2	4.2	3.4	3.2
Fresh	3.4	3.4	3.6	3.4	3.6	3.7	3.6	3.2
Low/no fat	4.0	3.4	3.3	3.0	2.6	2.5	2.4	2.8

*Does not include associated stock keeping units (SKUs, or variations in size and form). According to Datamonitor, the SKU count may produce erroneous results because a single new product introduction can have multiple SKUs, and each of these SKUs may or may not have certain package tags.
**A new product may have multiple tags or claims.
Source: Datamonitor.

Table 3: Percentage of new product introductions in the top 10 claim categories for 2003 – 2010.
Source: USDA

1.1.3. Cosmetics

The global cosmetic market is reaching an all-time high. Asia-Pacific emerging markets and Brazil are the strongest drivers of growth**.** Africa is also expected to grow in the near future.[63] It is a very high value added market (e.g. 38% average mark-up margin for makeup[64]). Most of the companies listed in the top 2500 companies investing in R&D are present in at least two segments out of three: cosmetics, perfume, and luxury goods.

There are currently thousands of cosmetic ingredients[65] available on the market. In the US, 2/3 of the 25,000 packaged new products in 2010 for non-food relate to personal care.[66] Like in the functional food sector, these "new" products typically involve variations such as new package sizes, or brand names developed across various ranges of (e.g., skin/hair type, shades for make-up). This practice suggests that cosmetics firms use new-product introductions as a differentiation strategy to present a fresh image to consumers, rather than providing truly novel or innovative products.

Hence, there are relatively few innovative ingredients. For instance, the In-Cosmetics Exhibition 2015, a major trade fair in the industry, lists the new ingredients entering the market within the previous six months as: 89 products in Europe, 37 in Asia, and 18 in Brazil (this includes all ingredients, natural and chemical).

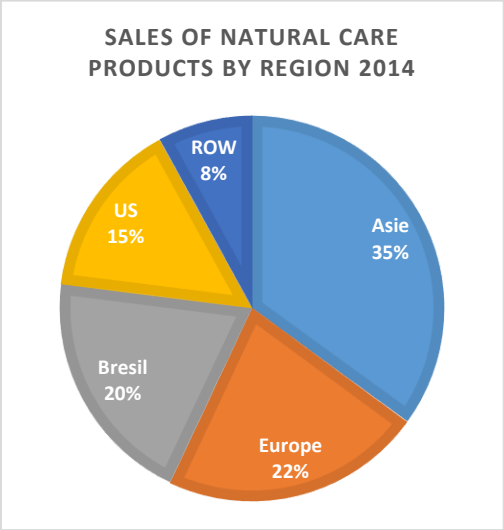
The sub-sector for cosmetic ingredients is growing at a faster pace of 5.2% per annum (CAGR) than the broader cosmetic sector at 3.8%.[67] Market size is expected to go from US $7.46 bn in 2014 to US $11.76 bn by 2023.[68] "*The demand for good quality cosmetic products is fuelling the cosmetic ingredient market. Changing lifestyle specially in developing regions of Asia Pacific and Latin America brings a sea of opportunities to cosmetic ingredients manufacturers and suppliers*."[69]

The cosmetic industry primarily uses chemical and synthetic ingredients. However, the "natural" personal care area is growing faster than the rest of the industry (10.6% increase globally to reach US $29.5 bn at the manufacturers' level in 2013).[70] This is due to a growing consumer preference for green credentials. The resulting range of products is going beyond skin-care and covers other segments (e.g., hair). The corresponding demand for R&D has increased significantly.[71]

Organic products, a subset of the natural ingredient segment, account for less than 5% of the sector (US $8.2 bn, 2013) but has a higher growth rate (7.9% in 2012).[72] Brazil and Asia confirm their predominance (Graphic 6). True Friends of Natural and Organic Cosmetics (Natrue), a natural and

[63] EY, Luxury and Cosmetic financial Factbook 2013
[64] www.loc.gov/rr/business/BERA/issue17/current.html (accessed 4 march 2016)
[65] Cosmetic ingredients are the specific sets of substance that are used in the formulation and composition of cosmetics.
[66] New food product introduction. USDA, 2010. http://www.ers.usda.gov/topics/food-markets-prices/processing-marketing/new-products.aspx (accessed 4 march 2016)
[67] Cosmetic Ingredients Market: Global Industry Analysis and Opportunity Assessment 2015-2025, futuremarketinsights, 2016. http://www.futuremarketinsights.com/reports/cosmetic-ingredients-market (accessed 4 march 2016)
[68] Growth of global ingredients market outpaces personal care industry, Cosmectic design, 2015. www.cosmeticsdesign.com/Market-Trends/Growth-of-global-ingredients-market-outpaces-personal-care-industry (accessed 4 march 2016)
[69] Ibid
[70] Natural Personal Care: Global Market Brief, Kline, 2015. www.klinegroup.com/news/global_natural_personal_care_market12-10-13.asp (accessed 4 march 2016)
[71] Ibid
[72] Organic Personal Care Market Analysis By Product And Segment Forecasts To 2020, GrandView Research, 2015. http://www.grandviewresearch.com/industry-analysis/organic-personal-care-market (accessed 4 march 2016)

organic cosmetic association, indicate a strong rise in demand for exotic extracts (e.g., argan oil, açai berry, pomegranate, calendula, aloe vera, etc.).



Graphic 6: Sales of natural care products by region, 2014.
Source: Natural Personal Care: Global Market Brief, Kline, 2015.

1.1.4. Pharmaceutical

Traditionally it is a market with a high profitability rate, but this trend is changing with the declining efficiency of R&D.[73] While North America remains the largest market, the highest growth forecasts are for Asia and Latin America (Table 4). Companies in the US, Europe, and Asia have increased their R&D expenses at similar and steady rates. In Europe, this represents, for instance, 116 000 employment units.[74]

The pharmaceutical industry is estimated to have a R&D pipeline valued at $493bn.[75] Developing a new drug is expensive, complex, and takes a long time. The diagram below presents an overview of the key stages of its R&D process. It starts with up to 10,000 compounds to produce a few chances to get an approved drug ten to 20 years later. The cost for developing a new prescription medicine that gains marketing approval is estimated to be US $2.6 bn; an increase of 145% since 2003.[76] This cost varies widely from one new medicine to another, depending on the type of medicine, the risk of failure, and whether the medicine is based on a new molecule or not.[77]

R&D efforts are directed to identifying promising lead compounds or new chemical entities, which are then subjected to numerous tests aimed at demonstrating safety and efficacy.[78] However, only 23.8%

[73] Scannel et al. 2012 http://www.nature.com/nrd/journal/v11/n3/full/nrd3681.html The research-based pharmaceutical industry is estimated to have spent nearly USD 137 bn globally on pharmaceutical R&D in 2012
[74] The Pharmaceutical Industry in Figures. EFPIA, 2014. http://www.efpia.eu/uploads/Figures_2014_Final.pdf (accessed 4 march 2016)
[75] World Preview 2015, Outlook to 2020, 2015. Evaluate groupe. http://www.evaluategroup.com/public/reports/EvaluatePharma-World-Preview-2015.aspx (accessed 4 march 2016)
[76] Cost to Develop and Win Marketing Approval for a New Drug. Tufts Center for the Study of Drug Development, 2014.
[77] International Federation of Pharmaceutical Manufacturers & Associations - http://www.ifpma.org/innovation/rd/about-research-development.html (accessed 4 march 2016)
[78] M. A. Desai, Assistant General Patent Counsel, Eli Lilly and Company, 2014. Pers. Comm.

of the R&D budget is allocated to the pre-human/pre-clinical phase[79]; where GRs are mostly used.[80] Furthermore, the use of biological or natural derivatives is only one avenue for discovering new leads (Diagram 2). There is a cyclical pattern and currently R&D based on natural molecular sources is regaining interest.[81] Eventually, the number of new or novel molecular-based drugs that gain final market authorisation each year varies between 25-30 for each of the major regulation centres (Graphic 9).[82]

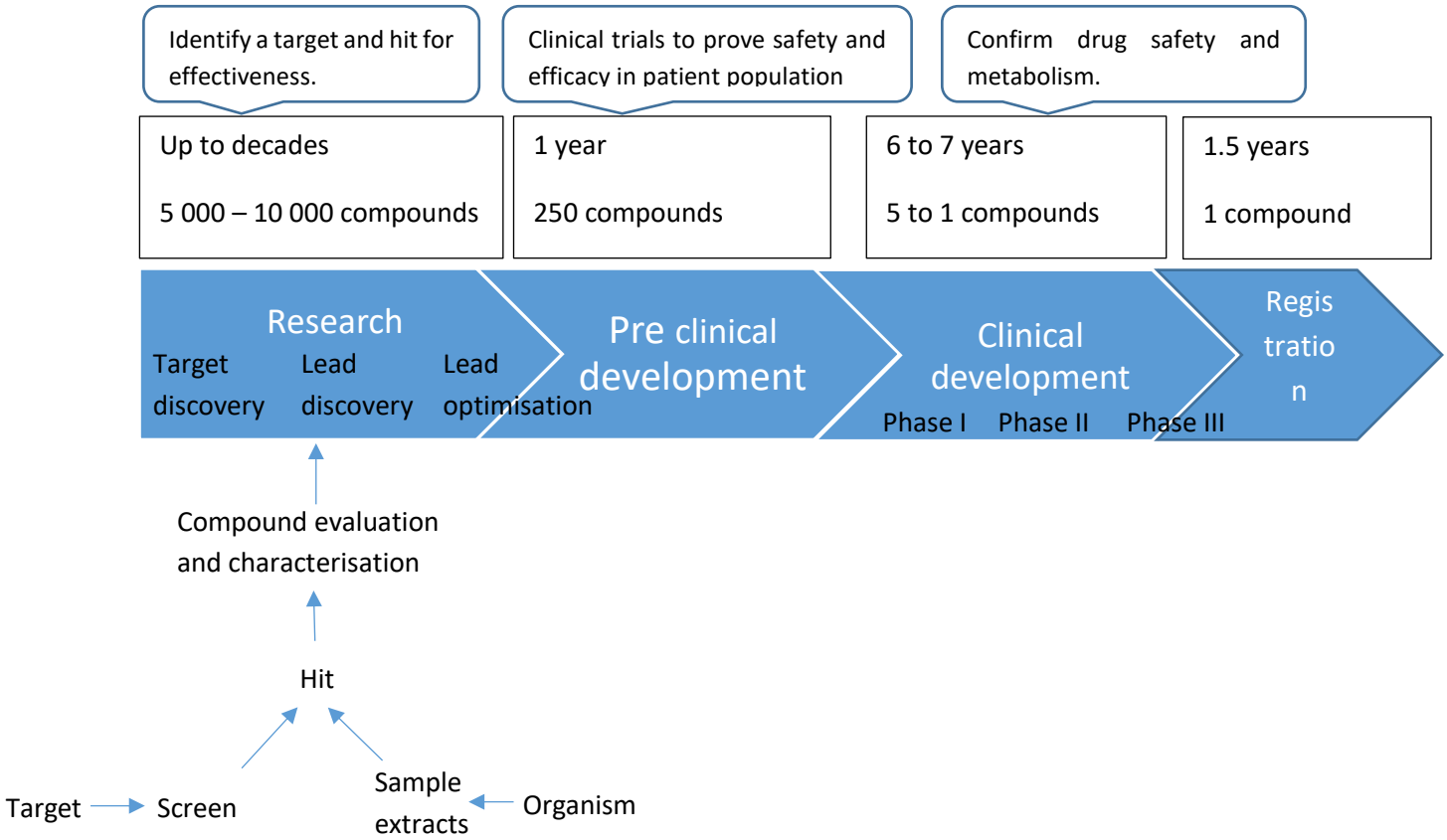
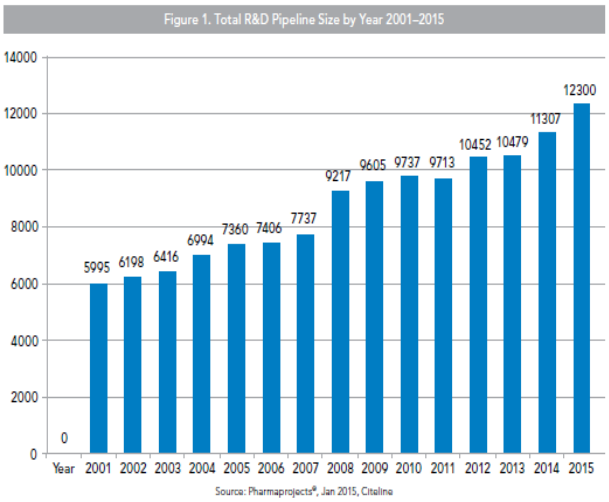
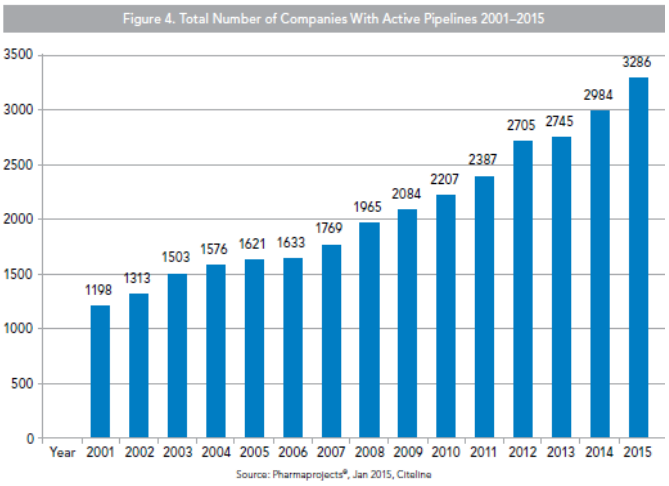


Diagram 1: Key stages of the drug-candidate discovery process
Source: Adapted from Hughes et al. 2011

From 2001 to 2014 there was a continuous upward trend of new R&D projects (12,300 in 2014) and of companies (3,286 in 2014) entering into R&D (Graphics 7 and 8). A pool of small companies with one to three projects is developing. In this pipeline of new projects, 1/3 are using biological or natural derivatives. This share has increased by 20% since 2000. Overall, 600 new companies have joined the R&D pipeline, while around 300 have withdrawn.[83]

[79] The Pharmaceutical Industry in Figures. EFPIA, 2014. http://www.efpia.eu/uploads/Figures_2014_Final.pdf (accessed 4 march 2016)
[80] GR can also be of interest in the development phase for production processes using biotechnology
[81] www.researchgate.net/publication/262771421_The_pharmaceutical_industry_and_natural_products_historical_status_and_new_trends (accessed 4 march 2016)
[82] In the USA, the highest number of molecular-based drugs approved by Food and Drug Administration (FDA) since 2000 was reached in 2012 due to the creation that year of the Breakthrough Therapy Designation list. The continuation of this program is expected to reduce time to market and development costs for the designated drugs. It is an important part of the FDA Safety and Innovation Act (FDASIA). This protocol enables to fast-track a new drug if it is promising in bringing significant improvement compared to existing drugs in the treatment of serious or life-threatening diseases. Sources: www.fda.gov, www.fdalawblog.net , www.PrNewswire.co (accessed 4 march 2016)
[83] Citeline Pharma R&D Annual Review 2015 Supplement: New Active Substances Launched During 2014. Citeline. 2015. https://citeline.com/wp-content/uploads/2015/03/CITIF_NASReport_031215.pdf (accessed 4 march 2016)





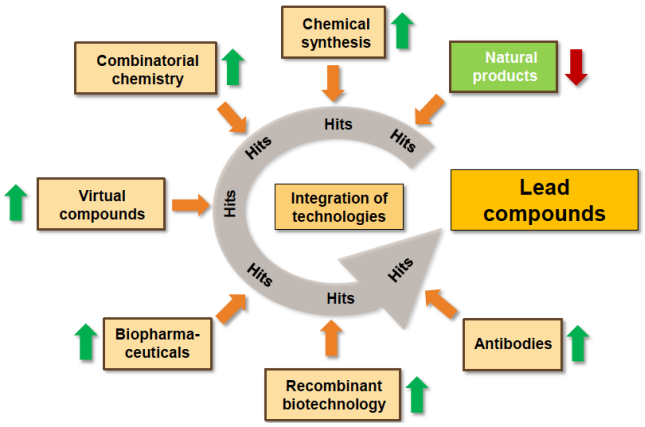


Diagram 2: Multiple research avenues
Source: B. Barnes, EFPIA

Graphics 7 & 8: Total R&D pipeline size, total number of companies with active pipeline, 2001 – 2015.
Source: Pharmaprojects, 2015, Citeline

PharmaBiotechnology revenues and R&D investments are rising quicker and are higher than the average pharmaceutical market. The R&D intensity (R&D expenses/turnover) is 32%.[84] A recent article indicates that: "*Biopharmaceuticals could become the core of the pharmaceutical industry. . . Today, biopharmaceuticals generate global revenues of $163 bn, making up about 20 percent of the pharma market. It's by far the fastest-growing part of the industry. . . Many large pharmaceutical companies are shifting their presence to biopharma. . . Investing in biotech R&D has yielded better returns than the pharma-industry average. . . The challenges are cost, complexity and regulatory scrutiny*".[85] This is also analysed as a biotech bubble.[86]

[84] Research and Markets, 2015. Transparency Market Research.
[85] Rapid growth in biopharma: Challenges and opportunities. Mc Kinsey, 2014.
http://www.mckinsey.com/insights/health_systems_and_services/rapid_growth_in_biopharma (accessed 4 march 2016)
[86] http://qz.com/324939/biotech-valuation-bubble/ (accessed 4 march 2016)

	2009 -2014	2014-2019
Total unaudited and audited global market	**CAGR% ** Const US$**	**CAGR% ** Const US$**
	5.4%	4.8%
Total unaudited and audited global market BY REGION		
North America	4.5%	2.7 +5.7%
Europe	1.9%	1.3 +4.3%
Asia (including Indian sub-continent) / Africa / Australia	12.4%	6.9 +9.9%
Japan	2.0%	-0.8 +2.2%
Latin America	10.2%	4.8 + 7.8%

Table 4: Total unaudited and audited global pharmaceutical market by region 2014 – 2015

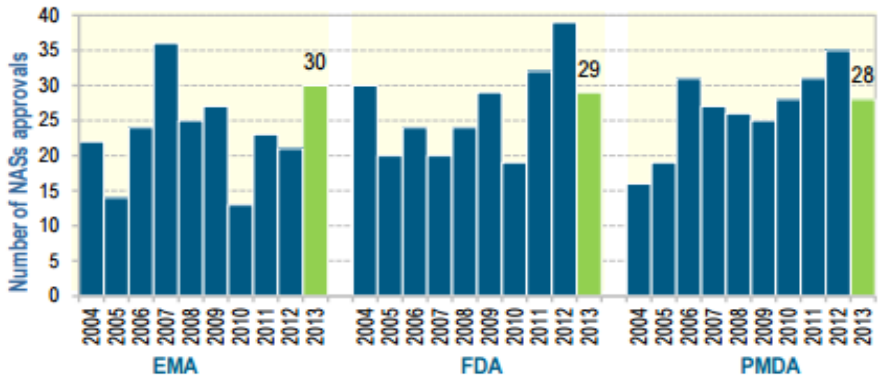
Source : Imshealth

Notes on numbers: all forecasts are from IMS Market Prognosis 2015-2019 which provides a view of the audited and unaudited market, using audited sales and adjusted unaudited sales.

** Constant $ uses Q4 14 average exchange rate (Q1 2015 rates for Algeria, Belgium, Brazil, Chile, China, Egypt, Mexico, Peru, Russia, Saudi Arabia, United Arab Emirates and USA).

Figure 1

Number of NASs approved by ICH agencies by approval year



Graphic 9: Number of New Active Substance (NAS) approved by ICH agencies[87] 2004 – 2013

Source: New drug approval in ICH countries 2004 -2013, Focus on 2013. R&D Briefing 54. Centre for Innovation in Regulatory Science, 2014

[87] The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a project that brings together the regulatory authorities of Europe, Japan, and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of pharmaceutical product registration.

1.1.5. Biotechnology

There is limited information on the biotechnology sector alone as the pharmaceutical sector accounts for 60% of this industry. The market for other sub sectors including bioagriculture, bioservice, and bioindustrial represents approximately US $129.6 bn.[88] The R&D intensity is high (35%) and increasing (Table 5).

The R&D phase in biotechnology can be as short as a few years or can last decades (Table 6). There are many potential biotechnological applications based on basic research findings. However, this requires a sound understanding of the actors' needs across sectors. For instance, at a large scale, biomass as by-products from major crops can be valorised through biotechnology in green products. This requires a coordinated effort amongst actors along the entire value chain and a fine understanding of the demands of actors in the transformation process. The main issue is to change the whole industry's very basic technology platform and feedstock base. This cannot be done by a single company. It needs a coordinated technology development and realisation spanning various markets (e.g., feedstock, plant engineering, process technology, and application research in different end consumer markets).[89]

Growth in established biotechnology centers, 2013-14
(US$b)

	2014	2013	% change
Public company data			
Revenues	123.1	99.0	24%
R&D expense	35.4	29.4	20%
Net income	14.9	4.5	231%
Market capitalization	1,063.4	794.8	34%
Number of employees	183,610	168,010	9%
Number of companies			
Public companies	714	619	15%

Tables 5: Growth in biotechnology centers, 2013 – 2014.
Source: EY Beyond border report 2015

Fig. 5 Academia and industry cooperate in developing process

Table 6: Academia and industry cooperate in developing process - Source: OECD

[88] Biotechnology Market - Global Industry Analysis, Size, Share, Growth, Trends and Forecast, 2010 – 2017, Research & Markets, 2013 www.researchandmarkets.com/research/lx22np/biotechnology (accessed 4 march 2016)

[89] OECD workshop on "outlook on industrial biotechnology" Discussion Paper - Session Trends in Technology and Applications, 2010.

1.2. Micro-analysis in Functional Food and Cosmetics

Interview results[90] confirm that there are no rules for success, as is also indicated in the literature.[91] Small projects can deliver blockbusters and large projects can fail while, nevertheless, they allow for the development of expertise. As companies are moving away from mass and blind screening to a more informed selection of species, they have a higher interest in the accompanying scientific information. Hence they are looking for R&D partnerships from the very start of the research phase to ensure a common understanding and to hold a similar vision.

In this context, there are huge variations in R&D expenses depending on the corporate strategy used and its business model. The budgets per R&D project vary from a few thousand Euros to several millions. Small projects tend to be undertaken in-house, while larger ones are generally realised in partnerships. Consequently, the number of R&D actors involved varies, also partly depending on the activities that are outsourced.

Overall, 2/3 of R&D is done using existing or well-known ingredients. This is explained by regulatory constraints and having a client base that is more comfortable using known ingredients. This is referred as the "new but known" trend. For instance, a scientific study in 2015 on the cosmetic application of flavanoids[92] is based on apples.[93] The minimum cost for developing a new ingredient is estimated at around €300 000, although there are examples of initial screening phases identifying potential leads in user countries with budgets ranging from €5 000 to €15 000. The registration of a new ingredient is expensive and adds up to the development costs while the market prospects are uncertain. Some rough figures of registration costs are:

- Food ingredient: US (generally recognised as safe regulation): from €400 000 up to €1.5 million
- EU (novel food): around €300 000
- Cosmetic ingredient: around €300 000.

The success rate of R&D for new ingredients introduced to the market averages ten %. This, however, does not guarantee a commercial success. On average, out of 100 ingredients initially screened, 25 will undergo deeper tests. The volume of raw material necessary for the production of an ingredient that is successfully commercialised can vary from a few hundred kilograms (kg) (cosmetics) to a few tons (cosmetics, functional foods). For a few rare cases that are similar to commodities, such as Argan or *Centella asiatica* extracts, volumes can reach up to 100 tons (cosmetics and functional food).

Consequently, the evaluation of the return on investment on R&D is complex. For instance, a new ingredient is rarely commercialised alone but as part of a mix. Furthermore, companies have different

[90] Antoine Billy, Director R&D, Naturex. Patrice André, Director Cosm'ethic (former Director of Botanical Innovation, LVMH). Francesco Gatesco, Senior R&D scientist, Indena. Cyrill Lomard, CEO, Phytotrade Africa. Oriane Lafon, Expert in agro-industry strategy, independent. Xavier Brochet, Director of natural innovation, Firmenich. Chloé Ambroset, ingénieure de recherche en biologie Anses laboratoires de Lyon.
[91] Creating an R&D Strategy, G. Pisano 2012. www.hbs.edu/faculty/Publication%20Files/12-095_fb1bdf97-e0ec-4a82-b7c0-42279dd4d00e.pdf (accessed 4 march 2016)
[92] Flavonoids are multi-active components used in common cosmetics primarily for antioxidant and soothing actions. http://www.ncbi.nlm.nih.gov/pubmed/18691514 (accessed 4 march 2016)
[93] http://www.cosmeticsdesign-europe.com/Formulation-Science/Scientists-discover-naturally-occurring-flavonoid-as-a-new-anti-acne-agent/?utm_source=newsletter_daily&utm_medium=email&utm_campaign=22-Jan-2016&c=Nxni8m81E0SQHRx9W5ixOg35zn1JtRbb&p2 (accessed 4 march 2016)

marketing strategies with various levels of emphasis on the ingredient (e.g. technical, innovation, brand focus). For some companies, their objective is for ten % of their turnover to be derived from ingredients used for less than ten years, thus ensuring the regeneration of their product portfolio.

Key findings

In 2014 the aggregated market size for all four sectors is around US $1,846 bn (see table 2 above). The annual growth forecast to 2020 ranges from 3.8% for pharmaceuticals, 3.8 to 6.7% for cosmetics, 8.5% in functional food, and for 12.3% in biotechnology. R&D expenses follow growth trends as well, with an aggregate US $124.4 bn spent in 2014. The R&D intensity ranges from 1.2% in functional foods to 20.5% in biotechnology.

This represented an output of 87,169 patent grants in 2013 and these are rising too. Asia is the most dynamic region across all sectors. The patent propensity (less patent applications, more patent grants) is increasing. While all regions are on the rise for patents, albeit at a different pace, Africa has the lowest figures and these are decreasing.

The pharmaceutical sector spent US $137 bn on R&D in 2012. However, only 28% was allocated to the pre-clinical phase, where new GR are mostly utilised. GRs are only one research avenue among seven others. There are high numbers of new R&D projects and companies; many of these companies are SMEs. The pharmaceutical biotechnology market is also rising quickly. The biotechnology sector has a higher rate of R&D, around 32%. There are many opportunities emerging, but some products are complex to manufacture at a large scale. This complexity, however, offers some protection against competition from biosimilars.

The cosmetics and functional food sector spent on aggregate US $12.1 bn on R&D in 2014. They have similar drivers, such as the market interest in "new but known" ingredients. Up to 2/3 of new R&D projects focus on well-known species. Their ingredient segments are growing faster than the sector average with a cumulated market size estimated to reach US $14.25 bn by 2020. Natural and green credentialed products are on the rise, including related R&D expenses. Although it represents a relatively small market (e.g., 5% for cosmetics), it has an interesting absolute size of US $23 bn. Finally, the cosmetic sector typically pays higher prices for ingredients, but requires smaller volumes than functional foods, which pays less to producers, but requires higher quantities.

In practice, companies in these two sectors have an average 10% success rate for their R&D projects. R&D processes are therefore complex, costly, and risky. There are no rules of success for an R&D project. Companies are increasingly interested in the scientific information accompanying the samples in order to reduce failure. An average minimum figure for an R&D project is €300,000. The budget for the screening phase to identify potential leads obtained from a provider country can range from €5,000 to €15,000. The cost of regulation, including new ingredient registration, is rising in all regions. In this context, it is difficult to evaluate the Return On Investment (ROI) in R&D. The number of new ingredients in a product portfolio is often used as an indicator. For new ingredients successfully marketed, the volumes of raw material necessary for their production may vary from a few hundred kilograms to a few tons.

2. Challenges and R&D Drivers

This section provides an overview of the trends, the drivers, and the practices that are structuring R&D across the four sectors. Five global R&D trends[94] constitute the background of this analysis. These are:

- Global expenditure on R&D will continue to grow
- Developing countries will increase R&D spending
- China will emerge as the global scientific force
- Academia and industry will both fund R&D
- Global expansion of the researcher community will continue

2.1. Common Features

Challenges

On top of economic matters, social and environmental issues raise new challenges.[95] Companies respond to these challenges by offering new products and services that best respond to the emerging needs. Specific R&D goals and strategies are thus developed. The recent Sustainable Development Goals provide a framework for identifying the main R&D goals relevant for the four sectors.[96] To cut across complexity, four are identified as particularly relevant (table 6 below). Two are categorised as being overarching (i.e., demographic growth and climate change) and the other two are specific to mature markets on which the companies mostly concentrate (i.e., aging population, unhealthy lifestyle).

This is a basic framework as industry responses depend on the market segment they serve, the geographical area they cover, and their business model. This is relevant for potential provider institutions in order to appreciate the fit between their research themes, goals and results, and those of user institutions or potential partners.

[94] The future of science: 5 Predicted global trends in R&D expenditure and research output, The International Association of Scientific, Technical and Medical Publishers, 2015 http://www.editage.com/insights/the-future-of-science-5-predicted-global-trends-in-rd-expenditure-and-research-output

[95] Science, Technology and Industry Outlook, OECD, 2014. http://www.keepeek.com/Digital-Asset-Management/oecd/science-and-technology/oecd-science-technology-and-industry-outlook-2014/summary/english_4b88d3e1-en#page1

[96] https://sustainabledevelopment.un.org/?menu=1300

Societal challenge	Description
Demographic growth	The world population is expected to reach 7 to 17 billion people by the end of the century.[97] This brings issues in terms of alimentation, health, and accommodation in a context of limited natural resources.
Climate change	Companies' operations are increasingly affected by climate change such as the availability of raw materials.[98] Some business models are at risk.
Aging population	The world's population is aging, which brings specific diseases (e.g., Alzheimer's, oncology, and rheumatology) and the need for new treatments and products (e.g., complementary diet, anti-aging creams).[99]
Unhealthy lifestyles	Poor nutritional habits and sedentary lifestyles, among other factors, are increasing, the prevalence of chronic diseases.[100]

Table 6: Social and environmental challenges that the sectors are facing

R&D drivers

Across all sectors, service and product innovation is key. It is about getting a big idea to the market, faster than the competition. Six vital drivers vital for the continued success and growth of R&D are identified below. They provide an outlook as new approaches to R&D arise.

This is relevant to potential provider institutions to appreciate the forces driving user institutions' R&D. In this context, a key question for a provider institution is what kind of competitive advantage or the market potential is it providing to an R&D process or to the final product or service?

Activity of the GR first, but also access to talents and technology

The activity and the efficacy of the GR against the R&D goal are of paramount importance.[101] However, an interesting feature found in a GR, even an exceptional one, is not of economic interest unless it meets a specific need.[102]

More generally, businesses are constantly looking for ways to maximize the return on R&D investment in order to access cutting-edge technology, ideas, and human resources. For instance, some biotechnology companies promote the access to their expensive technology to the cosmetic and functional food sectors to explore the mass production of ingredients.[103]

Competition is leading to new innovation models such as outsourcing

There is a constant pressure to innovate in order to keep up with demand and to face the competition. For instance, in the cosmetic sector, large multinational firms are facing stiff competition from other

[97] http://www.unfpa.org/news/10-things-you-didn%E2%80%99t-know-about-world%E2%80%99s-population (accessed 4 march 2016)
[98] http://www.mckinsey.com/insights/sustainability/how_companies_can_adapt_to_climate_change (accessed 4 march 2016)
[99] http://www.un.org/esa/population/publications/worldageing19502050/ (accessed 4 march 2016)
[100] http://www.who.int/mediacentre/factsheets/fs355/en/ www.who.int/ageing/events/world-report-2015-launch/en/ (accessed 4 march 2016)
[101] F. Gattesco, Senior R&D scientist, Indena. pers. comm., 2015
[102] M. Rots, Deputy Head of Patent Group, VP Patents - Food & Refreshment, Unilever Patent Group pers. comm., 2015
[103] Biotechnology development just got easier for specialty chemical, fragrance and cosmetics companies, Cosmeticdesign, D. Utroke, 2016 http://www.cosmeticsdesign.com/Formulation-Science/Biotech-development-just-got-easier-for-specialty-chemical-fragrance-ingredient-and-cosmetics-companies (accessed 4 march 2016)

popular brands and smaller companies are pushing ahead.[104] This has a strong impact on how companies organise their R&D.

The outsourcing of R&D is an emerging model[105] in response. Companies are moving toward lean organisations. They focus on obtaining the best talent and ideas, while leveraging a range of external commercial and academic partners for early-stage research through product testing and manufacturing.[106] In practice, this includes various forms of partnership such as joint ventures, contract research or manufacture, and academic as well as consortium collaboration.[107]

This is relevant to provider institutions to properly understand the flow of their GR along a specific R&D value chain.

Regulation on new ingredients for consumer products

In most markets, companies must comply with increasing regulation to ensure consumer safety (e.g., new product registration, health related claims and labelling). For instance, in the functional food sector, companies must guarantee ingredient safety, establish the beneficial effect, and indicate how to safely use the product.[108] In the cosmetic sector, there is a new Chinese list of authorised ingredients. Although, China is a huge and important market, companies are reluctant to engage into costly new product registration. The cost implications have concrete impacts on new product development. So, R&D development tends to focus on well-known ingredients or is pursued only if there is a strong commercial interest.[109]

R&D cost versus market benefits: balancing the accessibility of the innovation against the opportunity it opens up in the market

There are two major criteria to determine an R&D project's inception and continuation: accessibility of the innovation and the opportunity it opens up in the market (e.g. potential revenue).[110] The table below presents further detail about these criteria. They are useful for provider institutions to evaluate the relevance of their R&D offer. For instance, Nestlé indicates that: *"An innovation, however exceptional, still remains just that unless it fulfils a range of further imperatives. It must find a relevant application within the business, meet a consumer need, be developed into a product or service, comply with all relevant regulations, have its intellectual property protected and above all be commercialised"*.[111]

The dichotomy between these two criteria is well illustrated in the pharmaceutical sector. The research agenda is driven by the unmet need to treat a disease and the scientific opportunity to find a medicine

[104] Global Insight, 2007
[105] R&D outsourcing in hi-tech industries, A research study. PwC, 2014. https://www.pwc.com/gx/en/pharma-life-sciences/assets/pwc-r-and-d-outsourcing-in-hi-tech-industries.pdf (accessed 4 march 2016)
[106] Science, Technology and Industry Outlook, OECD, 2014. http://www.keepeek.com/Digital-Asset-Management/oecd/science-and-technology/oecd-science-technology-and-industry-outlook-2014/summary/english_4b88d3e1-en#page1 (accessed 4 march 2016)
[107] www.idbs.com (accessed 4 march 2016)
[108] M. Rots, Deputy Head of Patent Group, VP Patents - Food & Refreshment, Unilever Patent Group pers. comm., 2015
[109] P. André, Director Cosm'ethic (former Director of Botanical Innovation, LVMH), 2014. Pers. Comm.
[110] Key trends in R&D in relation to food, beverages, nutrition & health. New nutrition business 2011. http://www.mbie.govt.nz/info-services/sectors-industries/food-beverage/documents-image-library/Key%20trends%20in%20R-D%20in%20relation%20to%20food-%20beverages-%20nutrition%20-%20health%20-%20what%20these%20trends%20mean%20for%20NZ%202011%20-PDF%206.5%20MB.pdf (accessed 4 march 2016)
[111] Nestlé, R&D brochure 2010

that can be marketed. Hence, from a commercial perspective, there should be enough scientific potential to develop a medicine and a target population allowing a return on investment.[112]

Efficient ingredients may not be commercialised because of unsound business plans. This is partly related to the level of understanding of the disease. For instance, cancer and Alzheimer's are two diseases where there are unmet needs and different sized target populations. For cancer, there is a lot of research and scientific progress; whereas for Alzheimer's disease, the science is difficult as the disease is not understood well enough.[113] [114] These lead to different R&D strategies.

The development of new antibiotics is quite illustrative for the second criteria on the market opportunity. While the primary knowledge exists to some extent, the regulators voluntarily limit the market in order to protect antibiotics' effectiveness.[115] The over-utilisation of antibiotics is counterproductive, as many bacteria tend to become resistant to them and antibiotics are ineffective against viruses. Under-regulation or ineffective regulation hastens this process.

Companies also consider R&D projects within their overall R&D portfolio in order to balance the risks (e.g., high to low risk, short to long term). They apply stringent selection criteria of promising cases throughout the R&D process. However, a project perceived as risky by a company can be evaluated differently by another one, depending on their context. For example, a drug may not have potential for human use, but may be a suitable drug for veterinary use.

Accessibility	Science to develop Generic science currently available or medium long-term development needed.	Regulatory Approved for use? Are claims possible?	Ingredients Clearly defined to be able to deliver the benefit. Easy to integrate into a product or service.	Ownability Proprietary technology or patent?
Opportunity	Product or service category Can be executed in current categories? Provides opportunities to move into new categories? Is the benefit and the ingredient logical and acceptable for consumers?	Relevance Is there any related need?	Competition Does this provide the opportunity to fill a gap in the market or to create a new category?	Consumer interest At what level is consumer awareness of this benefit? What is its credibility?

Table 7: Balancing accessibility against opportunity in R&D
Source: New nutrition business, 2011

[112] Chatham House, 2015. http://www.ip-watch.org/2015/10/09/chatham-house-report-on-antibiotics-gives-evidence-for-drug-rd-delinkage/?utm_source=IP-Watch+Subscribers&utm_campaign=ba878e321d-WEEKLY_SUMMARY&utm_medium=email&utm_term=0_b78685696b-ba878e321d-352152213 (accessed 4 march 2016)
[113] B. Barnes, Director IP & Global Health, European Federation of Pharmaceutical Industries and Associations, 2014. Pers. Comm.
[114] With regard to validated targets, there are many potential targets that scientists in the Alzheimer's field believe are the key to developing a therapeutic, but there is still disagreement as to which target is linked with the disease, or indeed, if it will require drugs aimed at more than a single target.
[115] B. Barnes, op. cit., p, 26

Secure and reliable sourcing of raw material

The setup of the supply chain is a big part of the R&D work. While in the pharmaceutical and biotechnology industry there is a tendency to synthesize ingredients, the use of natural ingredients still remains important in cosmetics and functional foods. Hence the security of ingredient sourcing to ensure a constant quality and the consistency of volumes is of paramount importance. The integration of social and environmental considerations is also gaining increased attention.[116] A new ingredient where the growing conditions are uncertain or where the intermediaries in the supply chain are not professional enough would be discarded in most cases.[117]

2.2. Sector Specificities

There are specificities across the sectors regarding the social and environmental challenges they face and the R&D drivers (Table 8). These are generic elements providing a framework to further understand a specific user institution context.

[116] C. Eberhardt, Key Account Manager Ingredients EMEA, Mane. 2013. Pers. Comm.
[117] C. Lombard, CEO Phytotrade. 2014. Pers. Comm.

<table>
<tr><th></th><th colspan="2">Functional food</th><th>Cosmetic</th><th>Pharmaceutical</th><th>Biotechnology</th></tr>
<tr><td>Specific challenges</td><td colspan="2">- Consumer demand is the major driver:
o Functional food: convenient, healthy diet, and ethical sourcing[118] [119]
o Cosmetics: pleasure, health, well-being[120]</td><td></td><td>- Improve the targeting of healthcare[121] [122] [123]
- Emerging markets are becoming growth markets with specific needs[124]</td><td>- Energy scarcity
- Demand for cleaner and more efficient industry
- Finite resources are missing (inc. raw materials, water and fertile soil).
Source:[125]</td></tr>
<tr><td rowspan="2">Specific R&D drivers</td><td colspan="2">- Cost of raw materials and maintaining the quality and supply of key raw material[126]</td><td rowspan="2"></td><td rowspan="2">- Patent cliff[127]
- Increasing cost of R&D and speed to market introduction[128]
- Slow progress of projects in the R&D pipeline[129]
- Pressure from stakeholders (e.g., willingness to pay for an innovation)[130]</td><td rowspan="2">- Lack of finance for R&D
- Changing an industry’s basic technology platform is complex
- Limited availability of well-educated scientists and engineers
- Necessity to operate close to the biomass.
Source:[131]</td></tr>
<tr><td>- Public acceptance of some technologies in some regions (e.g., GMO in Europe)[132]</td><td>- New entrants from the food, pharmaceutical and biotech sectors[133]</td></tr>
</table>

Table 8: Overview of sectors R&D specificities (all data accessed *4 March 2016)*

[118] We are what we eat, Healthy eating trends around the world. Nielsen, 2015.
[119] Mapping current innovation and emerging R&D needs in the food and drink industry required for sustainable economic growth. Arthur D Little, 2013.
[120] EY, Luxury and Cosmetic financial Factbook 2013, http://www.xtc.fr/upload/uploads/Image/produits_services/XTC_tree_imp.jpg
[121] Pharma 2020, the vision path. PwC, www.pwc.com/gx/en/industries/pharmaceuticals-life-sciences/pharma-2020/industry-strategies-trends-analysis.html
[122] M. A. Desai, Assistant General Patent Counsel, Eli Lilly and Company, 2014. Pers. Comm.
[123] http://dz.sanofi.com/l/dz/fr/layout.jsp?scat=E465F5D9-69F8-47E1-8EDB-64C6CD12C853
[124] Ibid
[125] Laird, S. and Wynberg, R. 2013. Bioscience at a Crossroads: Access and Benefit Sharing in a Time of Scientific, Technological and Industry Change: The Biotechnology Sector
[126] Managing raw material in supply chains, A. Agrawal, 2014 http://www.sciencedirect.com/science/article/pii/S0377221714004950
[127] Laird, S. and Wynberg, R. 2013 Bioscience at a Crossroads: Access and Benefit Sharing in a Time of Scientific, Technological and Industry Change: The Biotechnology Sector
[128] http://www.ifpma.org/innovation/rd/about-research-development.html
[129] Decision-making in product portfolios of pharmaceutical research and development – managing streams of innovation in highly regulated markets, A. Jekunen., 2014
[130] Trends Developments R&D Asia: Pharmas Biotechs' Future 5th Annual Biopharma Asia Convention 2012, Andreas Busch, Head of Global Drug Discovery, Bayer Heathcare
[131] OECD workshop on “outlook on industrial biotechnology” Discussion Paper - Session Trends in Technology and Applications, 2010.
[132] Socio-psychological determinants of public acceptance of technologies: A review. N Gupta et al. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3546631/
[133] http://www.sustainablecosmeticssummit.com/index.htm

Key findings

Companies search for innovative products and services in response to a range of social, economic, and environmental challenges. A basic framework of the challenges relevant for the four sectors includes: demographic growth, climate change, aging population and unhealthy lifestyles.

Furthermore, a range of drivers guides industry R&D practices. Companies consider in priority the activity of the GR as well as access to relevant human skills and technology. They take into account a wide range of factors to balance the development costs against the predictability of profits. The importance of regulation on new ingredient safety and its integration in R&D set up, the production of raw materials, if production is required, are becoming key. In an increasingly competitive environment this leads to various types of R&D organisations and partnerships such as outsourcing. This provides a framework for looking into the specificities of each sector and user institution.

3. Opportunities for the Valorisation of GR (Qualitative Analysis)

This section provides a qualitative assessment of potential valorisation opportunities for GR across the four sectors. They are identified across a range of elements such: research areas and objects, R&D activities and organisational approaches. Some are common across the four sectors and others are specific to each one. Further analysis is needed to confirm their relevance for specific provider institutions.

3.1. 4 Common Opportunities

Systematic sampling

A common valorisation opportunity across the four sectors stands out for actors able to carry out systematic sampling. There is a demand for particular types of species or genes from companies that target specific activities.[134] Furthermore, instead of storing multiple samples and trying to find a use for them, a new trend is emerging. This is based on finding out what samples are needed in research and then seeking them specifically.[135]

Some user institutions are also interested in species with limited economic importance that are less well researched. R&D actors in provider countries, such as botanical gardens, can undertake this activity without having to be expert in the underlying science. They should, however, be able to provide correct taxonomic information that is crucial for IPR.[136] [137]

[134] B. Barnes, Director IP & Global Health, European Federation of Pharmaceutical Industries and Associations, 2014. Pers. Comm.

[135] Global biobanking conference, 2016

[136] B. David, Institut de Recherche Pierre FABRE, 2015. Pers. Comm.

[137] There is a best practice experience from the Griffith University AstraZeneca partnership for natural product discovery. This collaboration arose in a unique business environment and has delivered diversified benefits in the short, medium and long term. Although it may be difficult to duplicate, it does constitute a reference for projects aiming to address similar or more focused needs (Laird et al. 2008) as most countries have at least one or two public institutions where biodiversity collections are held. *'Monetary and non-monetary benefits in this case fall within the standard package for "best practice", but it is in the accumulated and multi-faceted nature of the benefits that the real gains for the State and country are to be found. These include the collections and compound libraries, the advanced natural product discovery unit, and the enormous gains in taxonomic and ecological understanding that resulted from the collections. This case demonstrates that these benefits can be of equal, or greater, importance to the potential monetary benefits from royalties should a product be commercialized (Department of the Environment, Water, Heritage and the Arts. 2008).'*

This is, however, a big and potentially slow undertaking in terms of scientific work. It implies a readiness to invest in building the knowledge and sharing it for innovation purposes.[138] Some companies also mention the missed development and conservation opportunities for providing countries when a partner company drops a candidate. They emphasize that it is paramount to continue supporting and encouraging scientific research on biodiversity as conservation starts with knowledge.

Exotic GR

There is also an interest in exotic GR, especially when they can procure them exclusively.[139] There are various means to get exclusivity, such as intellectual property, but also through production when it necessitates a unique geographical environment or climate. There is an interest in African plants, due to their high biodiversity, but Asia and Latin America are important growth markets and they have also major biodiversity,[140] which has logistical and regulatory advantages.

Associated traditional knowledge

New models for the sustainable commercialization of indigenous natural plant ingredients based on associated traditional knowledge (TK) are also arising. For instance, the Phytotrade Africa trade association focuses on Southern Africa biodiversity to target innovative, novel food and beverage ingredients. Its members are the providers of the GR and it supports R&D partnerships between them and industry. Phytotrade works on TK that is documented and published. Its TK valorisation strategy has two components. First, it works with the holders of the TK that want to commercialize it. For instance, some holders proactively propose ingredients or knowledge that they want to valorise. Secondly, it screens potential ingredients by conducting literature reviews. This is the most widely used approach. A particular feature of this model is that it occurs in a pre-R&D phase before corporate R&D.[141]

Scientific partnerships

Companies are open to scientific partnerships. However, they point to the necessity to understand their needs and constraints. Hence, care and a comprehensive approach to designing collaboration structures for multi-partner R&D projects is necessary.[142] As the regulatory environment is becoming more demanding, including on ABS, some companies engage in R&D partnerships with providing institutions to facilitate administrative procedures, including ABS, and thereby reduce investment risk, delay, and cost**.**

[138] B. David, Institut de Recherche Pierre FABRE, 2013. Pers. Comm.
[139] M. Rots, Deputy Head of Patent Group, VP Patents - Food & Refreshment, Unilever Patent Group pers. comm., 2015
[140] X. Brochet, Director of natural innovation, Firmenich
[141] C. Lombard, CEO Phytotrade. 2014. Pers. Comm.
[142] Mishra et al. 2014. http://www.sciencedirect.com/science/article/pii/S0272696314000679 *Accessed 4 march 2016*

3.2. Sector Specificities

Functional food

First, there are demands for new ingredients with particular features.[143]

Focus on niche products - unique and ethical: There is a growing market for niche products, as they continue to emerge and are being provided to consumers as unique products, particularly in the context of the high-end market. Specialist suppliers will find less competition in the market for more exotic flavours, such as the ones made from raw materials collected in the wild or of unique origin. The story behind the product and the implementation of sustainability principles are key as well.

Target the processors in mature markets: In mature markets, food and beverage manufacturers increasingly need more complex flavours to differentiate their products from their competition. They rely on processors to do research and develop new products, such as unique low-cost flavours which retain their functional properties under specific conditions (e.g., heat and acidity).

Healthy lifestyles: The growing public concern about health has a positive effect on the market for improved or alternatives products such as species and herbs that can replace unhealthier food ingredients like salt, sugar, and synthetic additives.

The main research areas are:[144] [145]

- **Benefits** the ingredient is providing (e.g., natural, energy, weight management, cognitive, energy, diabetes)
- **Category** of the ingredient (e.g., dairy, fruits, grains)
- **Nutrition** needs (e.g., seniors, kids, sports, pregnancy, diabetes).

The food industry is regulated and new food or functional food must generally obtain public authorisation such as: Generally Recognised as Safe[146] (GRAS) in the USA or Novel Food[147] in Europe. A related opportunity relates to the need to **scientifically back the health claim of functional food**. There is an opportunity for some African health institutions to enter the value chain after the research phase. Furthermore, being close to the resource tested could provide logistical advantages. Some African hospitals and institutions have capacity to undertake such clinical trials; however, it is not clear whether they can yet carry out studies to the international Good Clinical Practice (GCP) standards.[148]

[143] CBI, Centre for the promotion of imports from developing countries. Market information report on Natural colours, flavours and thickeners. https://www.cbi.eu/market-information/ *Accessed 4 march 2016*
[144] M. Rots, Deputy Head of Patent Group, VP Patents - Food & Refreshment, Unilever Patent Group, 2015. Pers. Comm.
[145] Key trends in R&D in relation to food, beverages, nutrition & health. New nutrition business 2011. http://www.mbie.govt.nz/info-services/sectors-industries/food-beverage/documents-image-library/Key%20trends%20in%20R-D%20in%20relation%20to%20food-%20beverages-%20nutrition%20-%20health%20-%20what%20these%20trends%20mean%20for%20NZ%202011%20-PDF%206.5%20MB.pdf *Accessed 4 march 2016*
[146] http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/ *Accessed 4 march 2016*
[147] http://ec.europa.eu/food/safety/novel_food/index_en.htm *Accessed 4 march 2016*
[148] ANDI Promote African-led health innovation to address African public health needs. http://www.andi-africa.org/# *Accessed 4 march 2016*

Cosmetics

The main opportunity is in meeting market needs in terms of **new active or functional botanicals for mature markets** where consumer demand is the main driver (e.g., pleasure, health, well-being[149] and green credentials). There is also an embryonic move towards a 100% vegetal industry, using only natural ingredients.[150] For instance, there are also innovative ways to formulate existing natural ingredients or to identify new targets within the skin.

Furthermore, although most ready-to-use and innovative proprietary extracts still come from developed countries, there is increasing **value addition in origin countries with extraction** taking place at the source.[151]

A key success factor for providers is to be well-informed on the evolution of consumer preferences, to capitalise on their commercial and scientific knowledge of this rapidly evolving market.[152] Specific **research areas** focus on developing products for targeted customer segments including:

- Anti-aging
- Developing allergen free products
- Nutricosmetic
- New colour palettes
- Treatments to target specific skin types
- Multifunctional formulas answering different needs
- Male cosmetics.

Pharmaceuticals

Three main valorisation opportunities have been identified. They depend on the actor's level of expertise in pharmaceutical R&D and their capacity to translate basic research into a potential commercial application. In any case, the user institution will increasingly seek to prove the pertinence of the concept early in the development process in order to manage costs.

Establish R&D partnerships: Companies are looking for breakthrough innovation that typically derives from biotechnology and academia.[153] Among the many kinds of partnerships between pharmaceutical companies and smaller actors, two types seem particularly relevant for African actors. Firstly, there is "crowd sourcing" to access the worldwide ideas pool. While numerous targets exist, many are invisible to large companies. The objective is to bring knowledge inside the company. Second is, the "science

[149] EY, Luxury and Cosmetic financial Factbook 2013, http://www.xtc.fr/upload/uploads/Image/produits_services/XTC_tree_imp.jpg *Accessed 4 march 2016*
[150] P. André, Director Cosm'ethic (former Director of Botanical Innovation, LVMH), 2014. Pers. Comm.
[151] CBI, Centre for the promotion of imports from developing countries. Market information reports on Cosmetics ingredients https://www.cbi.eu/market-information/ *Accessed 4 march 2016*
[152] Global insight, 2007
[153] Trends Developments R&D Asia: Pharmas Biotechs' Future 5th Annual Biopharma Asia Convention 2012, Andreas Busch, Head of Global drug discovery, Bayer Heathcare

hub" that aims, in some geographical areas of commercial potential, to facilitate market understanding and further explore related innovation hits.

Focus on lead discovery: As the number of new drugs coming to the market is declining, some believe that an interest in natural product lead discovery should see a revival. However, although methods for isolation and identification of natural products have advanced in recent decades, methods for selection of potential leads are less developed. Hence, a new generation of research in the field of biodiversity-driven lead discovery is emerging.[154] In many cases, this requires better understanding of the science around the disease.[155]

Explore natural health trend demand: The demand for natural health care is increasing demand for herbal medicine, food supplements and medical nutrition products. This trend in turn strengthens the demand for medicinal and aromatic plants (MAPs) and their extracts. For instance, in Europe innovation in medical nutrition is expected to be further supported by new EU regulations (609/2013) that come into effect in 2016. While opportunities can be found in all these market segments, there are also threats stemming from strict legislation and buyer demands. The food supplement segment offers more options for innovation.[156]

Biotechnology

In general, there are difficulties to understand and translate the business potential of academic R&D results into the value chain. Furthermore, there are issues for academia and SMEs in the product development process to derive intellectual property revenues.[157]

There are nevertheless major opportunities in this booming sector, such as the **valorisation of biomass** (e.g., material by-products, waste). For instance, major crops can be valorised through biotechnology in green products. More widely, there are opportunities to **connect national research findings with sectors' R&D needs**. There are research findings at the national level that can be commercially exploited. However, this requires a sound understanding of user institutions' needs.[158]

There are also opportunities in the field of **carbon sequestration** as the bulk of the sequestration can be undertaken by microbiological action, for instance, in exploring how to increase the soil carbon sequestration through microbiology. This includes questions such as how to promote microbiological activity (which species and soil conditions?) and how to measure the sequestration that would allow for payments to be made under climate change tools.[159]

There is also an opportunity to create start-ups on the model of the pharmaceutical biotechnology industry for **cosmetics and functional foods with innovative ingredients** from academic labs. This is based on technology or original screening model from plant extracts.[160]

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[154] MedPlant. http://medplant.eu/about/ *Accessed 4 march 2016*

[155] B. David, Institut de Recherche Pierre FABRE, 2013. Pers. Comm.

[156] CBI, Centre for the promotion of imports from developing countries. Market information reports on Natural ingredients for pharmaceuticals www.cbi.eu/marketintel_platform/natural-ingredients-for-pharmaceuticals-/177534/trendmapping *Accessed 4 march 2016*

[157] OECD workshop on "outlook on industrial biotechnology" Discussion Paper - Session Trends in Technology and Applications, 2010.

[158] OECD workshop on "outlook on industrial biotechnology" Discussion Paper - Session Trends in Technology and Applications, 2010.

[159] G. Burton, Adjunct Senior Fellow of the United Nations University (UNU), 2014 Pers. Comm.

[160] Evolution des stratégies industrielles de R&D : une opportunité pour la recherche académique et la création d'entreprises ?, Journée valorisation et création d'entreprise, INRA, Léon et Le Tinévez, 2015

Key findings

A range of common opportunities to valorise GR across the four sectors as well as sector-specific ones could be identified. They constitute a basis for provider institutions and domestic R&D actors to explore how their GR and related R&D findings can be of interest to user institutions.

4. The R&D Process and Requirements

There is a basic R&D process with three phases (basic research, applied research, market development), through which most GR will go in order to develop a new product or service. There are also sub-phases that are sector-specific with various levels of cost and complexity. In addition, there are major differences within a sector depending on the complexity of the R&D involved and the strategic approach to R&D undertaken.

The three phases of basic R&D may be understood as:

- **Basic research**, also called fundamental, to identify a compound of interest. Activities include: literature review, providing samples, taxonomy, preliminary analysis, and screening.
- **Applied research** to confirm compound efficacy, safety, regulatory compliance and industrial scalability. Activities include: safety studies, regulatory dossier, clinical trials, pilot and industrial scale studies.
- **Development** to produce the raw material, transform it and to market the ingredient. Activities include: production and transformation of raw material, regulatory dossier, branding, distribution, and promotion.

It should be noted that during the basic and applied research phases, the distinction and sequencing of these phases can be a grey area, due to the serendipitous nature of discovery.[161] Although user institutions have longstanding research themes (e.g., anti-aging in the cosmetic industry), R&D is not a rational or sequential process with regard to the emergence of a new idea. While it often starts with the bibliography, there is a conjunction of elements, based on social interactions, which motivate the inception of an R&D project.[162] For instance, a newly developed thickener for the food industry could also hold strong potential for the cosmetics and functional food industry as a probiotic.[163]

This over-simplified description is relevant for potential provider institutions in order to appreciate the complexity of the user institution R&D process. It can further assist in the identification of the phases remaining to complete--as well as the investment needed--before a product or service can be marketed. Detailed R&D processes for each sector are presented in Annex 3. This can help to manage stakeholders' expectations.

[161] G. Burton, Adjunct Senior Fellow of the United Nations University (UNU), pers. comm. 2014
[162] C. Fromageot, Director of Sustainable development, Yves Rocher, 2015, Pers. Comm.
[163] http://www.cosmeticsdesign-europe.com/Formulation-Science/Newly-developed-probiotic-has-cosmetic-potential/?utm_source=newsletter_daily&utm_medium=email&utm_campaign=12-Jun-2015&c=Nxni8m81E0Qt3uMcG3cn7WH3EF6K7toX&p2= (*Accessed 4 march 2016)*

4.1. R&D Requirements for Using a GR

There is no one-size-fits-all model for the utilisation of GR in R&D and no uniform requirements.[164] As indicated above, the activity and the efficacy of the GR are always of paramount importance, but the requirements for utilising a GR vary depending on a wide range of factors. User institutions indicate that they are potentially interested in any type of GR, especially when they can get a form of exclusivity.[165] Hence, potentially all types of GR are considered (e.g., endemic and exotic). They can be provided through a variety of research partners (e.g., raw material suppliers, NGO, academia, public research institutions).

There are some sector specificities[166] and each user institution will have very specific requirements depending on:

- The market it serves
- The specific research question and the scientific knowledge available
- The level of science and technology it masters
- Its existing R&D network
- Its knowledge or presence in the target geographical area.

For instance, a specific R&D requirement of the biotechnology sector in the early research phase is that user institutions seek polymorphic variations of an organism to identify the optimal strain (a genetic variant or subtype of a micro-organism). This involves collecting the examples of the organism at different stages of its life cycle or in different ecological environments (e.g., water stress).[167]

4.2. User institutions R&D Requirements that Qualify a Partner

R&D partnerships are increasingly seen as a key success factor to the success of an R&D strategy.[168] In this context, the user institution's requirements that positively qualify a domestic R&D actor to enter in the R&D activities are analyzed beforehand. A focus is made on private companies that place more importance in building trust with an R&D partner that is capable of understanding their precise needs rather than on those interested in a one-off access or mass sampling.

As a general rule, user institutions engage in few new R&D partnerships. They generally already have an existing network of scientific and research partners that continuously propose new ideas.[169] Hence, considering the cost of R&D and the risk of failure, actors have tough criteria with which to evaluate new R&D partners. Before selecting an R&D partner, user institutions tend to target geographic areas with potential for new ingredient identification. This is based on criteria such as the degree of biodiversity or the favourable location of targeted specie(s)/activity, and in some cases, the existence

[164] C. Lombard, CEO Phytotrade. 2014. Pers. Comm.
[165] M. Rots, Deputy Head of Patent Group, VP Patents - Food & Refreshment, Unilever Patent Group. 2015, Pers. comm.
166 Laird, S. and Wynberg, R. 2013. Bioscience at a crossroads: Access and benefit sharing in a time of scientific, technological and industry change: the biotechnology sector. Secretariat of the Convention on Biological Diversity, Montreal.
167 G. Burton, Adjunct Senior Fellow of the United Nations University (UNU). 2014, Pers. Comm.
[168] Trends Developments R&D Asia: Pharmas Biotechs' Future 5th Annual Biopharma Asia Convention 2012, Andreas Busch, Head of Global drug discovery, Bayer Heathcare
[169] C. Fromageot, Director of Sustainable development, Yves Rocher. 2015, Pers. Com.

of TK. Some countries are no-go areas due to a perceived negative business environment (e.g., corruption, inconsistent policy, absence of legal certainty).[170]

Most user institutions exploit their existing supply chains of raw materials as the main avenue for accessing new samples. They rarely go onsite. However, they also participate in scientific events and undertake field trips (e.g., to visit suppliers of the raw material) where they are introduced to new ideas and samples. Furthermore, industry practices are constantly changing due to the rapid development of science and technology (e.g., genomics, and robots for automating tests).[171]

In order to ensure the robustness of an R&D project, private actors tend to weave a diverse network of actors (e.g., scientists, local communities, NGOs, small domestic private companies) in order to ensure the sustainability of the upcoming supply-chain. They support them to intervene at different phases of the process.[172]

Two types of user institutions' requirements for doing R&D with a provider institution are identified. Firstly, there is a range of basic requirements used to evaluate the credibility of potential partners. Secondly, user institutions have requirements specific to each phase of the R&D process. Moreover, further requirements arise as more actors within and outside the company become involved. This is relevant to provider institutions in order to align their core strengths with the needs of the user institution and supplement their weaknesses.

Basic R&D requirements to evaluate potential R&D partners:[173]

- Overall level of R&D expertise (e.g., scientific knowledge, technical know-how, R&D partnerships)
- Innovativeness and track record in developing original projects, ingredients, or products
- Adherence to sustainability principles and regulatory requirements
- Connection with public administration to ensure legal certainty
- Capacity to build trust by maintaining communication, keep confidentiality, and share knowledge
- Financial stability and capacity to leverage funds.

[170] B. H. Jensen, Hammer IPR (former Senior Patent Counsel Novozymes). 2014, Pers. Comm.
[171] C. Fromageot, Director of Sustainable development, Yves Rocher, 2015, Pers. Comm.
[172] Ibid.
[173] CBI, Centre for the promotion of imports from developing countries. Market information reports on A) : cosmetics ingredients, B) Natural ingredients for health products, C) Natural colours, flavors and thickeners. https://www.cbi.eu/market-information/ *Accessed 4 march 2016*

Specific requirements for the basic and applied phases:

These phases are deemed to be the closest fit to most of the domestic R&D actors in the six countries covered by this report.

Basic research phase

User institutions generally do not expect their R&D partner in the providing country to find the final ingredient.[174] However, the R&D partner is expected to facilitate the R&D in order to find a match between the potential of the country's biodiversity and the needs of the company. As they often have longstanding relationships, user institutions see their R&D partners as much more than a mere provider of GR. The human factor is important. In this context, a range of requirements is identified:[175]

- Understanding of the user institution's need and scientific knowledge (e.g., plants, microorganisms and fungi, associated TK) such as taxonomic expertise to identify potential target species
- Local knowledge of collection areas and capacity to provide good quality samples at a reasonable cost
- Knowledge to evaluate the potential of a species as an ingredient and to transform the biomass and or extract the ingredient
- Regulatory knowledge (i.e., identify the conservation status of the species, custom regulations, phytosanitary regulations, ABS requirements). This knowledge is important, otherwise protected species could be collected and production problems could occur.
- Capacity to provide feedback and share information with other local and national stakeholders.

In this phase a key success factor is the presence of a supportive environment. During the research phase, user institutions not only look at the active ingredients, the technical and commercial skills of their partner, they also anticipate the design of the supply chain if commercial development is successful. In doing so, they take into account the supportive environment of the other partner or provider institution. The reason for this is that the set-up of the production and the initial value addition activities such as quality control and processing are often realised by local SMEs. As these often have limited capacities (e.g., management of quality), the presence of a support environment by a partner institution to improve and leverage these skills is a key criterion.[176] Weak infrastructure, lack of capacity, and the inability to meet technical product specifications and stringent requirements in terms of quality, safety, and health impede product integration into global markets.[177]

[174] C. Fromageot, Director of Sustainable development, Yves Rocher, 2015, Pers. Comm.
[175] B. David, Institut de Recherche Pierre FABRE, 2013. Pers. Comm.
[176] C. Lombard, CEO Phytotrade. 2014. Pers. Comm.
[177] Challenges in agri-food exports: Building the quality infrastructure, International Trade Center for Sustainable Development, 2010. www.intracen.org/Challenges-in-Agro-Food-Exports-Building-the-Quality-Infrastructure/ *Accessed 4 march 2016*

Applied research

The key user institutions' criteria are:

- Equipment and know-how for technological, toxicology and eco-toxicology studies, as well as on domestic regulation
- Robustness, replicability, and capacity to test and set up at a larger scale the production or the harvesting process (e.g., carrying capacity to meet production needs) to produce a high quality raw material
- Adherence to sustainable principles (e.g., able to inform about what constitutes a fair price paid to the producer) and monitoring of the project's advancement.

There is a trend for higher domestic and international standards and legal requirements. Provider institutions face similar barriers as new entrants for the supply of raw material. They also face considerable barriers as the user institutions' requirements are demanding and strict. Convincing these companies of their reliability is a big challenge. Without proof, including thorough, solid documentation, they avoid investment in the establishment of new relationships. In the medium to long-term, stricter legislation will significantly increase the burden for new entrants.[178]

In this phase, a key success factor is the capacity to carry out a cost-effective, small-scale pilot project. As there is a high risk of failure of the innovation process, user institutions are reluctant to invest in the set-up of a pilot from scratch. They often look for existing capacity in the provider country where their innovation can be piloted at a small scale. They typically look for national programs offering the framework and the capacity for testing.[179]

Key findings

There is a basic R&D process with three phases: basic research, applied research, and market development. The distinction and sequence of these phases can be a grey area, due to the serendipitous nature of discovery. The study has shown, nevertheless, this type of information is useful to identify the phases remaining to complete the R&D and the level of investment needed before a product or service can be marketed.

It is also clear that R&D partnerships are proving to be of greater interest than simple access to a GR. However, user institutions have existing scientific networks and tend to engage in few new R&D collaborations. When they do, provider institutions are evaluated against their ability to understand a user institution's R&D needs and goals and their scientific knowledge of relevant species. Two key success factors are needed to meet a user institution's R&D requirements. First, they must consider right at the beginning the support environment of their R&D partner (e.g., commercial, technical) in order to produce an ingredient, should the R&D be successful. Secondly, in order to limit risks and costs, they are looking for existing capacity in the provider country to run small-scale pilot tests.

[178] CBI, Centre for the promotion of imports from developing countries. Market information reports on A): cosmetic ingredients, B) Natural ingredients for health products, C) Natural colours, flavors and thickeners. https://www.cbi.eu/market-information/ *Accessed 4 march 2016*

[179] Cyril Lombard, CEO Phytotrade. 2014. Pers. Comm.

5. Challenges for the Valorisation of GR in Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) (ABS Agreements) and Potential Solutions

Three main challenges regarding ABS requirements in PIC and MAT (ABS agreements) are identified in order to support the valorisation of G R. Potential solutions are also highlighted. An overview of other issues is introduced in the table 9 below.

Lack of legal certainty and unclear scope

The ABS regulatory environment of provider institutions is perceived as complex by user institutions.[180] Hence, while there is an interest in GR, some user institutions are reluctant to engage in some markets.[181] Companies indicate that legal certainty must be secured for engaging in R&D on GR. They are looking for a regulatory and legal framework where the policies, laws and regulations are simple, clear, and consistently applied (i.e., not subject to arbitrary changes). There should also be clarity of the definitions, the ABS procedures, their timeline, and the definition of roles.[182]

High transaction costs to get the ABS contracts

In general, user institutions indicated that provider institutions and governments lack understanding of their business models, R&D processes and practices (e.g., botany and economy of the species) as well as the related level of investment needed to complete the R&D process. Similarly, the visibility or the functioning of some providers is unclear.[183] This limits the possibility for mutual understanding.

In this context, model contracts are cumbersome to implement considering the heterogeneity of the situations.[184] For instance, there can be lengthy negotiations of the benefits that might arise from commercialization of a product containing a GR, while in reality few products or services will actually be commercialized. This is often the result of unrealistic expectations, which slows down ABS deals and entails high transaction costs, while minor but concrete benefits could be easier to negotiate.[185]

Furthermore, the fact that some companies seek to build a diverse network of actors in the providing country in order to ensure the sustainability of their R&D projects (e.g., scientists, local communities, NGO, small private companies) further complicates ABS deals. As a consequence, ABS is perceived as an additional regulatory burden that can quickly get very expensive. This deters some user institutions that then turn to well-known species, which are easier to access.

[180] 4th ABS Business Dialogue Public-Private Partnerships for Sustainable Development, GIZ. 2015. http://www.abs-initiative.info/fileadmin//media/Events/2015/28-29_January_2015_Copenhagen_Denmark/REPORT_4th_ABS_BUSINESS_DIALOGUE_27_03_15_final_FINAL.pdf *Accessed 4 march 2016*
[181] B. H. Jensen, Hammer IPR (former Senior Patent Counsel Novozymes). 2014, Pers. Comm.
[182] 3rd ABS Business Dialogue Public-Private Partnerships for Sustainable Development, GIZ. 2014. http://www.abs-initiative.info/fileadmin//media/Events/2013/4-5_September_2013__Copenhagen__Denmark/20130904-05_Report_Business_Dialogue_III_2013_September_Final.pdf *Accessed 4 march 2016*
[183] 4th ABS Business Dialogue Public-Private Partnerships for Sustainable Development, GIZ. 2015. http://www.abs-initiative.info/fileadmin//media/Events/2015/28-29_January_2015_Copenhagen_Denmark/REPORT_4th_ABS_BUSINESS_DIALOGUE_27_03_15_final_FINAL.pdf *Accessed 4 march 2016*
[184] C. Lombard, CEO Phytotrade. 2014. Pers. Comm.
[185] B. David, Institut de Recherche Pierre FABRE, 2013. Pers. Comm.

Mistrust

Mistrust is the most common barrier to putting ABS principles in practice through ABS agreements.[186] On the one hand, mistrust—particularly the fear of facilitating bio-piracy—has led many governments to opt for building elaborate and complex legal and administrative systems on ABS. Some provider institutions such as universities are now reluctant to share samples. In some cases, it also inhibits non-commercial scientific research and can lead to the exclusion of local scientists from partnering with companies.[187]

On the other hand, there is mistrust in the private sector in relation to the legal uncertainty arising from the gradual implementation of ABS rules and procedures. Attempts to request permits are often frustrated by the lack of capacity in the public sector and from gaps in ABS governance due to a lack of knowledge of the R&D activities being regulated. This has fuelled mistrust and unrealistic demands compared to the reality of the concrete, shareable benefits. With respect to monetary benefits, private actors are often reluctant to pay such types of benefits as they have limited understanding where the money goes despite the conservation and development objectives of ABS. They also ask for transparency.[188]

Potential solutions

In this context, a range of potential solutions is suggested to address these issues. In many cases, ABS requirements depend on the very specific characteristics of the actors involved[189] (e.g., academia, large multinational company, small start-up) as well as the nature and objectives of the R&D project. Therefore, some level of flexibility is needed. Possible solutions include:

- **Simple access to information** (e.g., establishment of national focal points, competent national authority(ies) operating with clear timelines and efficient procedures in order to improve transparency and simplicity.[190]

- **Simple guidelines** could be provided for the development ABS agreements. A regular review would then allow for their improvement. The priority is to get started with experimental cases and to learn from them.[191]

- The development of **partnerships between provider and user institutions**, with regular dialogues to exchange information, is another solution as trust takes time to develop. Often restrictive guidelines are eased or reversed after the partnership has had time to develop. A willingness to work within the country's requirements and to find workable solutions, to respect country's concerns, without forcing the issues initially, has been a successful strategy within the International Cooperative Biodiversity Groups (e.g., export of self-replicating organisms, export of DNA, etc.). This requires flexibility, ingenuity, and patience on all sides. Similarly, countries must

[186] Putting in practice ABS: views and needs of the private sector, GEF workshop, 2014

[187] B. David, Institut de Recherche Pierre FABRE, 2014. Pers. Comm.

[188] 4th ABS Business Dialogue Public-Private Partnerships for Sustainable Development, GIZ. 2015.

189 Selim Louafi, Marie Curie Fellow at the Center for Science, Technology and Environmental Policy Studies, Arizona State University - Center for Science, Technology and Environmental Policy Studies. 2015, Pers. Comm.

[190] 3rd ABS Business Dialogue Public-Private Partnerships for Sustainable Development, GIZ. 2014

[191] P. André, Director Cosm'ethic (former Director of Botanical Innovation, LVMH). 2014, Pers. Comm.

respect the confidentiality issues of the private sector and find creative solutions to work within those constraints while still obtaining some level of data transparency on the use of their GR.[192]

- Greater **use of free, internationally recognised Certificates of Compliance** (as established by the Nagoya Protocol) to demonstrate legal certainty and transparency - at no cost.[193]

- The legal obligations to **disclose origin and/or source of GR in patent applications** for significant markets (e.g., some European countries, India, Brazil and China) could contribute to building trust.[194]

- **Model clauses pre-approved by the government** could be used more easily by some user and provider institutions.[195]

- **Trusted third parties**, acting as intermediaries, could ensure continuous communication between the user and the provider institutions as well as the government. This could be an institution at the international level that provides a mediation process to facilitate negotiation and contract setting. It could also be a local or national institution in the provider country, preferably one that can "speak the language of business". The latter option has the advantage of reducing the transaction cost with a trusted partner close to the resource that can also save significant time in dealing with public officials.[196]

- A **two-phase approach in the ABS authorization process** (i.e., basic research and commercial development), with a commercial trigger that activates a second round of negotiation around the specific product or service. In this approach, initial agreements should focus on more near term and deliverable benefits such as training, technology transfer, and research opportunities.[197] However, some companies prefer a unique PIC and MAT without having to renegotiate.

- In any case, it is important for the development and implementation of **ABS agreements to reflect sectoral specificities,** including existing practices on sustainability, transparency and benefit sharing.[198]

- It is necessary to find a balance between specific and flexible ABS requirements that **trigger benefit sharing**. The market share of a finished product is a potential indicator of success. However, this does not in and of itself quantify the contribution of the new ingredient in the marketing success (e.g., functional ingredients).[199] Two other indicators can be considered: changing the goal of the R&D in early research phase and collection and re-collection of samples (what does this tell about product development?).[200] It is however unclear if a patent is a good trigger point, as it may come quite early in the innovation process when the likelihood of a final product/service is still uncertain.[201] Moreover, for lower value commodity based products, trade

[192] F. N. Katz, Fogarty International Center National Institutes of Health. 2013, Pers. Comm.
[193] G. Burton, Adjunct Senior Fellow of the United Nations University (UNU). 2014. Pers. Comm.
[194] ibid.
[195] B. David, Institut de Recherche Pierre FABRE, 2013. Pers. Comm.
[196] G. Burton, Adjunct Senior Fellow of the United Nations University (UNU). 2014, Pers. Comm.
[197] F. N. Katz, Fogarty International Center National Institutes of Health. 2013, Pers. comm.
[198] S. Benard, Diretor of the Environment, LVMH. 2012, Pers. Comm.
[199] X. Brochet, Head of Natural Ingredient Innovation, Firmenich. 2015, Pers. Comm.
[200] G. Burton, Adjunct Senior Fellow of the United Nations University (UNU). 2014, Pers. Comm.
[201] X. Brochet, op. cit., p, 42

secrets may play a more significant role. In this regard, consideration might be given to the valorisation of trademarks and copyright at significant points along the value chain.[202]

Other issues[203]

Challenges	Approaches to address these problems
Lack of **clarity** with respect to the final beneficiaries Complex R&D processes with many **intermediaries** Difficulty to **monitor** and ensure compliance	Potential approaches to: a) Facilitate actors to determine the remit of their individual responsibilities • Standard clause in commodity contracts that material cannot be used for R&D on the GR or its biochemical composition • Companies integrate ABS in their due diligence process b) Clarify who is entitled to pay what, when, and to whom: • Clarity from the beginning the parties at the provider end that the user institution is dealing with • If indigenous peoples or local communities are involved, their representative legal entity should be involved.
Catering for **complex** and specific cases	There are instances, where the final use of the GR has nothing to do with the original GR (e.g., GR used as tanning agent for airplane seats leather outfit). The consistent application of a change of intent clause could avoid such complex cases. The level of utilisation that triggers the payment of financial benefits (e.g., business to business, business to consumer) should also be clarified.
Intellectual property rights & **disclosure** requirements	ABS contracts should include a clause addressing intellectual property rights, for example in the event that a product based on genetic resources is patented or otherwise protected.
Lack of **awareness**	Sensitize the private sector, providers, users and institutions carrying R&D.

Table 9: Challenges related to PIC and MAT agreements for the valorisation of GR

Key findings

The lack of legal certainty and any unclear scope is fuelled by a lack of understanding by providers of the user institutions' practices and business models, and by the user institutions' difficulty in navigating some complex regulatory environments and meeting competing expectations. This leads to mutual mistrust and high transaction costs. In all cases, understanding of the user institution's R&D needs and goals is paramount. In this context, potential solutions to facilitate P I C and MAT (ABS agreements) are suggested.

[202] G. Burton, op. cit., p, 42

[203] 3rd ABS Business Dialogue Public-Private Partnerships for Sustainable Development, GIZ. 2014

Recommendations

This sectoral analysis shows that there is a range of clear opportunities for the valorisation of GR of relevance for provider countries. This raises two main questions for provider countries' public policy. First, in practice, how to close the R&D gap with user institutions in order to take advantage of potential opportunities for the valorisation of GR. Second, what are the policy requirements needed to create a favourable institutional and business environment to facilitate access to GR and share in a fair and equitable manner the benefits arising from their utilisation?

There is dense literature on measures to stimulate innovation policy and tools to foster its creation. For instance, actions targeting knowledge diffusion and absorption are just as important as investment in knowledge generation.[204] With regard to sustainable development matters, such as ABS, a main challenge is to navigate through complexity by strengthening impact assessment and institutional capacities to identify and drive reform priorities. This includes paying greater attention to the stakeholders' needs.[205] In this context, two main recommendations are presented.

Continue closing the R&D gap: Focus on domestic strengths aligned with relevant user institutions R&D needs

The principle to be applied is to align core national domestic R&D strengths with relevant user institution's R&D needs to uncover valorisation opportunities for GR. A focus should be placed on realistic R&D activities that can be undertaken in the short- to medium-term and that meet specific R&D needs nationally. National and regional markets are often easier to exploit and provide shorter returns than international ones. For instance, there are existing scientific results that can be further valorised and there are R&D partnerships than can be deepened or created, in line with ABS principles.

It is possible to postulate, as a methodological starting point, that R&D priorities are most pertinent when they first respond to local needs, and then manage to equitably meet the interests of more distant stakeholders. The initial results thus achieved can then be structured and scaled up with a continuous alignment with the changing needs of the user institution. This dynamic allows progress to reach a critical size sufficient, to explore more distant opportunities and maximise the likelihood of further success.

The following steps can be undertaken within various parameters (e.g., national, regional, cluster):

Identify the capacities and support needs of domestic R&D institutions

Before engaging with user institutions, it is necessary to gain a solid understanding of the landscape of the actors related to R&D and the scope of their capacities and related support needs.

Clarify market trends and user institutions' R&D requirements

The understanding of the market trends is a basis to identify potential opportunities. A key feature of this analysis is to clarify the user institutions' requirements that qualify a domestic R&D actor to enter their R&D process and the related potential benefits that can be shared in.

[204] Science, Technology and Industry Outlook, OECD, 2014
[205] Regulatory Policy and the Road to Sustainable Growth, OECD, 2010

Target valorisation opportunities, leverage strengths and engage in R&D partnerships

Key valorisation opportunities should be identified as a synthesis of the strengths, weaknesses, opportunities and threats (SWOT) analysis. Analysis should confirm the match between the domestic R&D strengths against the market opportunities. In this context, the development of partnerships between domestic actors and user institutions should be encouraged. As provider R&D institutions tend to have limited financial resources, the strategic communication of scientific results in industry and public research networks appears as a pertinent tool.

Create an environment that facilitates access for targeted user institutions and benefit sharing

It is beneficial to establish a clear, low cost and transparent ABS framework to attract user institutions for the valorisation of GR**.** Such a framework takes into account the country's goals for its development and the conservation of biodiversity. Its key features include:

A conducive business environment to leverage national strengths on R&D

Initially, this may call for a mechanism or forum to facilitate exchange of information with a view to capitalise the R&D strengths and also to address weaknesses. In time, capacity can be developed to handle different types of R&D partnerships and to support those aligned with national goals.

Simple, clear and flexible ABS procedures to accommodate different type of user institutions

Considering the low chances of R&D leading to the effective commercialization of a product or a service, access requirements to GR should be adapted and proportionate to various user institutions' needs and capacities. For instance, consideration could be given to the development of access procedures that take into account the specificities of sectors (e.g., length of the R&D, budget) and the type of R&D actors (e.g., small, large, public, private). Different types of contracts could be considered in light of their adaptation to the specificities of the R&D project.

The targeting of benefit sharing that allow domestic actors to move up the value chain

As most GR only undergo the initial stages of the research phase (e.g., preliminary screening for bioactivity), where the occurrence of failure is high, benefit-sharing requirements should be realistic and proportionate to the level of R&D investment of partners. The alignment with national R&D and valorisation goals (e.g., training of local researchers, sharing of research results, technological transfer) should be considered. In many cases there is space for creativity to best meet the needs of the provider institutions and the related stakeholders.

Monitoring R&D practices

Publicly available information is often incomplete and does not provide a comprehensive picture of the use of GR in R&D processes. Furthermore, valorisation activities in the business-to-business segment are almost invisible. This may call for specific requirements to monitor GR along the value chain and in markets. This may be supported by greater use by provider and user institutions of internationally recognised Certificates of Compliance.

Policy makers may wish to build on these recommendations when updating or developing national ABS frameworks so that they can contribute to the valorisation of their GR.

Annex 1: R&D intensity and dynamic across sectors and geographical regions

Source: Adapted from IRI's Worldwide top 2500 Industrial R&D Investment Scoreboard (million €).

	FOOD&BEVERAGE					Pharmaceuticals & Biotechnology				
	Number of cies in top 2500	R&D invest. in 2013	R&D rate 2013 (% turnover)	Evol R&D CAGR 2010-2013	Evol CA CAGR 2010-2013	Number of cies in top 2500	R&D invest. in 2013	R&D rate 2013 (% turnover)	Evol R&D CAGR 2010-2013	Evol CA CAGR 2010-2013
Europe	25	4 410	1,3%	+2,2%	+2,6%	76	42 739	14,4%	+2,5%	+3,1%
North America	16	1 770	0,9%	+2,9%	+5,3%	146	41 572	16,4%	+2,8%	+0,9%
Pacific & asia	8	382	0,8%	+22,0%	+12,7%	42	1 884	4,8%	+26,0%	+14,6%
Japan	23	1 416	1,4%	+0,2%	+2,5%	28	9 493	14,6%	+3,0%	+5,4%
ROW	1	21	0,2%	+49,1%	+10,4%	1	1 031	7,0%	+15,1%	+8,0%
Total World	**73**	**8 000**	**1,2%**	**+2,7%**	**+4,0%**	**293**	**96 719**	**14,5%**	**+3,1%**	**+3,1%**

	Personal Care & Goods					Chemical / Oil&Gas				
	Number of cies in top 2500	R&D invest. in 2013	R&D rate 2013 (% turnover)	Evol R&D CAGR 2010-2013	Evol CA CAGR 2010-2013	Number of cies in top 2500	R&D invest. in 2013	R&D rate 2013 (% turnover)	Evol R&D CAGR 2010-2013	Evol CA CAGR 2010-2013
Europe	9	1 547	2,6%	+8,8%	-4,8%	48	10 641	0,8%	+7,8%	+7,1%
North America	7	708	1,4%	+5,2%	+2,8%	48	9 017	1,2%	+6,3%	+5,3%
Pacific & asia	13	546	2,3%	+9,0%	+8,5%	31	3 882	0,4%	+9,5%	+13,0%
Japan	16	944	2,7%	+3,2%	+5,1%	46	6 136	1,9%	+1,9%	+6,2%
ROW	2	47	3,9%	+11,7%	+54,0%	9	2 188	0,5%	+8,7%	+14,7%
Total World	**47**	**3 792**	**2,2%**	**+6,7%**	**+1,1%**	**182**	**31 864**	**0,8%**	**+6,4%**	**+8,8%**

Annex 2: Patent applications and grants

Source: WIPO statistics database / OECD 2014

	Biotechnology								
	Patent application 2003	Patent Grant 2003	Patent application 2013	Patent Grant 2013	applic. Evol. 2003-2013 CAGR	grant evol. 2003-2013 CAGR	application efficiency 2013	share of world grant 2013	share of the grants for the 5 technos 2013
Europe	8 835	3 025	7 464	3 036	-1,7%	+0,0%	41%	15%	11%
USA	15 452	3 684	11 434	4 835	-3,0%	+2,8%	42%	24%	15%
Rest N. Am	2 615	391	186	1 020	-23,2%	+10,1%	NA	5%	15%
Japan	4 627	753	4 512	2 515	-0,3%	+12,8%	56%	13%	8%
Rest Asia	3 845	1 099	15 170	7 129	+14,7%	+20,6%	47%	35%	13%
Oceania	2 184	1 117	1 820	1 444	-1,8%	+2,6%	79%	7%	17%
Latin Amer	1 101	3	1 287	62	+1,6%	+35,4%	5%	0%	6%
Africa	245	223	96	75	-8,9%	-10,3%	78%	0%	11%
Total gén	**38 904**	**10 295**	**41 969**	**20 116**	**+0,8%**	**+6,9%**	**48%**	**100%**	**12%**

	Pharmaceuticals								
	Patent application 2003	Patent Grant 2003	Patent application 2013	Patent Grant 2013	applic. Evol. 2003-2013 CAGR	grant evol. 2003-2013 CAGR	application efficiency 2013	share of world grant 2013	share of the grants for the 5 technos 2013
Europe	15 238	6 244	11 319	5 858	-2,9%	-0,6%	52%	18%	21%
USA	14 281	4 247	13 290	6 980	-0,7%	+5,1%	53%	21%	22%
Rest N. Am	4 310	718	253	2 041	-24,7%	+11,0%	NA	6%	31%
Japan	6 153	850	7 753	4 337	+2,3%	+17,7%	56%	13%	15%
Rest Asia	9 714	2 651	31 283	10 563	+12,4%	+14,8%	34%	32%	19%
Oceania	3 939	2 281	3 208	3 008	-2,0%	+2,8%	94%	9%	36%
Latin Americ	4 667	10	3 450	101	-3,0%	+26,0%	3%	0%	10%
Africa	1 109	990	273	244	-13,1%	-13,1%	89%	1%	36%
Total génér	**59 411**	**17 991**	**70 829**	**33 132**	**+1,8%**	**+6,3%**	**47%**	**100%**	**20%**

	Food chemistry								
	Patent application 2003	Patent Grant 2003	Patent application 2013	Patent Grant 2013	applic. Evol. 2003-2013 CAGR	grant evol. 2003-2013 CAGR	application efficiency 2013	share of world grant 2013	share of the grants for the 5 technos 2013
Europe	4 459	2 969	6 288	4 499	+3,5%	+4,2%	72%	24%	16%
USA	3 832	2 014	3 767	2 241	-0,2%	+1,1%	59%	12%	7%
Rest N. Am	628	178	108	417	-16,1%	+8,9%	NA	2%	6%
Japan	3 356	1 288	3 027	1 672	-1,0%	+2,6%	55%	9%	6%
Rest Asia	4 770	1 678	25 721	9 489	+18,4%	+18,9%	37%	50%	17%
Oceania	674	391	539	581	-2,2%	+4,0%	108%	3%	7%
Latin Americ	843	4	896	96	+0,6%	+37,4%	11%	1%	9%
Africa	170	161	46	35	-12,3%	-14,2%	76%	0%	5%
Total génér	**18 732**	**8 683**	**40 392**	**19 030**	**+8,0%**	**+8,2%**	**47%**	**100%**	**12%**

	Personnal care & goods								
	Patent application 2003	Patent Grant 2003	Patent application 2013	Patent Grant 2013	applic. Evol. 2003-2013 CAGR	grant evol. 2003-2013 CAGR	application efficiency 2013	share of world grant 2013	share of the grants for the 5 technos 2013
Europe	5 839	3 098	6 945	2 839	+1,7%	-0,9%	41%	19%	10%
USA	6 144	3 032	6 408	3 549	+0,4%	+1,6%	55%	24%	11%
Rest N. Am	938	207	302	422	-10,7%	+7,4%	NA	3%	6%
Japan	8 324	2 437	6 022	4 120	-3,2%	+5,4%	68%	28%	14%
Rest Asia	5 020	2 175	17 696	3 471	+13,4%	+4,8%	20%	23%	6%
Oceania	585	273	513	423	-1,3%	+4,5%	82%	3%	5%
Latin Americ	794	2	768	70	-0,3%	+42,7%	9%	0%	7%
Africa	110	103	29	24	-12,5%	-13,6%	83%	0%	4%
Total génér	**27 754**	**11 327**	**38 683**	**14 918**	**+3,4%**	**+2,8%**	**39%**	**100%**	**9%**

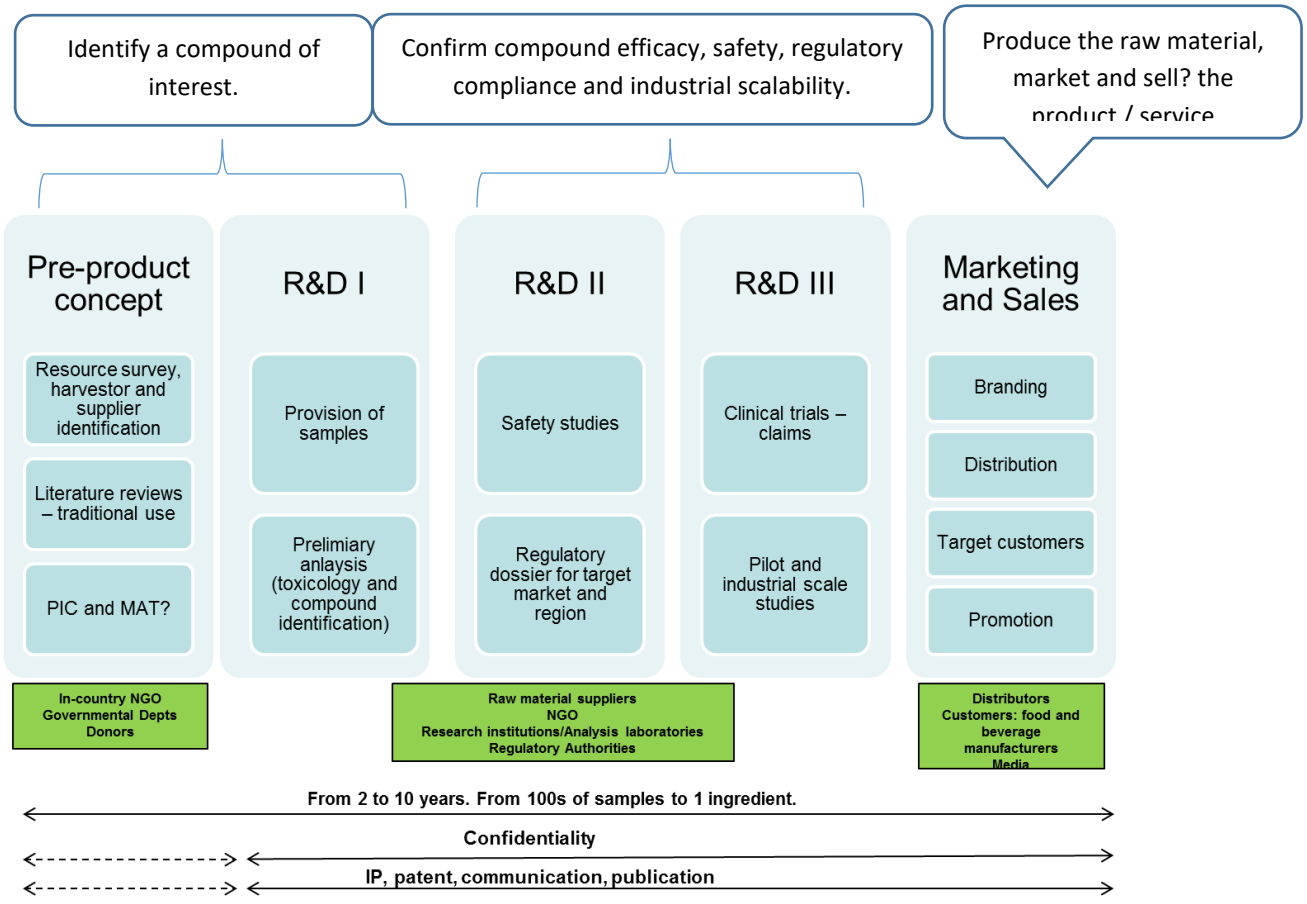
As basis for comparison

	Chemistry (basic/macromolecular & polymers/organic)								
	Patent application 2003	Patent Grant 2003	Patent application 2013	Patent Grant 2013	applic. Evol. 2003-2013 CAGR	grant evol. 2003-2013 CAGR	application efficiency 2013	share of world grant 2013	share of the grants for the 5 technos 2013
Europe	26 401	13 600	22 291	11 675	-1,7%	-1,5%	52%	16%	42%
USA	24 482	10 844	22 564	13 837	-0,8%	+2,5%	61%	18%	44%
Rest N. Am	4 925	1 613	525	2 750	-20,1%	+5,5%	NA	4%	41%
Japan	23 699	7 292	22 237	17 077	-0,6%	+8,9%	77%	23%	57%
Rest Asia	18 021	7 539	64 758	25 696	+13,6%	+13,0%	40%	34%	46%
Oceania	3 747	2 193	2 661	2 915	-3,4%	+2,9%	110%	4%	35%
Latin America an	7 206	69	5 462	712	-2,7%	+26,3%	13%	1%	68%
Africa	1 602	1 475	386	307	-13,3%	-14,5%	80%	0%	45%
Total général	**110 083**	**44 625**	**140 884**	**74 969**	**+2,5%**	**+5,3%**	**53%**	**100%**	**46%**

	Sum of 5 technologies (incl. Chemistry)							
	Patent application 2003	Patent Grant 2003	Patent application 2013	Patent Grant 2013	applic. Evol. 2003-2013 CAGR	grant evol. 2003-2013 CAGR	application efficiency 2013	share of world grant 2013
Europe	60 772	28 936	54 307	27 907	-1,1%	-0,4%	51%	17%
USA	64 191	23 821	57 463	31 442	-1,1%	+2,8%	55%	19%
Rest N. Am	13 416	3 107	1 374	6 650	-20,4%	+7,9%	NA	4%
Japan	46 159	12 620	43 551	29 721	-0,6%	+8,9%	68%	18%
Rest Asia	41 370	15 142	154 628	56 348	+14,1%	+14,0%	36%	35%
Oceania	11 129	6 255	8 741	8 371	-2,4%	+3,0%	96%	5%
Latin Americ	14 611	88	11 863	1 041	-2,1%	+28,0%	9%	1%
Africa	3 236	2 952	830	685	-12,7%	-13,6%	83%	0%
Total génér	**254 884**	**92 921**	**332 757**	**162 165**	**+2,7%**	**+5,7%**	**49%**	**100%**

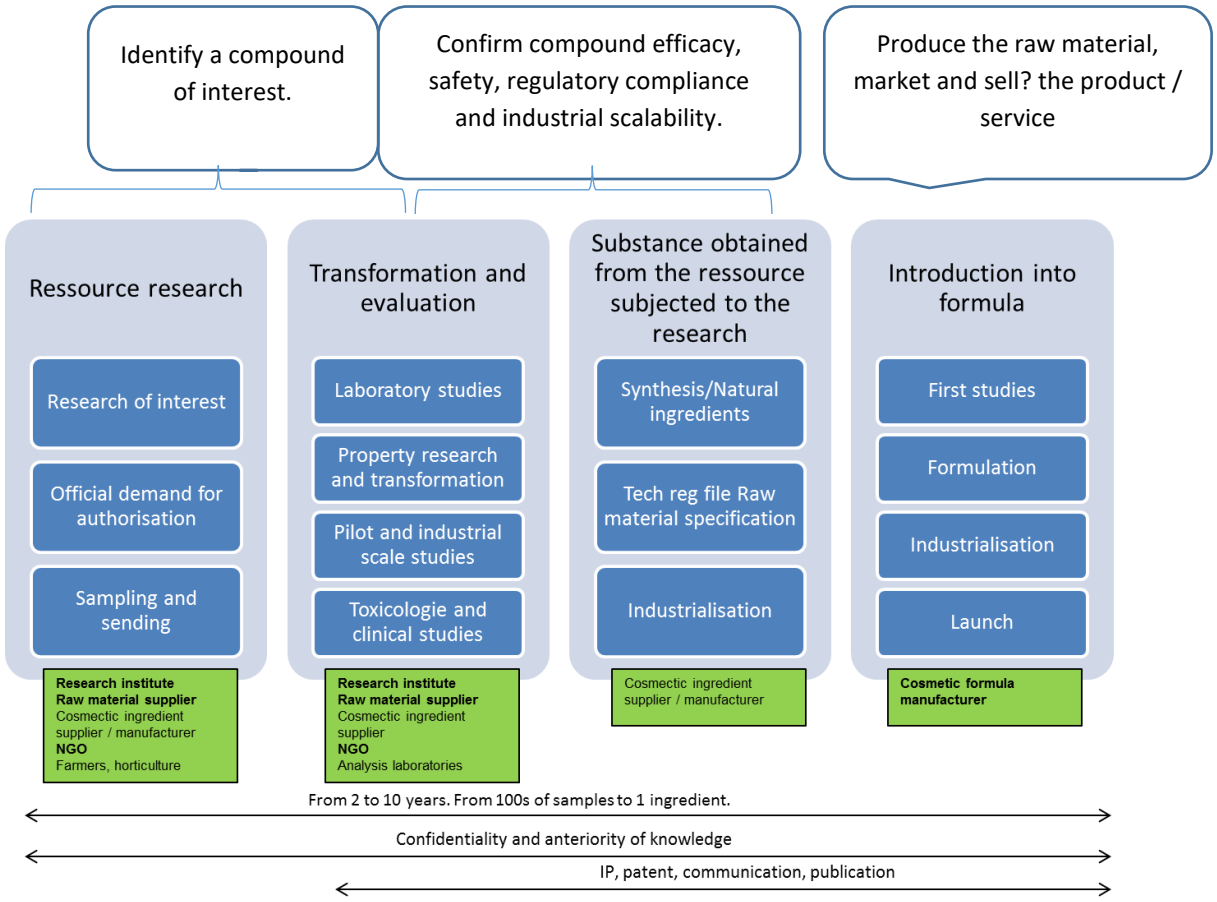
Annex 3: R&D processes across sectors

- **Functional food**[206]



[206] 3rd ABS Business Dialogue Public-Private Partnerships for Sustainable Development, GIZ. 2014.

- **Cosmetics**[207]



[207] 3rd ABS Business Dialogue Public-Private Partnerships for Sustainable Development, GIZ. 2014.

- **Pharmaceutical**

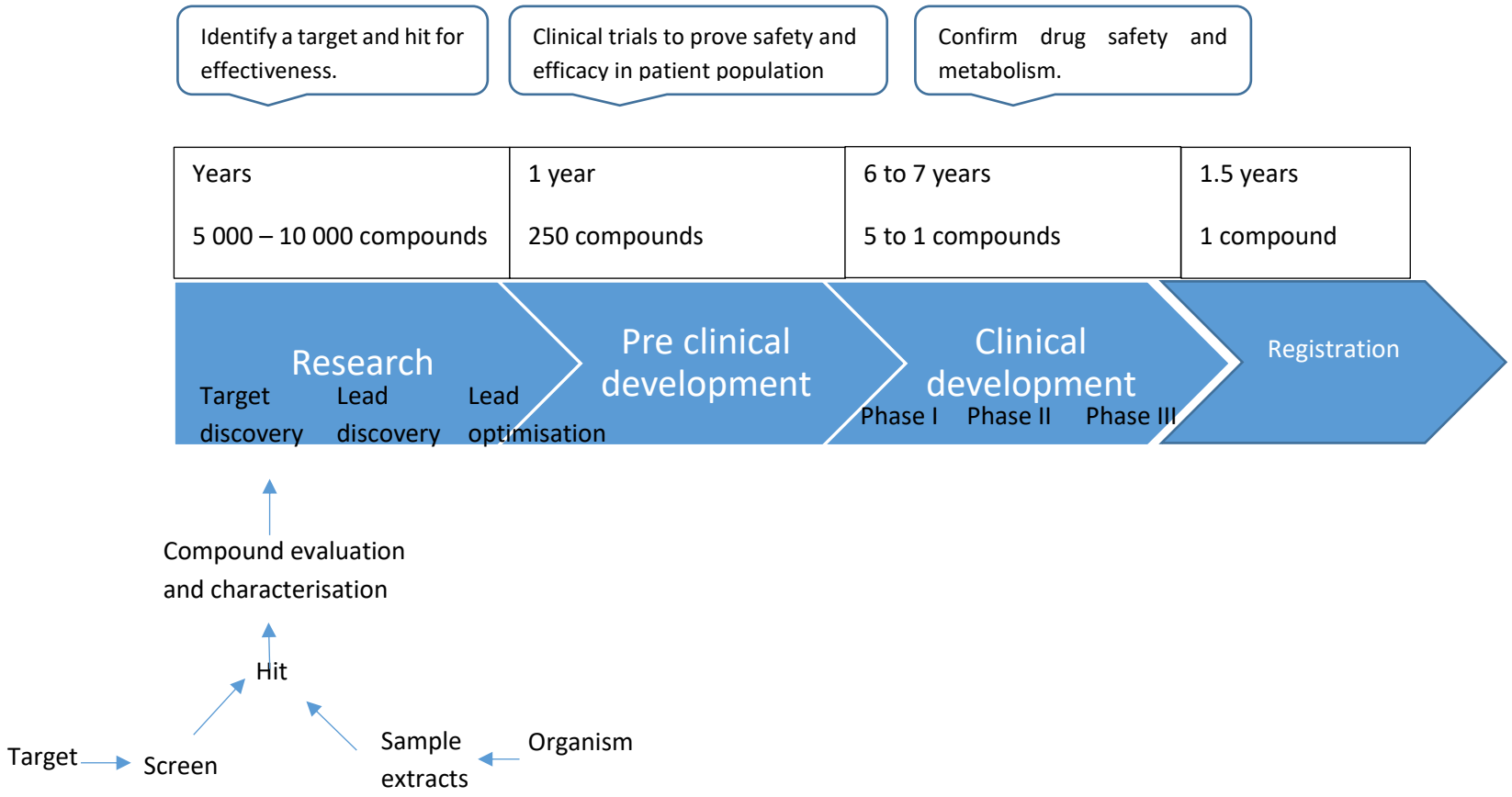
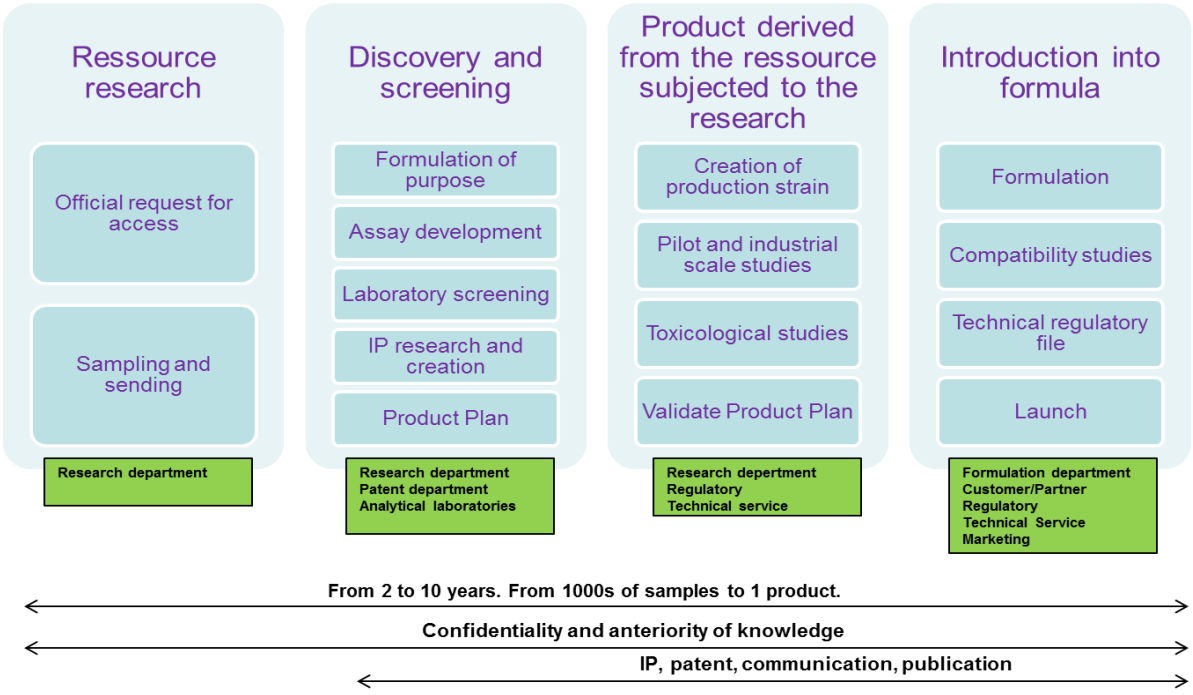


Diagram: key stages of the drug-candidate discovery process
Sources: Hughes et al. 2011. www.innovation.org/drug_discovery/objects/pdf/RD_Brochure.pdf

- **Biotechnology**[208]



[208] 3rd ABS Business Dialogue Public-Private Partnerships for Sustainable Development, GIZ. 2014.