# WIPO Webinar on IP and Genetic resources:

## Disclosure Requirements relating to Genetic Resources and Associated Traditional Knowledge

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Dominic Muyldermans
Senior legal consultant, CropLife International

# Key elements re disclosure

## Not needed & already covered

- Not needed:
  - ABS compliance covered by specific ABS laws;
  - Compliant use of genetic resources and transfer of relevant data in applicable ABS frameworks is endorsed and enforced;
  - Many innovations not covered by patents.
- Incompatible with TRIPS requirements;
- Already covered by the patent system:
  - To the extent needed for the enablement condition;
  - To avoid granting of erroneous patents.
- Economic cost-benefit analysis shows an increase of transaction costs and an undermining of innovation incentive.

# ABS Compliance

**Not needed:** ABS specific compliance rules

- ABS Regulatory context has fundamentally changed since 2000:
  - Nagoya Protocol requiring countries of use to implement an effective compliance system;
  - Effective ABS compliance rules specifically addressing compliance and ensuring transparency:
    - EU ABS Regulation (patent offices not retained as check points);
    - National laws.
- WIPO IGC discussions started when there were no ABS regulatory frameworks.

# ABS & the patent system

## **Incompatible** with principles of patent system

- No interference *per se* between patent law and ABS:
  - No conflict between the public ABS rights and private patent rights;
  - Complementary nature of obligations.
- Disclosure obligations raise questions of compliance with the principles of patent law:
  - Numerous clausus of patentability requirements;
  - Incompatibility with the prohibition of discrimination:
    - Products resulting from natural product research which are/cannot be patented.
  - Incompatibility with the reasonableness requirement:
    - It goes beyond what is required re the patent;
    - Risk of interference creates legal uncertainty.

# Patent system

## **Already covered** in the patent system

- Fundamental confusion between aim of **disclosure** *re* ABS and disclosure in a patent application:
  - ABS: enable the collection and transfer of relevant data to assess compliance with relevant ABS laws (GR);
  - Patent: obligation of complete disclosure to comply with the enablement condition under patent law (Invention):
- Key aim: **avoiding the erroneous granting of patents**;
  - No patent on the GR as such;
  - Defensive protection of GR and TK is ensured by the patent system;
  - To be enabled by information systems & databases;
  - For erroneously granted patents, ABS disclosure is useless.

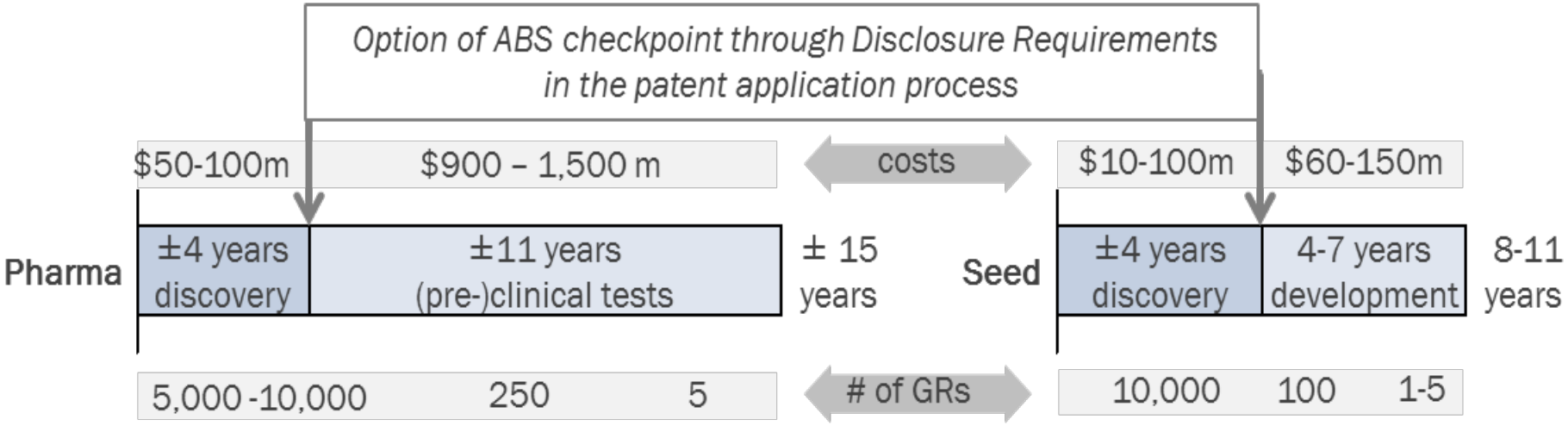
# Cost benefit analysis

## Higher transaction costs

- Industry experience:
  - Additional administrative burden + complexity;
  - Legal uncertainty:
    - Undermining effective patent protection during the R&D process impacts R&D and invested resources for all players in the value chain;
  - Higher transactions costs early in the R&D process, independent and remote from final product creating benefits:
  - **BUT:** no added value in ABS compliance.

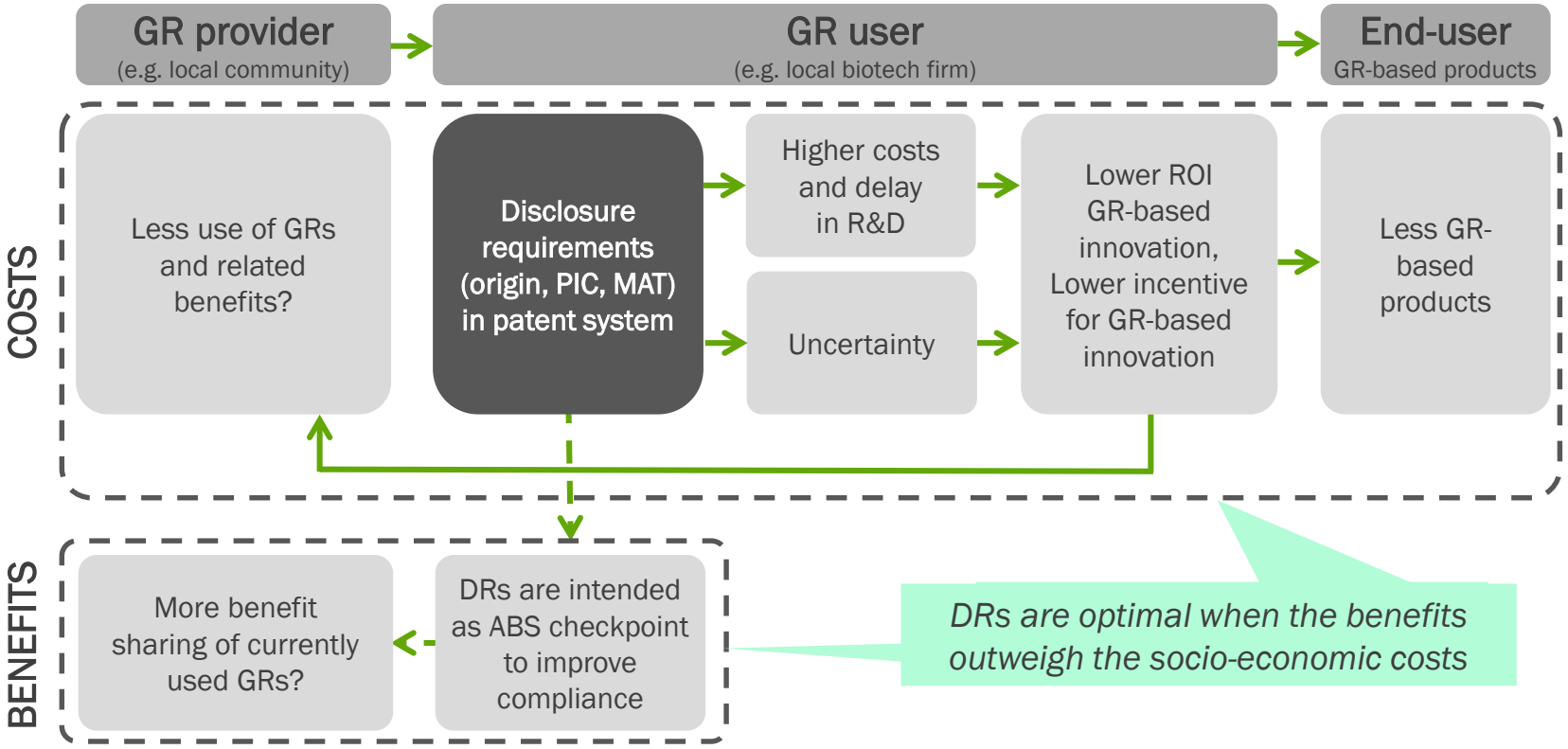
  ➢higher transaction costs – lower incentive for natural product research – less benefits to be shared.
- **Economic study** providing data on cost-benefit analysis, focusing on megadiverse countries with a disclosure obligation.

# How does it affect the R&D cycle?




DRs could affect the cost and time of the R&D cycle during the end of the discovery phase as extra condition of the patent process.

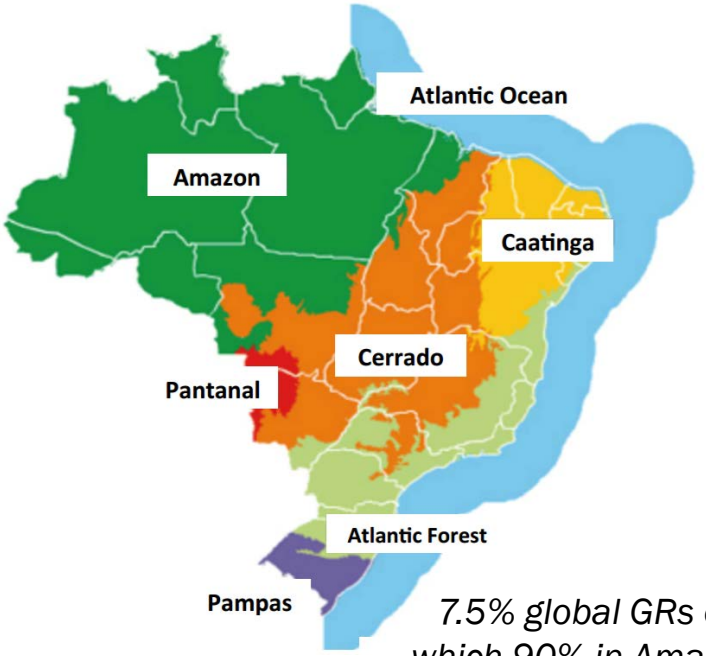
# Societal impact of DRs on all stakeholders in value chain of GR-based innovation




Is the DR introduction optimal for society? In other words: *Does the intended societal benefits of DR introduction outweigh the societal losses?*

# Case introduction Brazil: biodiversity regions & actors

Brazilian biodiversity regions



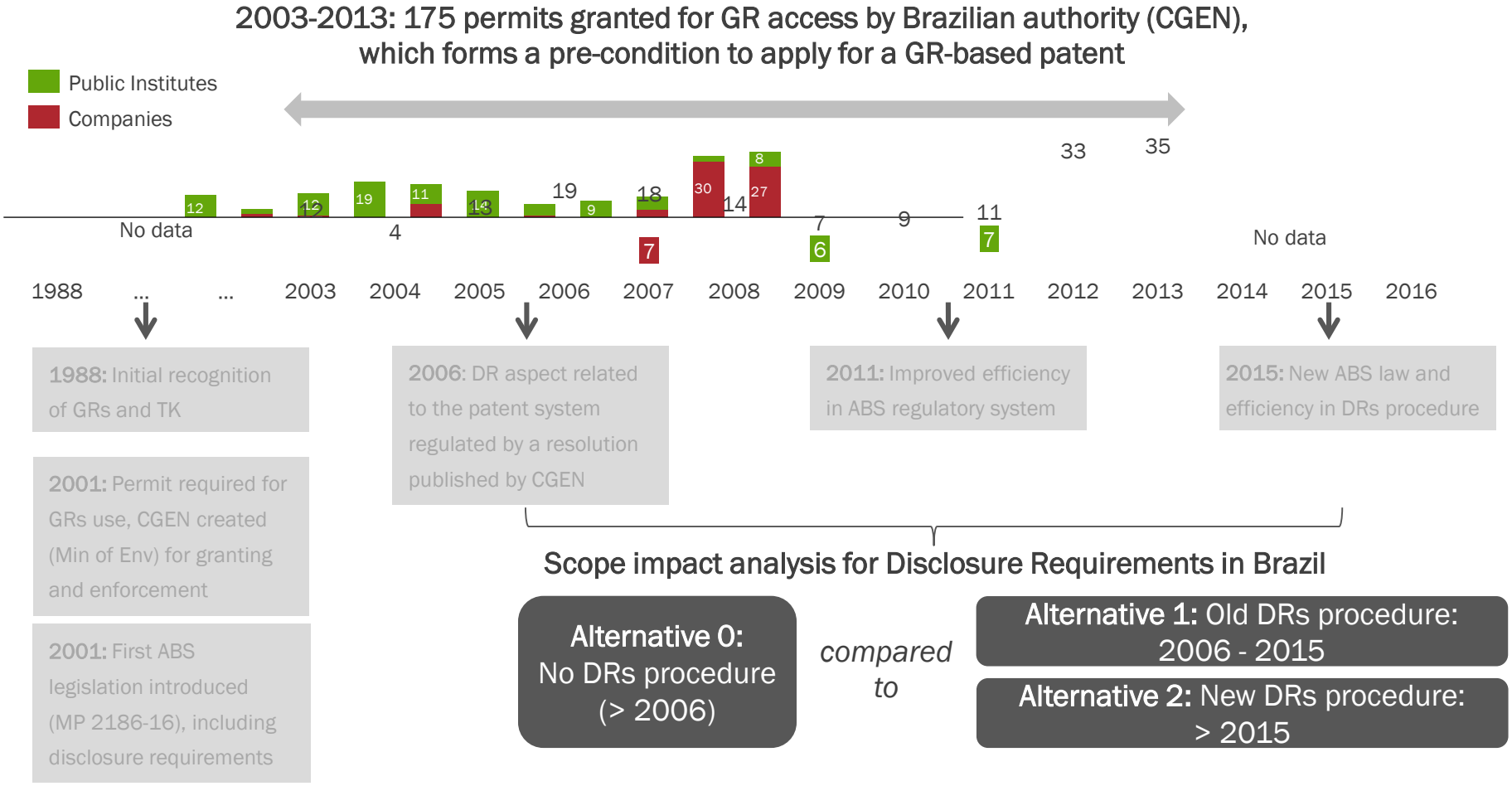

*7.5% global GRs of which 90% in Amazon*

| Actor in ABS system | Brazilian organizations |
|---|---|
| GR providers | Private landholders, local communities and gene banks |
| GR users | Direct users: Public institutions (e.g. Embrapa), local companies (e.g. Natura)<br>Indirect: Other local and foreign companies |
| End consumers | Industry & consumers GR-based products, within & outside Brazil |
| Government bodies | CGEN Genetic Heritage Management Council,<br>INPI: National institute for IPRs |

Between 2006-2015, DRs include evidence of source or origin, prior informed consent (PIC) and mutually agreed terms (MAT).

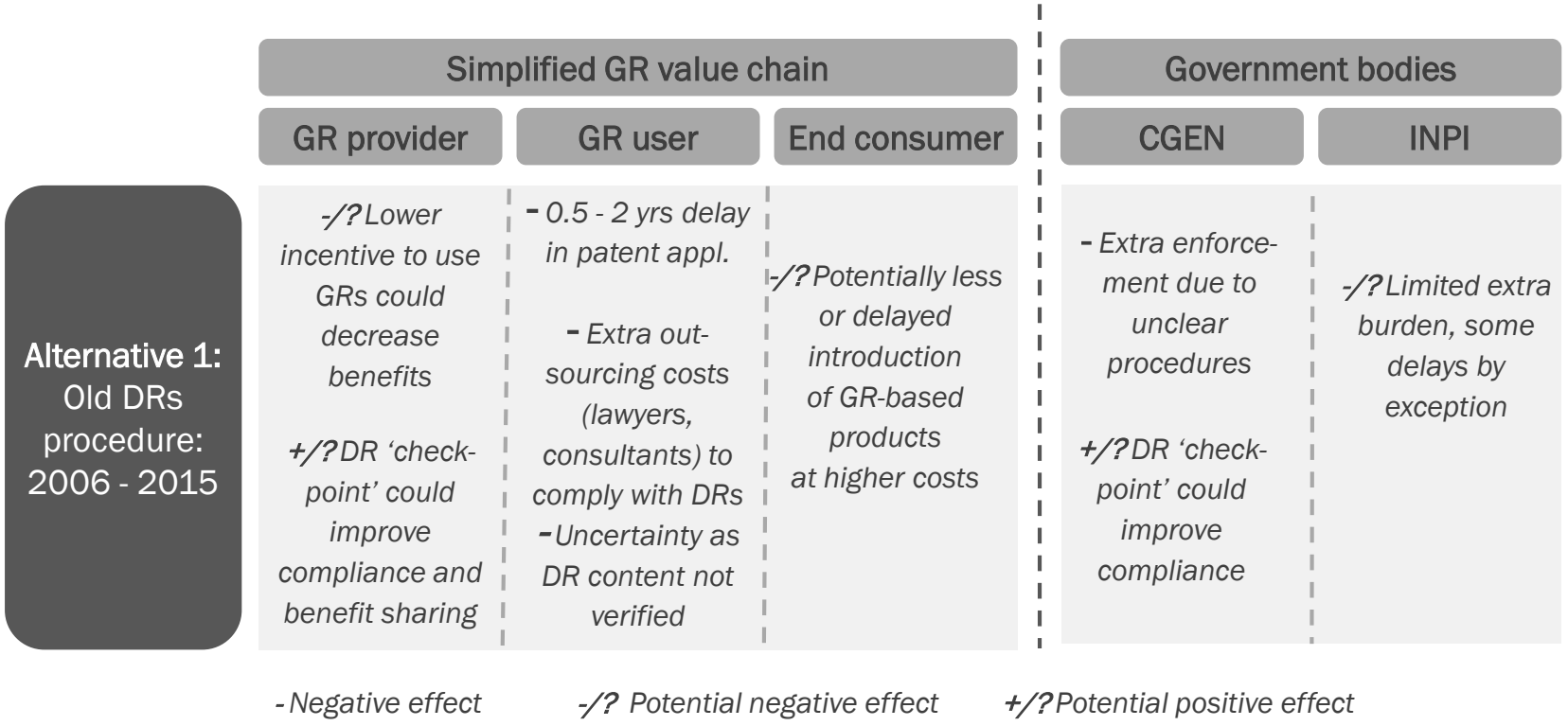
After 2015, MAT is removed and shifted to the final product development stage before commercialization

# In the Brazilian case, the old DR procedure (2006-2015) and new DR procedure (>2015) are compared to a situation without DRs (<2006)




Source: CGEN 2016, INPI 2016

# First 10 years of DRs delayed patent applications from months to over 2 years and increased third party costs for GR-using businesses




New DR system could limit burden by new, efficient (online) process and might clear procedures, but extra outsourcing for DR compliance and uncertainty remain.

Source: Interviews INPI, CNI, Grupo FarmaBrasil, IP division Brazil Min of FR, Steward Redqueen interpretation

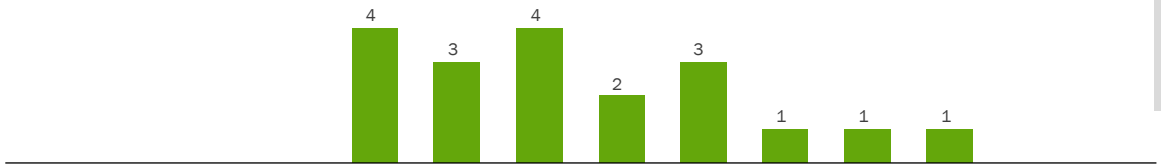
# Case introduction India: biodiversity regions & actors


| Actor in ABS system | Indian organization |
|---|---|
| GR providers | Private landholders, local communities & gene banks |
| GR users | Direct users: Public institutions (Indian Agri Research Institute) and local companies (e.g. Biocon)<br><br>Indirect: Other local and foreign companies |
| End consumers | Industry and consumers of GR-based products, within and outside India |
| Government bodies | Ministry of Environment, Forests and Climate Change<br><br>NBA: National Biodiversity Authority,<br><br>State Biodiversity Boards<br><br>Biodiversity Management Committees, established by local bodies<br><br>Intellectual Property (IP) India for IPRs (part of Ministry of Commerce and Industry) |

Since 2005, patent applicants using Indian GRs are obliged to comply with the 2002 Biological Diversity Act, which requires proof of ABS requirements (origin and source).

# In the Indian case, a situation with DRs (>2005) is compared to a situation without DRs (<2005)

Agreements signed between NBA and company/institution for access to GRs in India




***19 out of 133 requests*** *for access to GRs* ***were signed*** *between NBA and a company or institution*

*No data*

*No data*

1992 ... 2002-03 ... 2006-07 2007-08 2008-09 2009-10 2010-11 2011-12 2012-13 2013-14 2014-15 2015-16

**1992:** Initial recognition of GRs (i.e. India signs Convention on Biological Diversity, CBD)

**2002-2005 Major changes related to DRs**

**2002:** Biological Diversity Act (BDA) requires proof of meeting ABS requirements during patent application.

**2003:** National Biodiversity Authority (NBA) founded to authorize GR related issues

**2005:** For Indian GRs use, Disclosure of Origin and Source required in line with BDA during patent application

**2016:** Patent applicants receive an extra 2 months to comply with proof of ABS requirements

**Scope for DR impact analysis in India**

**Alternative 0:** No DRs procedure < 2005

*compared to*

**Alternative 1:** DRs procedure: > 2005

Source: India Habitat Centre (2014); Remfry & Sagar (2015)

# The patent process was delayed with 4 years, and recently improved to 'only' 1-1.5 years, while the procedure is also perceived as complex and inconsistent

| | Simplified GR value chain | | | Government bodies | |
|---|---|---|---|---|---|
| | GR provider | GR user | End consumer | NBA | IP India |
| **Alternative:** DRs procedure: > 2005 | *-/? Lower incentive to use GRs could decrease benefits (delays in NBA approval & unclarity in regulations)*<br>*+/? DR 'check-point' could improve compliance and benefit sharing* | *- Initially 4 years delay in NBA permission necessary for patent approval, decreased over time to currently 1 to 1.5 years*<br>*- Uncertainty as several definitions and procedures are unclear* | *-/? Potentially less or delayed introduction of GR-based products at higher costs (i.e. lower trend of Indian biotech patents is an indication)*<br>*+/? Insight in exact GR use* | *- Burden because of extra administrative work*<br>*+/? DR 'check-point' could improve compliance* | *? Limited extra costs* |

*- Negative effect* *-/? Potential negative effect* *+/? Potential positive effect*

# Cost benefit analysis

## Conclusions

- In both India and Brazil:
  - DRs seem to have delayed the patent process, a phase where the chance of commercial success of a products is still highly uncertain
  - Regulations are perceived by several stakeholders as unclear or inconsistent. This creates additional uncertainty for patent applicants, providers and users
- DRs undermine both innovation and the goals of the Nagoya Protocol and CBD, i.e. enabling and safeguarding value creation through innovation with GRs;
- ABS compliance under relevant frameworks is endorsed and fully implemented;
- Preventing of erroneous patents supported;
- DRs not needed for effective ABS compliance.

Thank you

dominic.muyldermans@croplife.org