

# Session 3: Harmonizing an Intellectual Property Rights Regulatory Regime in the Seed Industry

**Seed World 2019**

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**Place:** Bangalore, India

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# The New Markets Lab

- Non-profit **center for law and development** that houses comparative expertise and an international team of lawyers focused on **leveraging law and regulation as a tool for sustainable economic development** and building legal capacity in an evolving global market
  
- House a **innovative set of legal and regulatory tools** (Legal Guides, Regulatory Systems Maps, Case Studies)
  - Benchmark national systems against international rules and good regulatory practices
  - Highlight regulatory tradeoffs and options that will result in improvements in implementation
  - Tailor legal and regulatory approaches based on stakeholder consultations and scenario-based engagement
  
- NML works to **build legal capacity** throughout its network of lawyers and partners
  - Improve the design and implementation of economic laws and regulations,
  - Address regulatory bottlenecks as they arise
  - Support efforts to strengthen the feedback loop between regulators and local communities



# NML's Partnerships and Program on Plant Variety Protection and Licensing Agreements

- **NML** has a longstanding partnership with the **Syngenta Foundation for Sustainable Agriculture (SFSA) and its Seeds2B** project, which is designed to help farmers access quality, affordable seeds of improved varieties for the crops they need
- NML part of the **Partnership for Seed Technology Transfer in Africa (PASTTA)**, a USAID funded partnership among Seeds2B, NML, and the African Agricultural Technology Foundation (AATF) that aims to enable the transfer of best-bet seed-based technologies
- NML contributing to the **Accelerated Varietal Improvement and Seed Delivery of Legumes and Cereals in Africa (AVISA)** project is funded by the Bill and Melinda Gates Foundation and involves several partners, including the International Crops Research Institute for the Semi-Arid Tropics (ICRISAT), the International Institute of Tropical Agriculture (IITA), International Center for Tropical Agriculture (CIAT), National Agricultural Research Organizations, and SFSA and NML
  - NML will contribute through:
    - Regulatory guides to build awareness of plant variety protection (PVP) rules, licensing models, and rules for regional variety release
    - Practical legal and regulatory interventions to register seed within African regions & develop fair and equitable licensing models
    - Hands-on learning modules to build regulatory capacity
- NML is partnering with AGRA & a Regional Economic Community in Africa to assess regional harmonization of seed regulations, including Plant Variety Protection laws and regulations

# Introduction & Background – Elements of Seed Regulatory Systems

## □ **Plant Variety Protection (PVP)**

- Legal framework for ownership of varieties (aligned with UPOV); underpins licensing and commercialization of seed
- Arusha Protocol includes provisions on compulsory, exclusive, and non-exclusive licensing of regional varieties

## □ **Seed Variety Release and Regulation**

- Most countries have a formal process for seed variety release and registration that includes testing for Distinctness, Uniformity, and Stability (DUS) and Value for Cultivation and Use (VCU) before new varieties can be released; number of seasons of testing varies by country and region

## □ **Seed Certification**

- Many countries require that seed go through a formal process of certification before commercialization (seed must be formally released and registered before certification); also covered under regional rules in Africa

## □ **Seed Trade**

- National and regional seed rules govern the importation and exportation of seed, including sanitary and phytosanitary (SPS) controls

# Seed Regulatory Value Chain



## International/ Regional



## National



## Regulators/Actors

<ul style="list-style-type: none"> <li>• National Seed Authority</li> <li>• Agricultural Research Institutes</li> <li>• International Breeding Centers</li> <li>• Private Sector</li> <li>• National Agriculture Research Systems (NARS)</li> </ul>	<ul style="list-style-type: none"> <li>• PBR Registrar or Committee</li> <li>• NARS</li> </ul>	<ul style="list-style-type: none"> <li>• Ministry of Agriculture</li> <li>• National Seed Authority</li> <li>• National Variety Release Committee</li> <li>• NARS</li> </ul>	<ul style="list-style-type: none"> <li>• Agricultural Research Institutes</li> <li>• Private companies</li> <li>• Licensing agreements for the production of protected varieties</li> <li>• NARS</li> </ul>	<ul style="list-style-type: none"> <li>• Ministry of Agriculture</li> <li>• National Seed Authority</li> <li>• NARS</li> </ul>	<ul style="list-style-type: none"> <li>• National Seed Authority</li> <li>• Seed Companies</li> <li>• Agrodealers</li> </ul>	<ul style="list-style-type: none"> <li>• National Seed Authority</li> <li>• Seed Companies</li> <li>• Agrodealers</li> </ul>	<ul style="list-style-type: none"> <li>• Ministry of Agriculture</li> <li>• National Seed Authority</li> <li>• Ministry of Trade</li> <li>• Customs and Border</li> <li>• International Agricultural Research Centers</li> <li>• NARS</li> </ul>
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# Intellectual Property Rights (IPR) in Seed

Plant Variety Protection Laws and Regulations

# Plant Variety Protection Laws and Plant Breeders' Rights

- Once genetic material has been transferred or a new variety has been developed the question of IPR protection becomes relevant.
- Most countries around the world protect IPR for seed through plant breeder's rights (PBR) regimes, which are a *sui generis* approach designed to protect IPR related to plant varieties. PBRs are granted through plant variety protection (PVP).
- In general, IPR, including PBR over seed, does not vest automatically; breeders must claim protection over the material they develop according to the rules of the applicable legal framework.
- Once a right has been claimed, licensing agreements can be used to transfer rights to use the protected material. While a variety registration or other use right can also be licensed, a traceable right to exclusivity in the use, transfer, multiplication, and commercialization of seed is strongest when based on PBR.

# International PVP Frameworks

- There is a comprehensive body of international law related to PBR and plant genetic resources for food and agriculture (PGRFA). The main international instruments include:
  - **International Union for the Protection of New Varieties of Plants (UPOV)** that has adopted a Convention on the Protection of New Varieties of Plants (UPOV Convention), which has been updated several times.
    - Most UPOV Members adhere to the UPOV Convention of 1991, but some still adhere to the UPOV Convention of 1978.
    - The main difference between the 1978 and 1991 UPOV Conventions is the scope of Plant Breeders' Rights.
    - According to UPOV India has initiated the process for acceding to the UPOV Convention, but is not yet a member.





# International PVP Frameworks

- **The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization to the Convention on Biological Diversity (Nagoya Protocol)**, created with the objective of ensuring implementation of the **Convention on Biological Diversity (CBD)**, which focuses on the conservation and sustainable use of biodiversity and fair and equitable sharing of benefits arising from the use of genetic resources.
- **International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)**, includes provisions to grant access and equal benefit from the use of plant genetic resources and traditional knowledge. It also promotes countries' adoption of legislation that protects traditional knowledge relevant to plant genetic resources and recognizes farmer's rights to equitably participate in sharing benefits arising from the use of such resources.

# PVP Trends in Africa

- **African Regional Intellectual Property Organization (ARIPO):** The Arusha Protocol (*sui generis* framework based on UPOV 1991)
  - 19 Member States, 5 Members have signed the Protocol (Rwanda, Tanzania, Gambia, Ghana, Mozambique and Sao Tome and Principe), but only Rwanda has deposited in instrument of accession. The Arusha Protocol will enter into force after four Member States have deposited instruments of accession.
- **Organisation Africaine de la Propriété Intellectuelle (OAPI):** Annex X Plant Variety Protection (*sui generis* framework based on UPOV 1991)
  - 16 Member States. OAPI operates differently than ARIPO, it adopts a uniform regional system of intellectual property rights where member countries agree to 'renounce' to their national sovereignty in IP. Consequently there is a common regional authority that serves as the national IPR protection office for each country. A single title issued in a member country is valid throughout the region.
- **Southern African Development Community (SADC):** Protocol for the Protection of New Varieties of Plants (Plants Breeders' Rights) in SADC, (*sui generis* framework based on UPOV 1991): adopted, but not implemented.
  - 16 Member States. According to Article 3 of the Protocol, it will operate in the same lines as OAPI, where the SADC PVP system will override national PVP systems.
- **The East African Community (EAC) Seed and Plant Varieties Bill** (*sui generis* framework based on UPOV 1991) (still in draft and not yet in force)
  - 6 Partner States. When implemented, Partner States need to adopt national laws and regulations that comply with the EAC Seed Act. PVP will be administered regionally.

# National approaches to PVP Laws in Africa

- Several African Countries have adopted or are in the process of adopting their own PVP laws including, but not limited to:

## Through ARIPO:

- |                |                            |                     |
|----------------|----------------------------|---------------------|
| ■ Kenya        | ■ Benin                    | ■ Equatorial Guinea |
| ■ South Africa | ■ Burkina Faso             | ■ Gabon             |
| ■ Tanzania     | ■ Cameroon                 | ■ Guinea            |
| ■ Egypt        | ■ Central African Republic | ■ Guinea Bissau     |
| ■ Ghana        | ■ Chad                     | ■ Mali              |
| ■ Mauritius    | ■ Comoros                  | ■ Mauritania        |
| ■ Nigeria      | ■ Congo                    | ■ Niger             |
| ■ Zimbabwe     | ■ Côte d'Ivoire            | ■ Senegal           |
|                |                            | ■ Togo              |

# PVP Framework in India

- **The Plant Variety Protection and Farmers Rights Act (PPVFRA), 2001**, is a *sui generis* system to recognize and protect the rights of both commercial plant breeders and farmers in respect of their contribution made in conserving, improving and making available plant genetic resources for development of new plant varieties and to encourage the development of new plants varieties.
- **Four types of plant varieties can be registered under PPVFR Act, 2001.** 1) New variety, 2) Extant variety, 3) Farmers' variety, 4) Essentially derived variety (EDV)
- Farmers and farming communities may seek protection, and farmers may receive an award from the Gene Fund when conserving and improving landraces.
- Any variety where prevention of commercial exploitation of such variety is necessary to protect public order or public morality or human, animal and plant life and health or to avoid serious prejudice to the environment or any varieties which has terminator technology or any variety belonging to the species or genera which is not listed in the notification cannot be registered for the protection under the Act.

# IP Licensing - Background



- Licensing agreements can be tool for creating value for breeder and ensuring wide dissemination of seed varieties
- A licensing agreement is essentially a contract between two entities, or “parties”
- Licensing allows for the transfer of technology from the inventor to the user or commercializing entity, while still maintaining control of how the variety is used

# IP Licensing – Rationales

- Transfer seed technology and increase opportunities for commercialization
- Improve farmer access to diverse, high quality seed varieties
- Allow variety owners the option to try new geographical markets with relatively low upfront risk
- Provide possible source of funding for public research institutions and breeders
- The specific **terms**, or parts, of the licensing agreement will vary depending on the international, regional, and national legal frameworks applicable.
- The relevant legal/regulatory framework will:
  - Impact the strategies the licensor/licensee chooses to protect the variety
  - Apply in the event of a dispute or breach of rights



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# IP Licensing – Elements of a Licensing Agreement

- ❑ Definitions (Parties, Terms, etc.)
- ❑ **License Type/Exclusivity**
- ❑ **Territory/Scope**
- ❑ **Compensation/Royalties**
- ❑ **Termination and Dispute Resolution**
- ❑ **Other Considerations**
  - ❑ Sublicensing
  - ❑ Reporting
  - ❑ Flexible Clauses (e.g., smallholder-friendly clauses)
  - ❑ Compulsory Licensing



# Licensing in India

- Under the PVVFA Act, upon the registration of a variety (other than an essentially derived variety), the Registrar shall issue to the applicant a certificate of registration, which confers an **exclusive right** on the **breeder or his successor, his agent or licensee**, to **produce, sell, market, distribute, import or export** the variety
- A breeder may **authorize any person** to produce, sell, market or otherwise deal with the variety registered under the PVVFA Act subject to such limitations and conditions as may be specified by regulations.
- Where an agent or a licensee becomes entitled to produce, sell, market, distribute, import or export a variety, **he shall register his title** with the Registrar, Such an agent or licensee of a right to a variety shall be entitled **to call upon the breeder or his successor thereof to take proceedings to prevent infringement** and if the breeder or his successor refuses or neglects to do so within three months after being so called upon, institute proceedings for infringement in his own name.
- **Compulsory Licensing:** Under the PVVFA Act, Farmers have the right to access seed of registered varieties at a reasonable and remunerative price. When this condition is not met, the breeder's exclusive right over the variety is suspended under the provision concerning compulsory licensing, and the breeder is obligated to license the seed production, distribution and sales of the variety to a competent legal entity. Most of the laws for plant variety protection have provisions on compulsory licensing of protected varieties to ensure adequate seed supply to farmers, and several of them also use unfair pricing as grounds for compulsory licensing.

# Case Study – KALRO and Kisima Farms

- Agreement to license potato seeds in Kenya
  - National research institute (KALRO) had been doing licensing agreements for years, but with no royalties
  - KALRO wanted to find a way to **get its research out onto the market**, while also increasing **access to quality seed**
  - Seed company wanted to make the **latest variety of seeds available to its customers**
  - **Solution: Non-exclusive license with royalties and smallholder-friendly provisions**
- **Takeaway:** Well-designed licensing agreements can help public breeders and research institutions generate needed revenue through royalties, while holding true to public purpose and expanding access to seed



# NML Next Steps in PVP/PBR

- Develop set of regulatory tools focused on PVP laws across jurisdictions to compare and benchmark against good practices
- Assess different models for licensing agreements and collection of royalties and their use in different markets
- NML is currently looking for interesting case studies commercially neglected crops and how PVP or licensing agreements could be used to make these crops more commercial, please reach out if you have any ideas.

# Contact Us

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