

# Disclosure Requirements and Access and Benefit Sharing

Overview of recent  
developments in  
Brazilian biodiversity  
legislation

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# Brazilian biodiversity

- Brazil: one of 17 **megadiverse** countries, which together account for 70% of world biodiversity
- About 70% of Brazil still covered by natural ecosystems (c. **6 million km<sup>2</sup>**)
- About **15% of world's** currently described species
- **200,000 species** are known from Brazil
- Conservative estimate: **less than 10%** of total
- **1,600** federal, state and private **Conservation Units** protect 16% of continental territory and 0.5% of marine area: 1.5 million km<sup>2</sup>

# Brazilian biodiversity zones



# The Brazilian economy and the environment

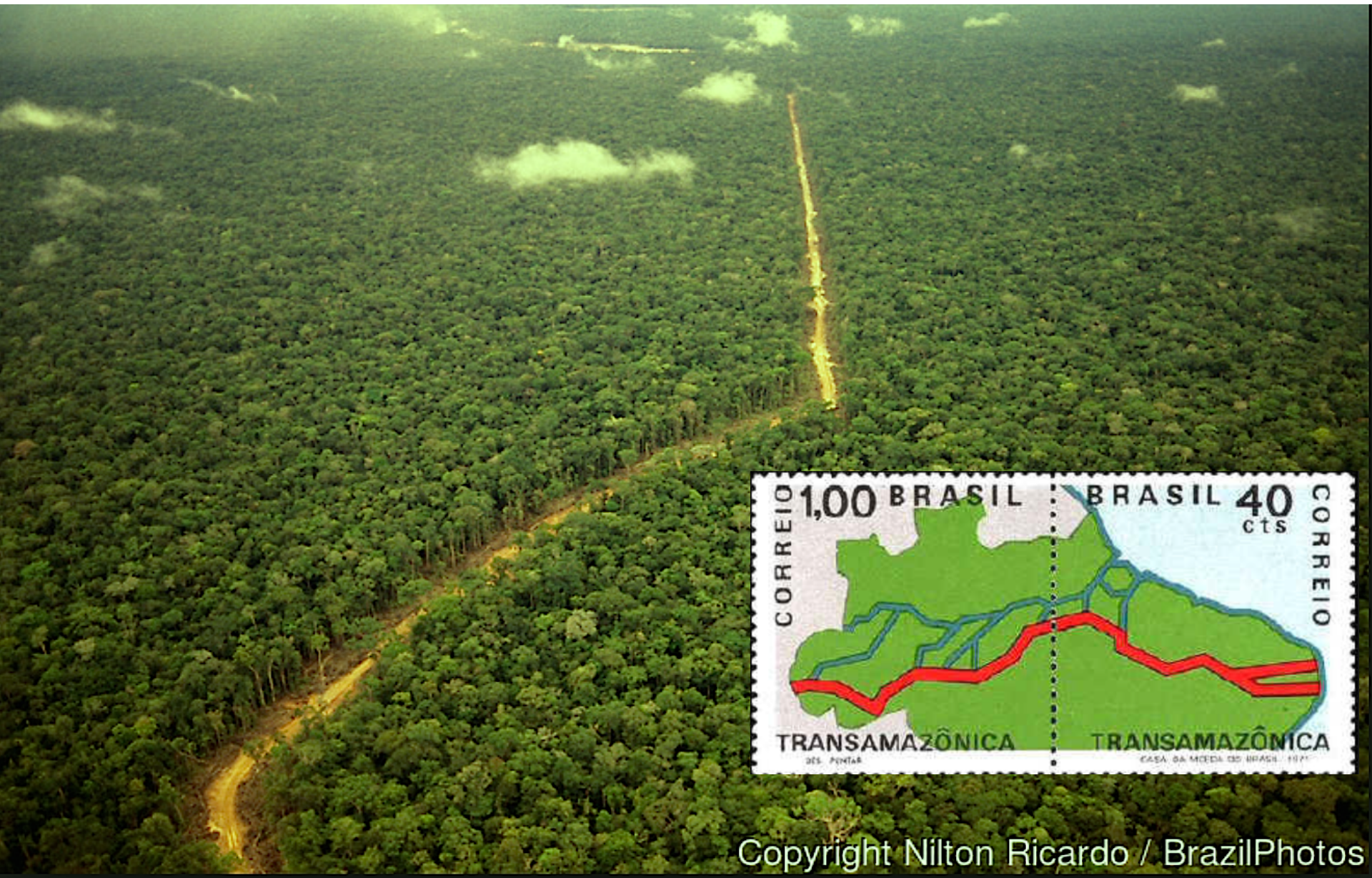
- 1500-1930: **"Extractivism"** and agriculture
- 1930-1985: **Industrialize** at all costs!
- Since 1980s: Growing local awareness of **"ecology"**, that resources are finite

Brazil in 1519: Extraction of the tree that gave the country its name





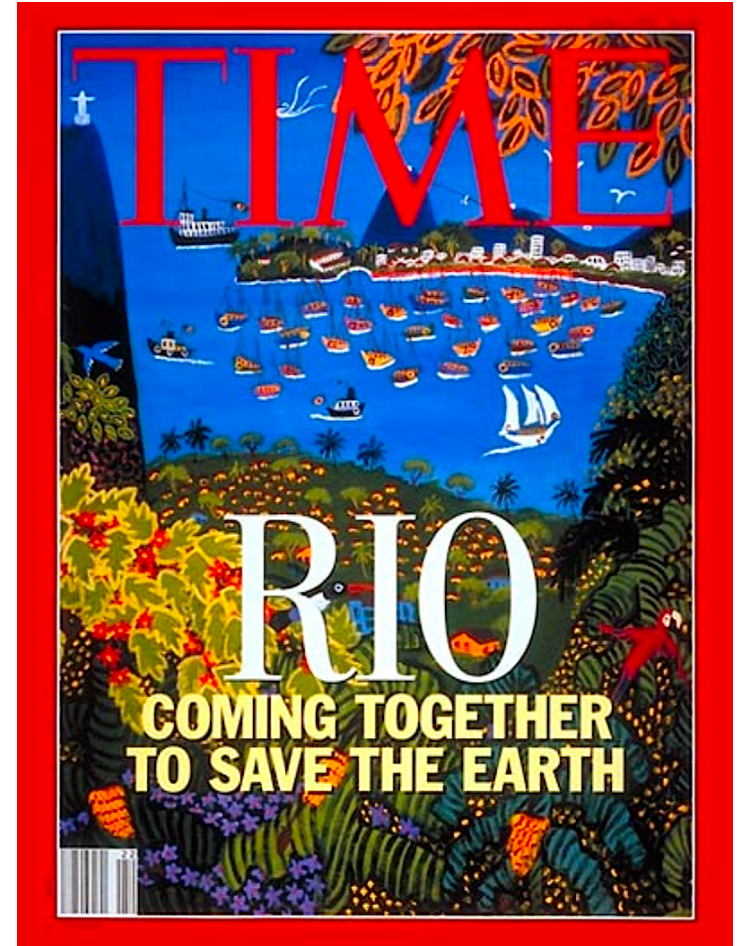
# Trans-Amazonian Highway (1970s)





# Two landmarks

- **Brazilian Constitution (1988)**
  - ✓ Right to **ecologically balanced environment**
  - ✓ Government to preserve **diversity and integrity of genetic patrimony** of country
- **Convention on Biological Diversity (CBD) (signed in Rio, 1992)**
  - ✓ **Sovereign rights** of States over their natural resources
  - ✓ **IPR to be supportive** of CBD's objectives



# The CBD: Justice at last?

“The main purpose of the CBD was to regulate access to genetic resources and benefit-sharing provisions. **Prior to 1992, genetic resources were deemed the common heritage of mankind.** But in contrast to the free accessibility of genetic resources, **intellectual property rights over inventions derived from those resources were completely privatized.**”

As wealth in genetic resources and industrialization seem to be inversely proportional, it is hardly surprising that the South, or at least some of its sectors, should perceive the CBD as an instrument of **redistributive justice.**”

(Manuela Carneiro da Cunha, anthropologist)



CBD

# Something missing in the picture

- Countries must develop a **sound regulatory framework** to reap to the full the benefits of its own biodiversity
- This happens in two **simultaneous scenarios**:
  - ✓ **Multilateral** (UN, WTO, WIPO, WHO, CBD, etc.)
  - ✓ **Internal** (clear rules, proper incentives, data management)
- Brazil in **multilateral scenario**: initiatives to **harmonize TRIPS & CBD**
- What's going on **internally?**...



# Industrial Property Law of 1996 (9,279)

Takes advantage of TRIPS flexibilities on **patentable subject matter**

Article 10: The following are **not considered to be inventions or utility models**:

IX. **all or part of natural living beings and biological materials** found in nature, even if isolated therefrom, **including the genome** or germoplasm of any natural living being, and the natural biological processes.

Article 18: The following are **not patentable**:

II. **all or part of living beings, except transgenic microorganisms** that satisfy the three requirements of patentability ... and which are not mere discoveries.

Sole Paragraph. For the purposes of this Law, transgenic microorganisms are organisms, except for all or part of plants or animals, that express, by means of direct human intervention in their genetic composition, a **characteristic normally not attainable by the species under natural conditions**.

# Events overtake regulatory process

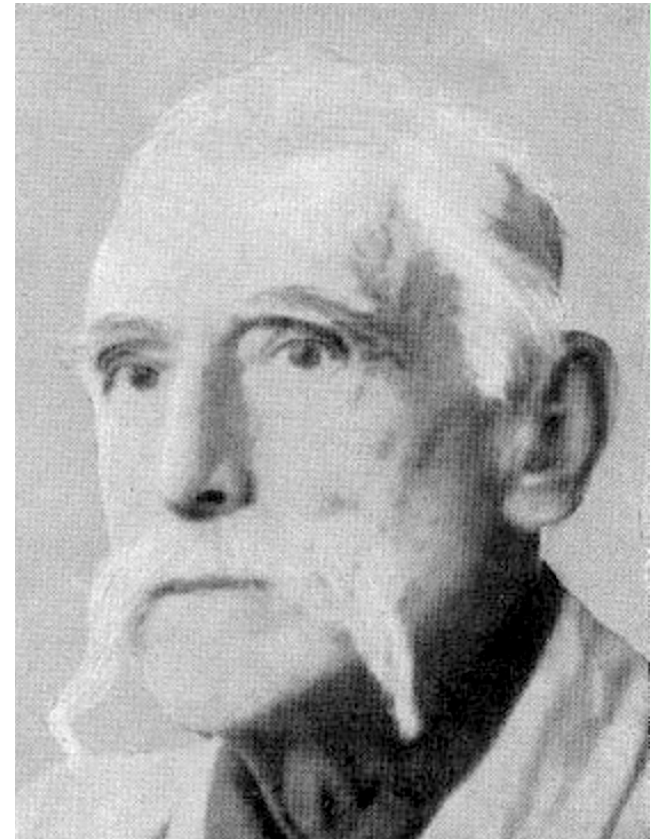
- Industrial Property Law of 1996 → living beings found in nature **“not patentable”**
- Presidential Decree 2,519/1998  
→ **Incorporates CBD** into Brazilian law “in full”

## *Other eyes on biodiversity wealth:*

- **Biopiracy** in 2000: One of largest illicit trades
- Brazil, India, other countries are major **targets**
- **Sensitive issue** in Brazil

# Biopiracy in Brazil: an old story

- Sir Henry Wickham (1846-1928): stole 70,000 seeds of rubber-bearing **Hevea Brasiliensis** in Amazon region
- Dispatched to **Malaysia, Ceylon** and other places
- End of **Amazonian rubber boom**
- Brazil **not beyond criticism**
- Did we learn the **wrong lessons?**



# The first attempt to legislate

## Provisional Act 2186-16

**Brazil's regulatory framework** for 15 years (2000-2015) for “access to genetic heritage, protection and access to associated traditional knowledge, benefit-sharing and access to and transfer of technology”

→ Enacted in **reaction** to highly publicized episodes of perceived **biopiracy** and **unfair ABS**



# Access and Benefit Sharing under P.A. 2186-16

- Managed by **Genetic Heritage Management Council (CGen)**, meeting monthly
- Heavy **government presence**: 9 ministries, 10 federal organizations with right to vote, incl. **Patent Office**
- Permanent guests from **civil society**, incl. Business, NGOs, traditional groups, **Federal Prosecution Office**
- **aTK of identifiable origin**: 0.2% of profits for 3 years to community who negotiated; **zero** to others with same aTK
- **aTK of unidentifiable origin**: no benefit sharing

# **Disclosure** under Provisional Act 2186-16/2001

## **Article 31**

“Granting of **industrial property rights** by the competent bodies over the process or product obtained from samples of genetic heritage components is **conditioned** to compliance with this Provisional Act. *The person or institution applying for the property rights must **inform the origin of the genetic material and the associated traditional knowledge**, as appropriate.*”

# Law of Unintended Consequences

- Benefit-sharing ineffective - most **TK holders not attained**
- **Low involvement** of tribes and traditional communities
- **Red tape** and complex requirements
- **Criminalization** → easy to violate, fines heavy
- **Disincentive** to research

**P.A. 2186-16: Insufficient R&D** and patent filing:  
in 14 years, only 136 contracts approved  
→ **No synergy with Brazilian innovation system**

# Revenue loss (2010 estimate)

- Brazil fails to generate **US\$ 5 billion** annually for not taking fuller advantage of its biodiversity
- Only one herbal medicine based on Brazilian biodiversity developed in the country: **Acheflan**, an anti-inflammatory drug
- 420+ herbal medicines registered with Ministry of Health
  - **Only ten** from national plants
  - Drugs developed **abroad**





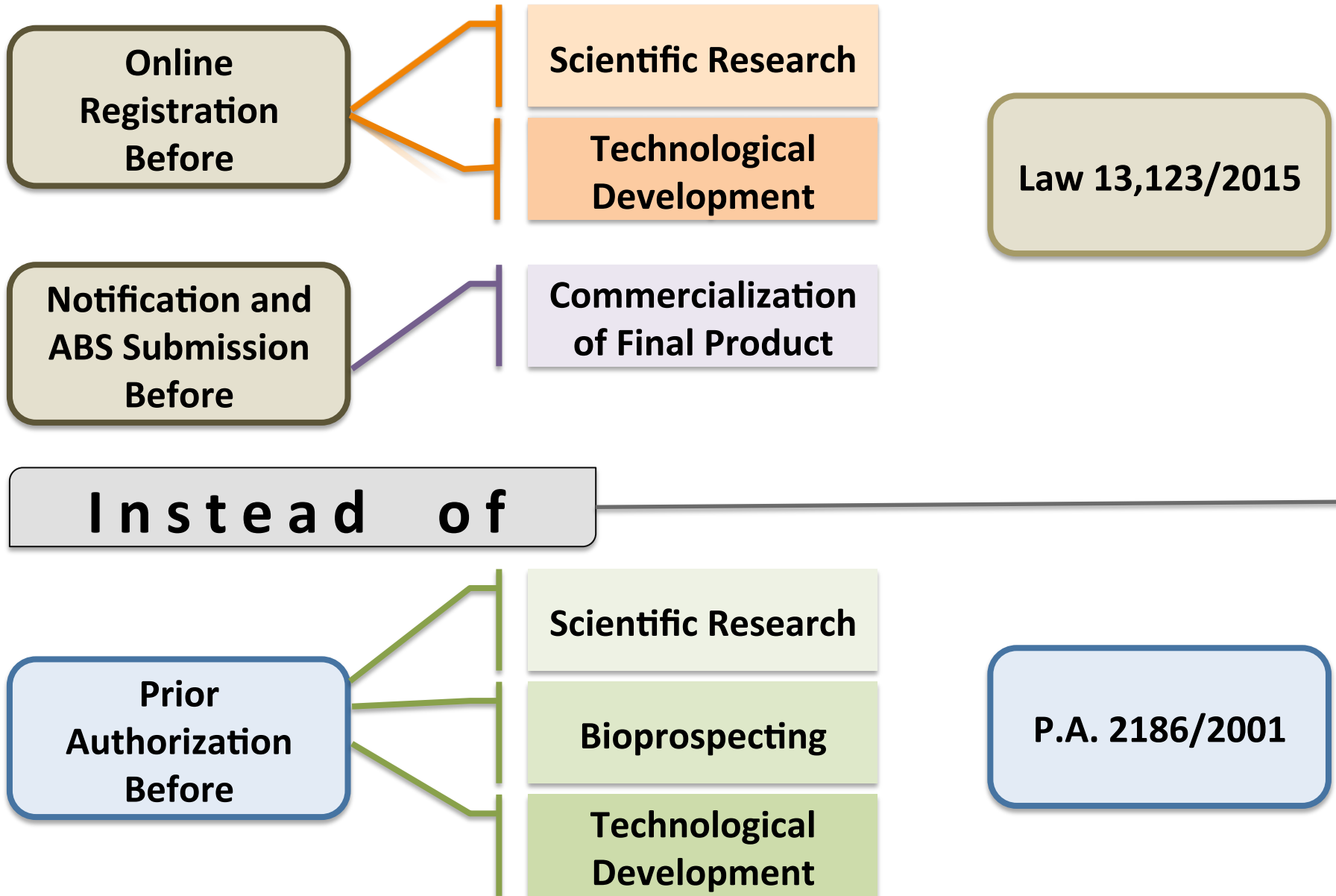
# Brazil as Scrooge?



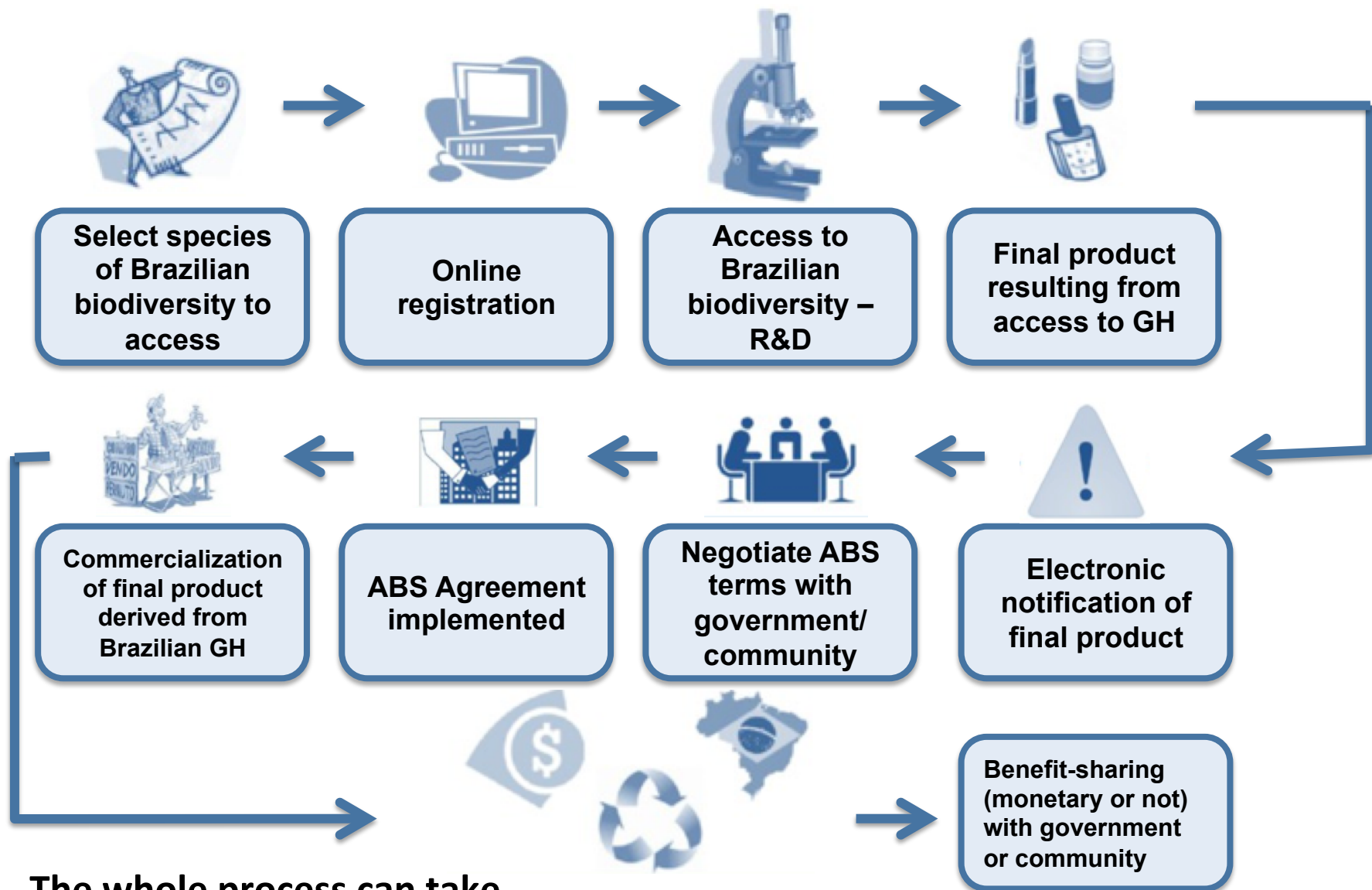
# New biodiversity law – 13,123/2015

- Approved by **vast majority** in Congress in a year of political polarization
- Sanctioned on May 20, 2015, entered into force on **November 17, 2015**
- Rules of application released on **May 11, 2016**
- New regulatory framework still under analysis, but response overwhelmingly **positive**

# Compliance with the new law



# Steps for the fulfillment of the law



**The whole process can take approximately three months (not counting research time)**



# More carrot, less stick

- Clearer (and much faster) rules of **access to GR and aTK**: *registration* in minutes instead of 2+ years wait for *authorization*
- **Legal certainty** to businesses, researchers, students...
- **Decriminalization** → fine reduction, easier to fix irregularities
- Benefit-sharing requirement only over **sale of final product**
- aTK holders have **greater participation** in decision-making
- Generates resources for **conservation** and **sustainable development**
- **EXPECTED RESULT**: Encourage **research, innovation** and new products

# More public participation

Membership of *Generic Heritage Management Council (CGen)* more **balanced**

- 60% Government: 12 Ministries
- 40% Civil Society (3 each)
  - ✓ **Business** Community
  - ✓ **Academia**
  - ✓ **Indigenous groups**, traditional communities, traditional farmers

# National Benefit-Sharing Fund (FNRB)

- Companies selling **finished product** deriving from genetic heritage make **annual payment** to FNRB equal to **1% of net sales revenue**
- Possibility of **sector understandings**, which could reduce this percentage to 0.1%
- Resources fund **National Benefit-Sharing Program**
  - ✓ Preserve **biodiversity** and encourage **sustainable use**
  - ✓ Develop **inventory** of genetic heritage
  - ✓ Distribute **benefits** to aTK holders

# Benefit-sharing rules

- **Identifiable** aTK holder
  - ✓ **Prior informed consent (PIC)** mandatory
  - ✓ Final recipient of benefits
  - ✓ **Direct** contract negotiations
  - ✓ **Other communities** with same aTK benefit
- **Non-identifiable** aTK holder
  - ✓ PIC not required
  - ✓ Benefit-sharing to fund **National Benefit-Sharing Program** (under Ministry of the Environment )

# IPR → Incentives rather than penalties

- **Ease and clarity** of new rules encourage compliance, **R&D**, and **innovation**
- Regulatory framework **does not discourage** disclosure
- **Disclosure** a precondition for patent granting
- **Facilitated settlement** of outstanding fines/penalties
- The law does have **teeth**: penalties still apply



# Disclosure requirements

## Article 12

The following activities must be **registered**:

**I to III - access** to genetic heritage or to associated traditional knowledge [*by different users, under different circumstances*];

**IV and V - shipping of sample of GH** abroad [*under different circumstances*]

§ 2 **Registration must be done prior to... requesting any intellectual property right**

# Disclosure requirements

## Article 47

“The **granting of intellectual property rights** by the competent organ, on the finished product or on reproductive material obtained from access to genetic resources or associated traditional knowledge, *is* **conditioned to registration or authorization** under the terms of the Law.”

# What's going on right now?

- Environment Ministry: satisfied with **“balanced text”**: business-friendly as well as protective
- Industrial Property Institute: **“major improvement”**, analyzing new procedures closely
- Private sector: **pleased** with clarity and simplicity
- Traditional communities: point to **lack of prior consultations**, but will have greater say from now on

Thank you for your attention!

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