Genetic Ressources and Intellectual Property

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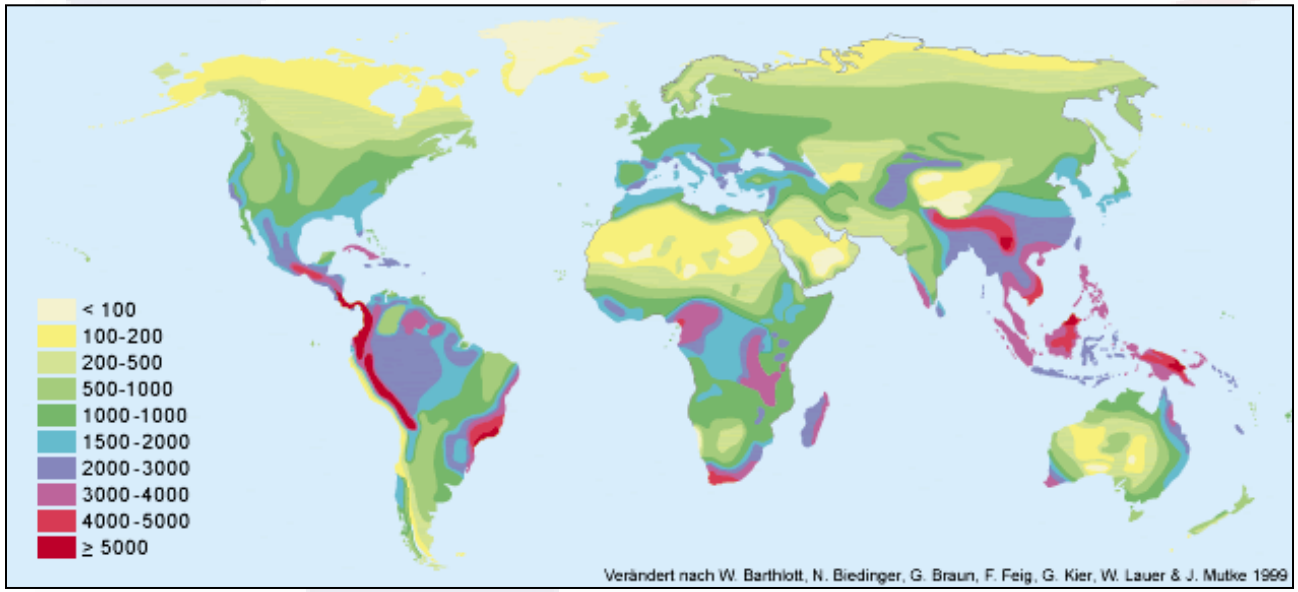
Biological / Genetic Resources - a Tremendous Potential under Threat



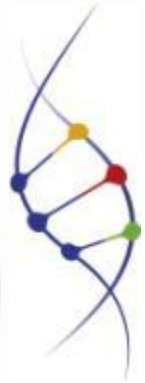
Facts:

- **only approx. 2 of 30 Mio species known**
- **~ 26.000 species / annum extinct**
- **hotspots: Developing Countries (80 %)**

Article 1 CDB

Conservation of biological diversity	**Sustainable use of it‘s components**	**Fair and equitable sharing of benefits arising from the utilization of genetic resources**
		by means of
Facilitated access to genetic ressources	**Technology - and Know how – transfer**	**Adequate financing :** • **upfront** • **milestone** • **royalties**

Use of GR: Concept



Different type of genetic resources

Animal, plant, microbial

Used for different purposes "Utilization"

Research & development
- commercial
- non commercial

based on PIC / MAT

Different types of users operating in different sectors

- Pharmaceuticals / biotech
- seed and crop protection
- personal care and cosmetics
- botanicals and horticulture
- (farm) animal breeding

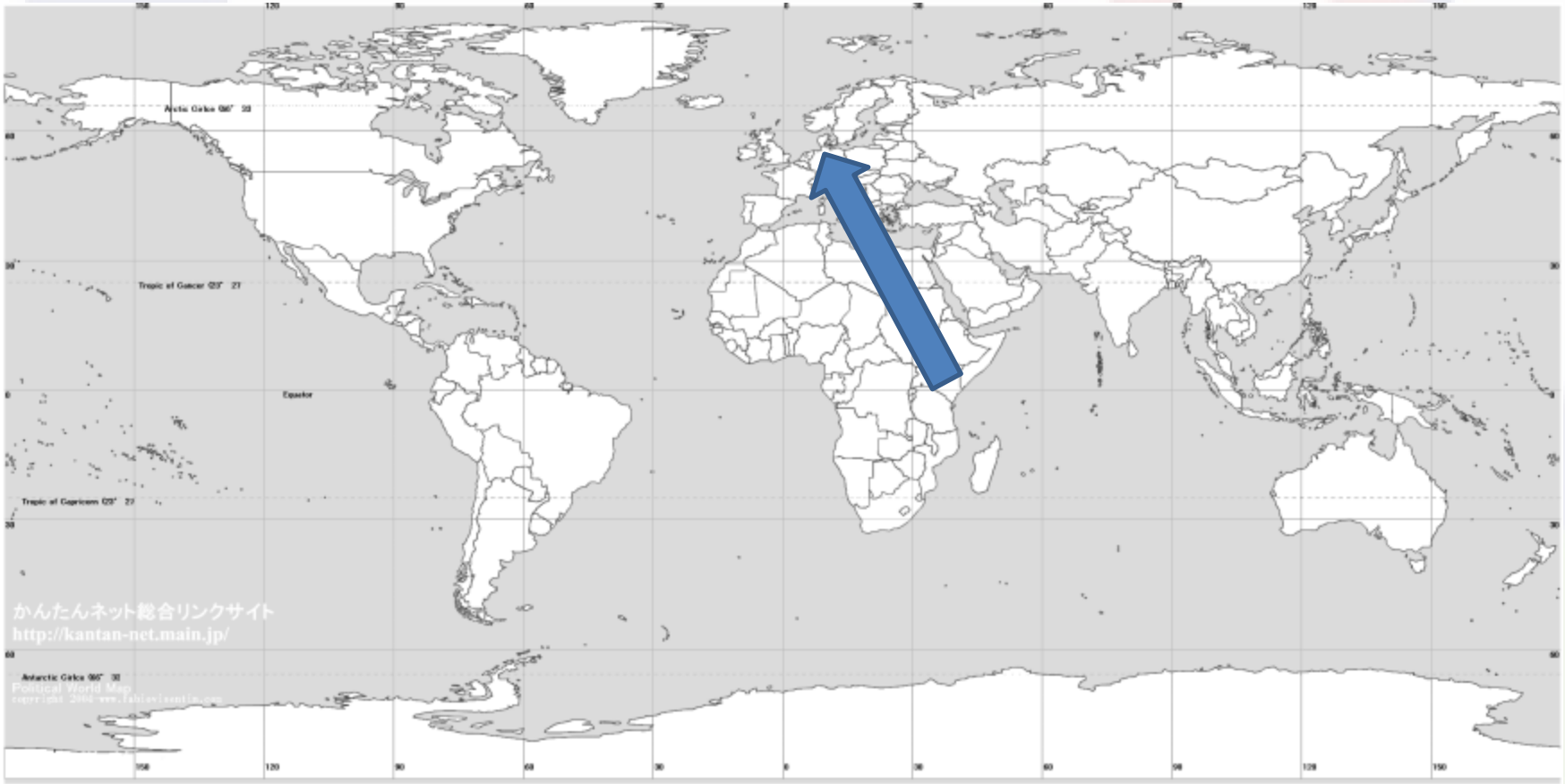
Focus: Commercial Applications of GRs

BIOSCIENCE AT A CROSSROADS: IMPLEMENTING THE NAGOYA PROTOCOL IN A TIME OF SCIENTIFIC, TECHNOLOGICAL AND INDUSTRY CHANGE*

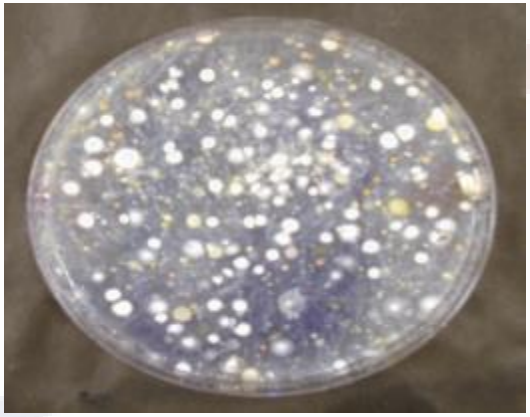
INDUSTRY	GLOBAL MARKETS (US$)
Pharmaceutical	$955.5 billion (2011)
Cosmetics	$426 billion (2012) – natural component $26.3 billion
Food and beverage	$11.6 trillion (2009) – functional beverages $23.4 billion
Seed	$45 billion (2011)
Crop Protection	$40 billion (2010)
Industrial Biotech	$65-78 billion (including biofuels, 2010) – industrial enzymes $3.3 billion
Botanicals	$84 billion (2010)

Source: UNCTAD

Microorganisms & Enzymes



Microorganisms & Enzymes



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Biotechnology

- **Market**
  - Global turnover around $ 75 billion
  - Young industry with 3 main sub sectors (green, red, white) (e.g. biochemicals, biofuels, biomaterials and some consumer products)
- **R&D**
  - Objective: prove activity and overall feasibility at large scale
  - Difficulty to understand business potential of academic R&D results & future industrial needs
- **Specifity of green biotech**
  - Focus: enzymes and metabolites from microorganisms that can endure difficult manufacturing conditions (e.g. pressure)
  - Some companies do bioprospecting (e.g. in extreme environments) but most use existing collection or domestic GR
  - Genome-mining :
    - search directly in soil or water without having to culture the organism
    - Publication of microbial genetic sequences and ability to transfer genetic material digitally
  - High degree of science and technology requires governmental support (e.g. biofuels) partnership to complete product development
  - B 2 B rather rule than exemption

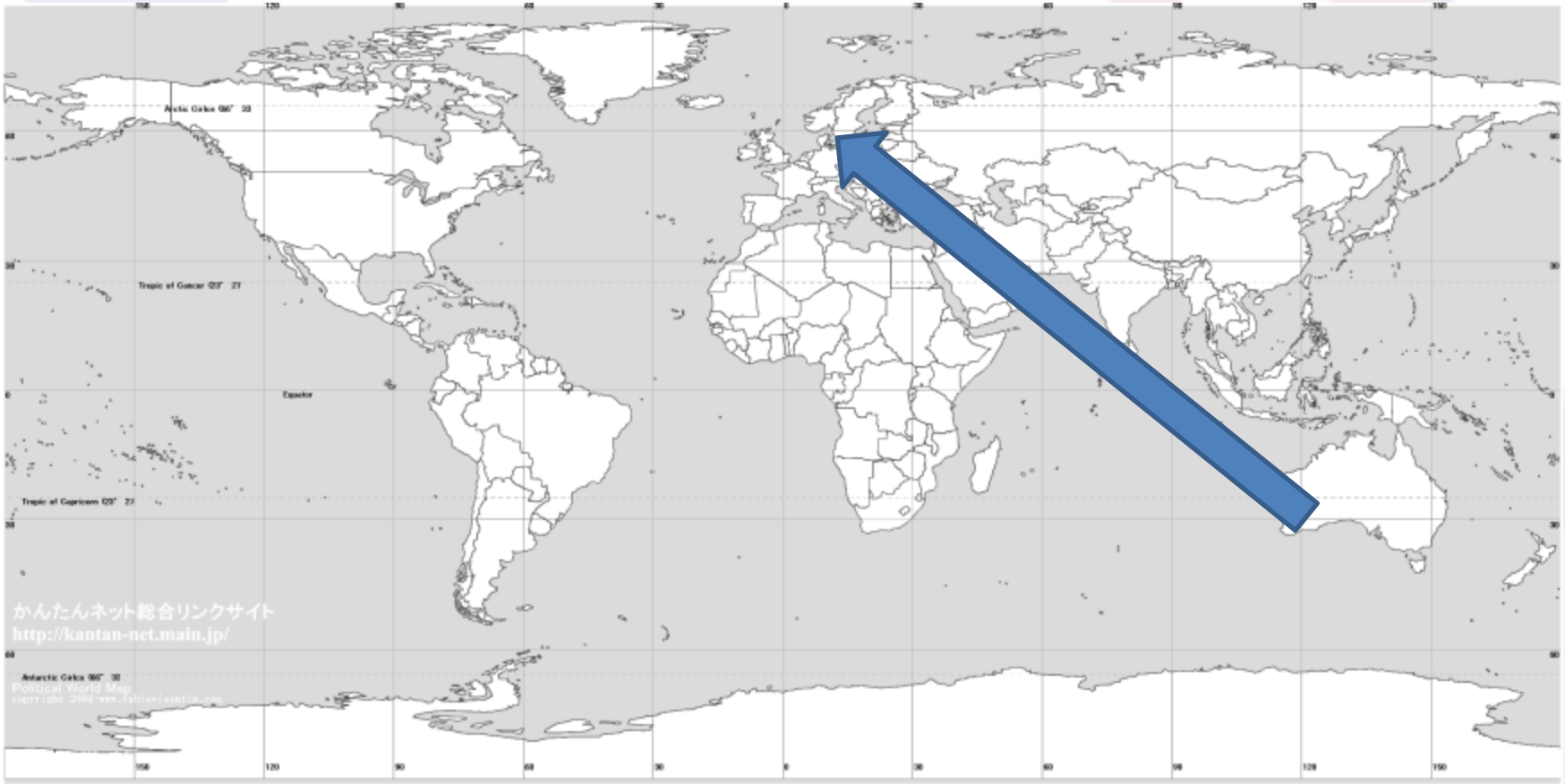
Sources: Literature review, interviews

Food and Beverages

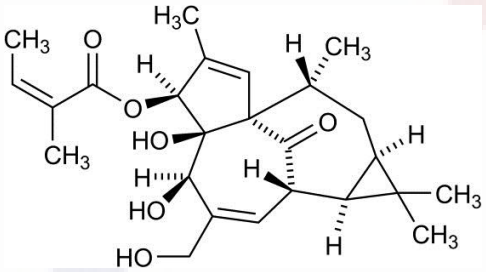
- **Market**
  - Turnover of $ 11,6 trillion (2009), expected to reach $15 trillion (2015) functional beverages: $ 23,4 billion
  - Mature, dynamique and diversified sector (9 billion people to feed !)
- **R&D**
  - Objective: health benefits (e.g. weight, energy,…)
  - Low level of R&D (process improvement) but innovation is increasing : functional food, natural (e.g. additive free, free from…)
- **Specificity**
  - Pre R&D before corporate R&D - Use of traditional knowledge as an indication of efficacy and safety
  - Commodities dominate - use large volumes – reliability of supply is key
  - Strong competition from ingredients in large user countries (e.g. olive, grapefruit)
  - Breeding and crop protection are key, interest in wild plants for domestication
  - Increasing integration of food with other sectors and increasing consumer interest in natural products (& sustainability) suggest an increasing trend of the use of GR (relevance of ABS)

Sources: Literature review, inteviews, EU COMTRADE, OECD, Laird & Wynberg,

Euphorbia Peplus



Euphorbia Peplus

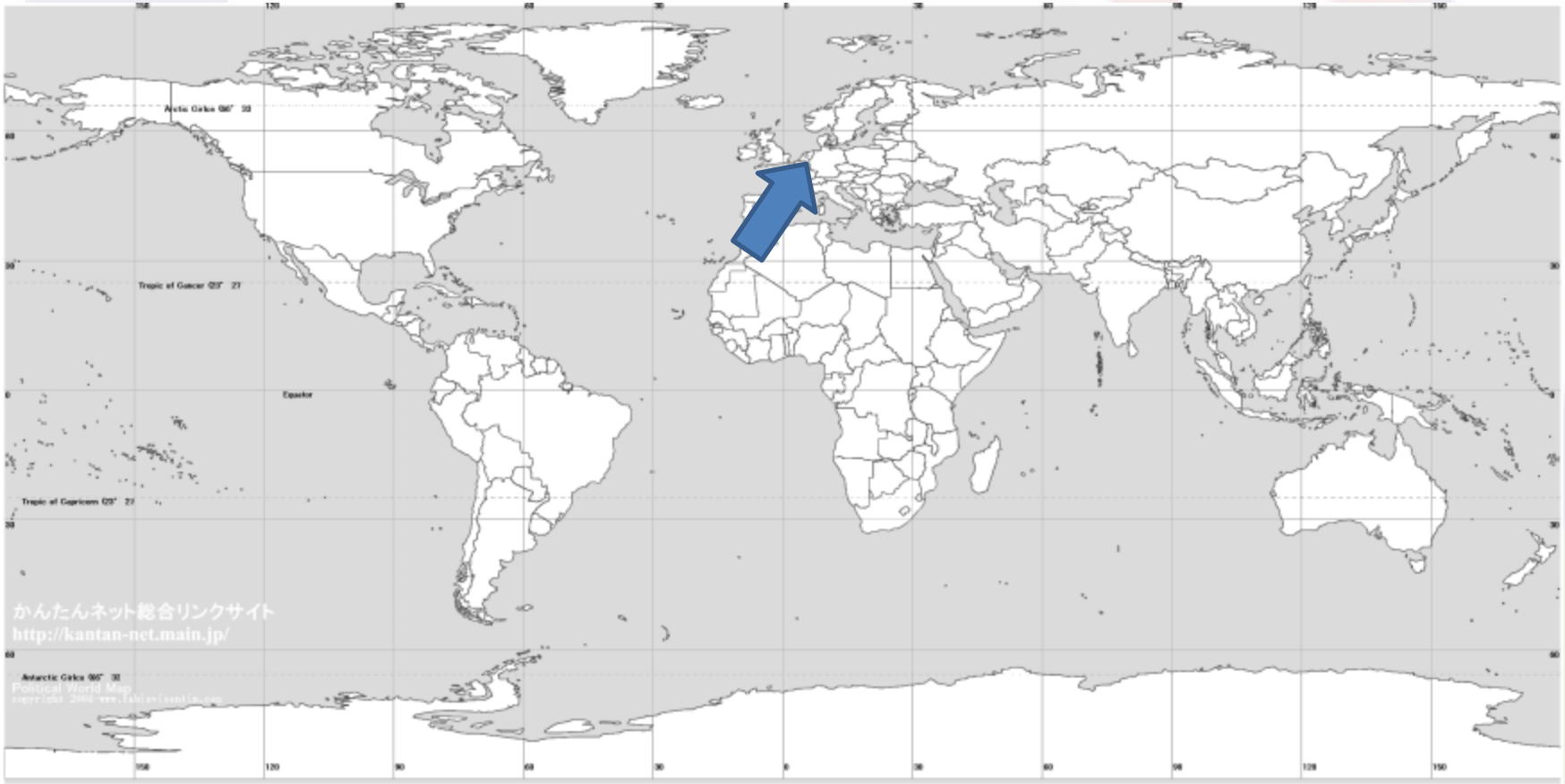


Pharmaceutical

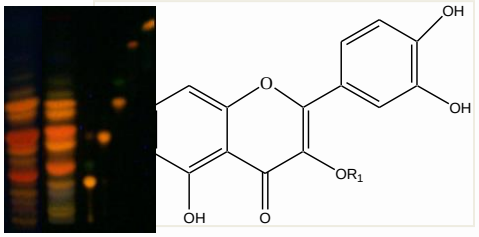
- **The market**
  - Estimated global revenues $ 955,5 (2011) expected to reach $1,2 trillion (2016)
  - Trend: large European and American based companies to do more R&D, with manufacturing in emerging markets, where domestic companies are also on the rise.
- **R&D**
  - Objective: prove activity
  - Companies collaborate on R&D as budgets stall
  - There are many ways to develop new actives. Most large natural R&D programs have closed. -> synthetic chemistry / biotechnology.
  - Natural product programs are found in SME; governmental programs and universities.
- **Sector specificities / trends**
  - Patent cliff – impact on corporate policies and investments
  - Some collection of microorganism and marine organism but overall, limited need to access “fresh” GR from the South. Very tiny quantities of material needed.
  - Domestic biodiversity and companies collections are first choice
  - High degree of science and technology (e.g. genomics) allows
    - faster and deeper screening (especially on microorganisms)
    - possibility to grow them and overcome supply issue
  - Decreasing interest in traditional knowledge due to focus on micro-organism

Sources: Literature review, OECD, Laird & Wynberg, interviews

Argan


Arctic Circle 66° 33
Tropic of Cancer 23° 27
Equator
Tropic of Capricorn 23° 27
Antarctic Circle 66° 33
かんたんネット総合リンクサイト
http://kantan-net.main.jp/
Political World Map

Argan



Polyphenoles

Cosmetics & Fragrance

- **The market**
  - For natural cosmetics, sales of $ 26,3 billion (2011) out of a global turnover of $426 billion
  - Oils, fats, waxes, essential oils, oleoresins and plants extracts are used in 'pure natural' and in conventional cosmetics (very small quantities)
- **R&D**
  - Objective of the research:
    - Fragrance : feature characteristics of ingredients
    - Cosmetic : active principle or ingredients (additif, excipient formulation). Anti aging!
  - Major companies focus on brand strategies and intermediaries do intensive research
  - R&D investments differ: from minimal processsing of raw material to advance research
  - Speciality raw ingredients and natural compound to guide synthetisation
  - Most ingredients are cultivated to master quality, secure supply and reduce costs
- **Sector specificities**
  - Strong regulation + new Chinese regulation - narrows the focus of GR and R&D
  - Brand image is key - pressure to innovate – demand for a «*story* » but short shelve life
  - Mix use of patents - due to short shelf life of products it's an expensive tool
  - Sustainability issues are high on the agenda of B2C companies due to their marketing potential
  - Niche interest in GR from the South & in traditional knowledge (to guide R&D)

Sources: Literature review, interviews, Laird and Wynberg 2013

Definition of Research and Development under the Nagoya Protocol

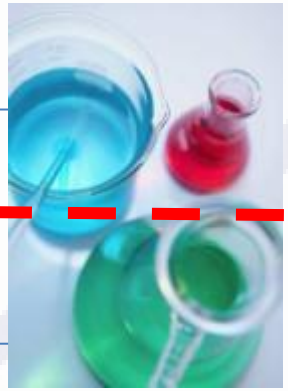
Art. 2

“Utilization of genetic resources” means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention.

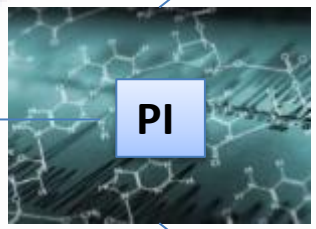
“Biotechnology” as defined in Article 2 of the Convention means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

R&D Process

(User country)

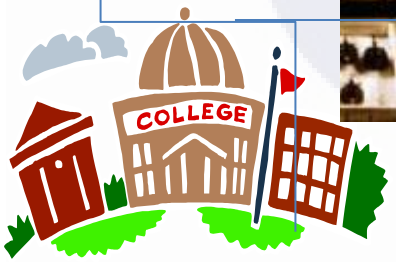


(Provider country)



Synthétique

Filiére de production



2 – 8 years

Huge variations :

- **level of science & technology used, investments in R&D (0 - 10 %)**
- **need to access GR (e.g. continuous, one-off, tiny samples)**
- **use of TK**
- **SOP (larger producer / retailer vs. small specialist intermediaries)**
- **level of internal R&D (from 100% in house to outsource of R&D)**
- **Different requirements with respect to IP / IP Protection**

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Pre-Acces

- research proposals
-funding

- market analysis,
- pre product analyis

Research & Development

Business Plan

- production
- sales
- compliance
- marketing

Production (commercialization)

Investments

IP protection ->

IP generation ->

MAT X

PIC X

MAT X1 ?

PIC X1?

0,5 – 10 years

upfront benefits

1 – 15 years

TT / CB / IP / publications

1 – 3 years

TT / cap dev - *nonetray*

3 – 25 years

TT / cap dev ***– monetary***

Time

funded by

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Organisation internationale de la francophonie

Institut de l'énergie et de l'environnement de la Francophonie IEPF

Norwegian Ministry of Foreign Affairs

Danish Ministry of the Environment

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