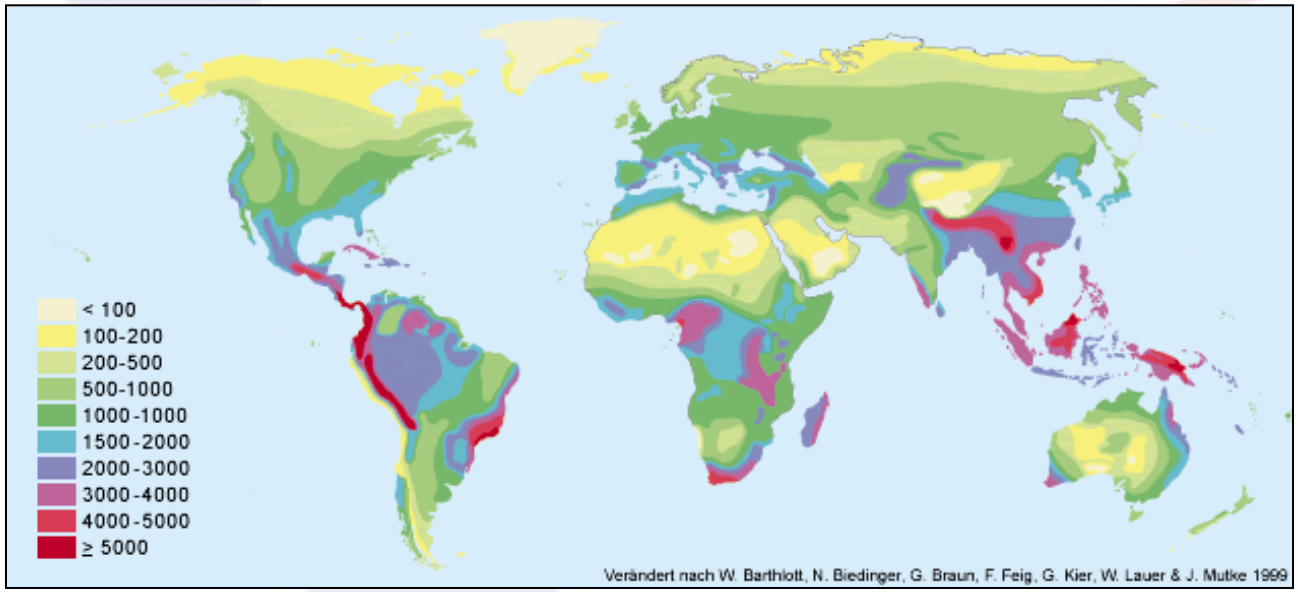
Genetic Ressources and Intellectual Property

Suhel al-Janabi
Co-Manager

ABS Capacity Development Initiative

funded by
BMZ Federal Ministry for Economic Cooperation and Development
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
European Commission
implemented by
giz Programme Implementing the Biodiversity Convention

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

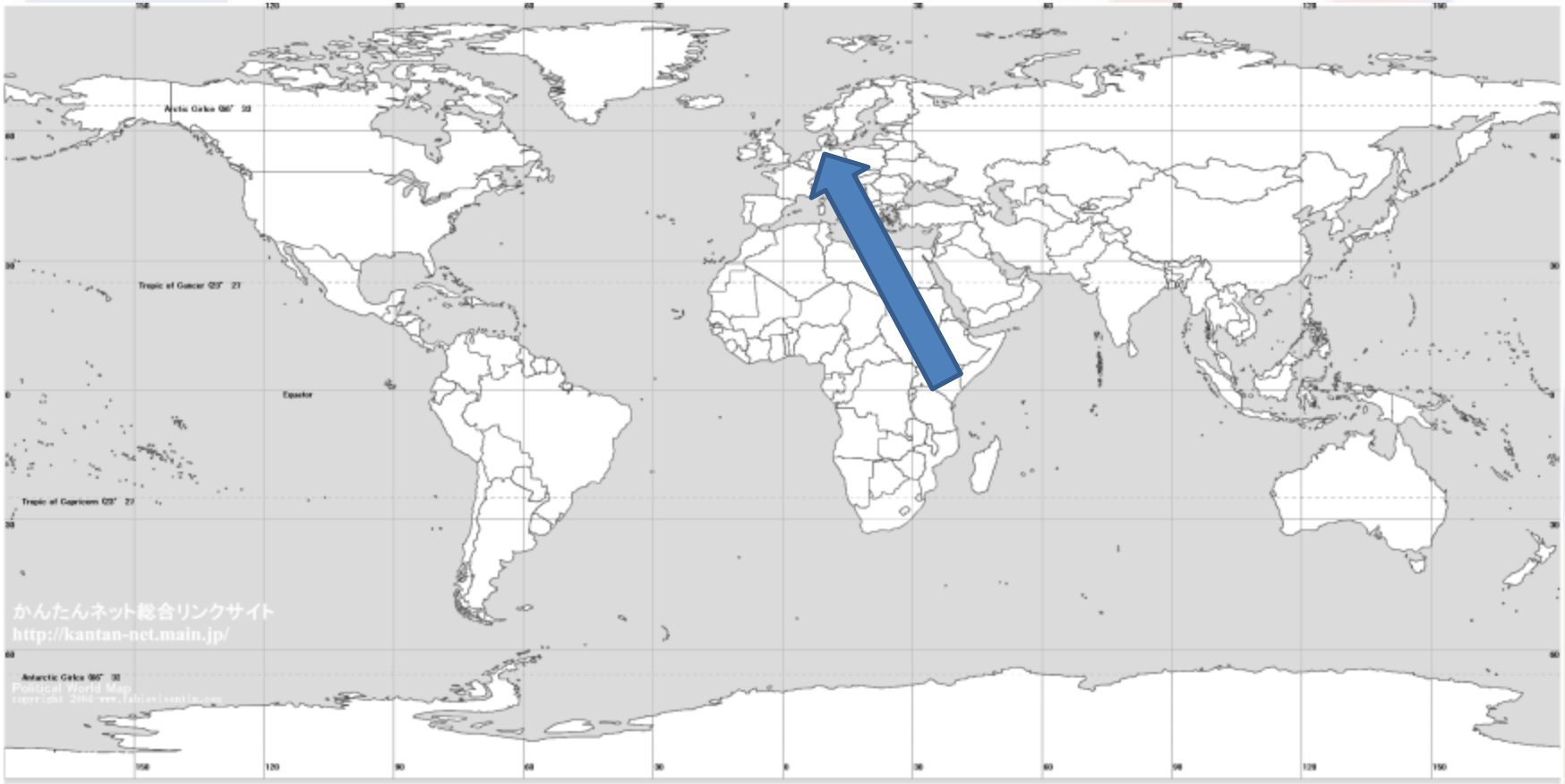
Focus: Commercial Applications of GRs

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

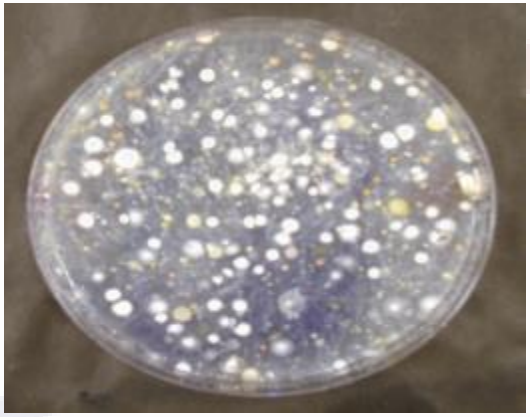
INDUSTRY	GLOBAL MARKETS (US$)
Pharmaceutical	$955.5 billion (2011)
Cosmetics	$426 billion (2012) – natural component $26.3 billion
Food and beverage	$11.6 trillion (2009) – functional beverages $23.4 billion
Seed	$45 billion (2011)
Crop Protection	$40 billion (2010)
Industrial Biotech	$65-78 billion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

Source: UNCTAD

Microorganisms & Enzymes



Microorganisms & Enzymes



BIOETHANOL

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

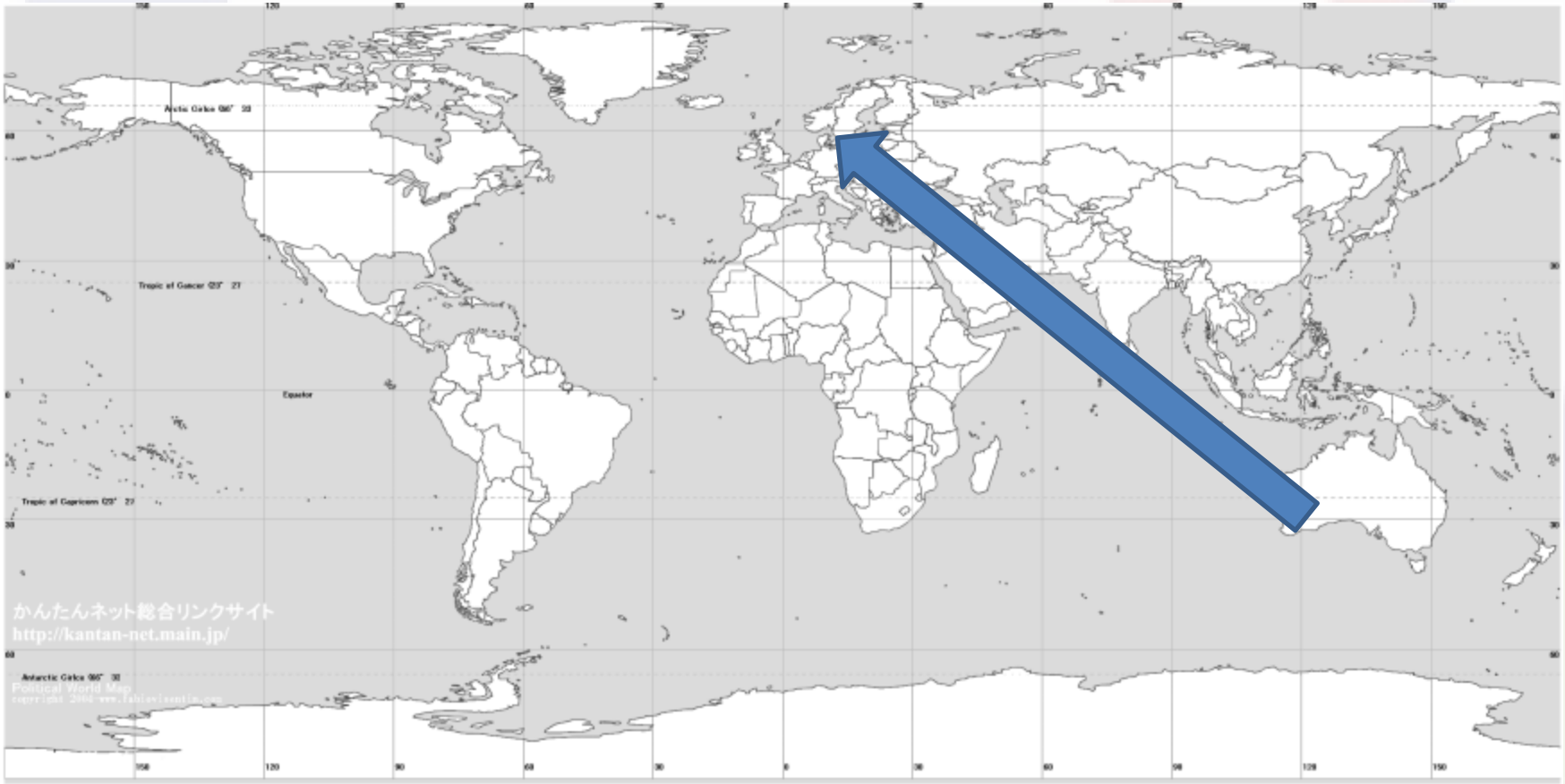
Sources: Literature review, interviews

Food and Beverages

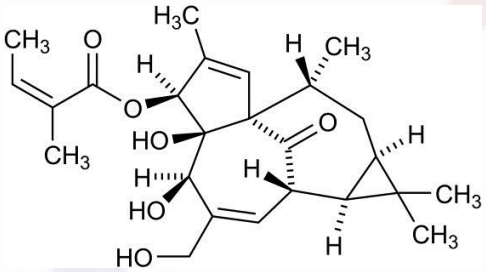
- **Market**
  - Turnover of $ 11,6 trillion (2009), expected to reach $15 trillion (2015) functional beverages: $ 23,4 billion
  - Mature, dynamique and diversified sector (9 billion people to feed !)
- **R&D**
  - Objective: health benefits (e.g. weight, energy,…)
  - Low level of R&D (process improvement) 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

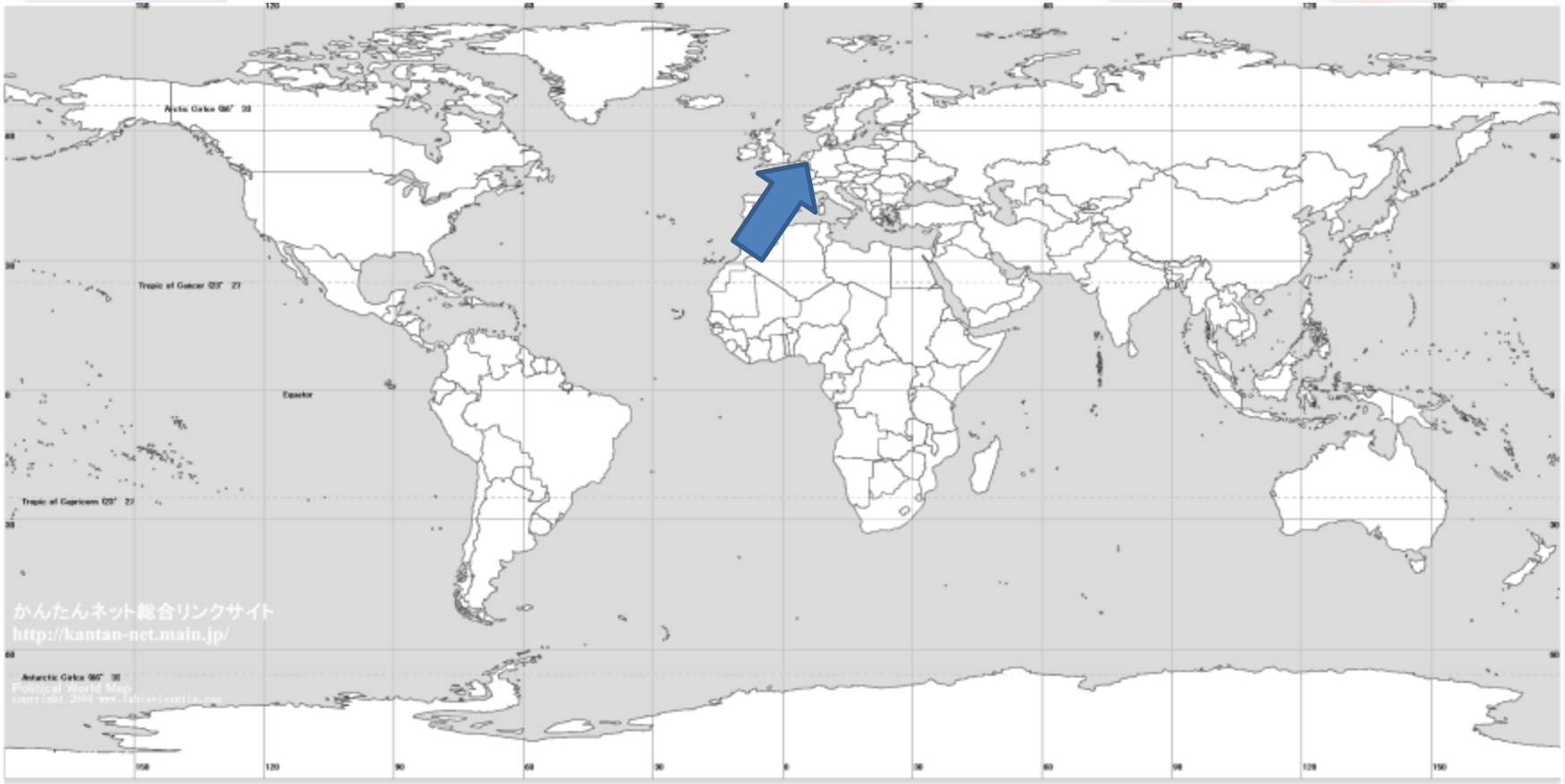


Pharmaceutical

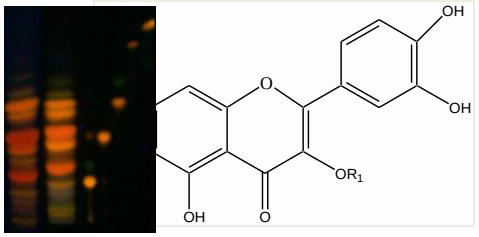
- **The market**
  - Estimated global revenues $ 955,5 (2011) expected to reach $1,2 trillion (2016)
  - Trend: large European and American based companies to do more R&D, with manufacturing in emerging markets, where domestic companies are also on the rise.
- **R&D**
  - Objective: prove activity
  - 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
かんたんネット総合リンクサイト
http://kantan-net.main.jp/
Antarctic Circle 66° 33
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

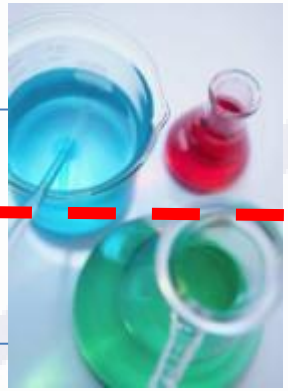
Art. 2

“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.

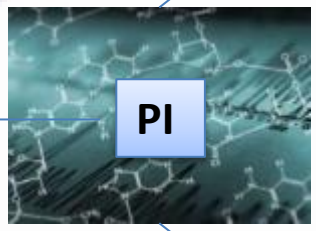
“Biotechnology” as defined in Article 2 of the Convention means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

R&D Process

(User country)

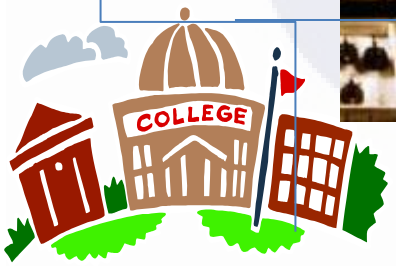


(Provider country)



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**

BIOETHANOL

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

BMZ Federal Ministry for Economic Cooperation and Development

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

European Commission

implemented by

giz Programme Implementing the Biodiversity Convention