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S34D Ethiopia

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The U.S. Government's Global Hunger & Food Security Initiative

FEED THE FUTURE GLOBAL SUPPORTING SEED SYSTEMS FOR DEVELOPMENT – S34D

Development and Comparison of Seed Regulatory Systems Maps in Ethiopia

January 2022

DEVELOPMENT AND COMPARISON OF SEED REGULATORY SYSTEMS MAPS IN ETHIOPIA

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PARTNERS OF THIS STUDY



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AGENDA OF THIS WORKSHOP

- Welcome and Opening Remarks (USAID Ethiopia)
- Update on Seed Sector Development in Ethiopia (Director General Ato Girma Bekele)
- Introduction and Objectives of the Study and Today's Workshop (Dr. Bhramar Dey)
- Regulatory System Maps (RSMs) Tool and Methodology (Prof. Katrin Kuhlmann)
- Approach to Stakeholder Consultations (Dr. Mulugetta Mekuria)
- Overview of Key Findings under RSMs (Prof. Katrin Kuhlmann)
- Matrix of Measurements (Dr. Bhramar Dey)
- Use Cases/Feedback on RSMs (Representatives from Public and Private Sectors)
- Conclusions and Next Steps (Dr. Bhramar Dey/Prof. Katrin Kuhlmann)
- Q&A (All)

OBJECTIVES OF THE ACTIVITY AND WORKSHOP

Objective of the Activity:

- Document the processes and procedures contained in the current seed legal and regulatory system
- Compare with the changes contemplated under the Draft Seed Proclamation to raise awareness of current and proposed legal and regulatory system and highlight important gaps and bottlenecks.
- Provide guidance to track progress/dynamics in the seed sector

Objectives of Today's Workshop:

- Disseminate key findings from the Activity
- Hear from national stakeholders on use-case value of RSMs
- Collect feedback

WHAT ARE REGULATORY SYSTEMS MAPS?

- RSMs are visual tools that depict, step-by-step, the systems, processes, and procedures underlying a specific legal and regulatory domain.
- RSMs function as analytical instruments to highlight gaps, challenges (including with implementation), intervention points, proposed legal and regulatory changes, and systemic shifts over time ("Regulatory Gateways", NML 2019); Regulatory Gateways also provide entry points for making law more inclusive, equitable, and flexible (Kuhlmann 2022 & Kuhlmann & Dey 2021).
- Thus, RSMs serve as one of the regulatory tools that could potentially raise awareness about policies, laws, and regulations that govern a regulatory domain and increase transparency of systems and processes amongst stakeholders.
- RSMs were developed by the New Markets Lab in 2016 and have been adapted under the current S34D Activity with CRS to encompass additional dimensions (such as gender, cost, and links to forms).

METHODOLOGY

Review of Current and Proposed Ethiopian Seed Laws and Regulations

1

- Comprehensive assessment of the relevant laws and regulations set out in Table 2.
- *This helped identify the strengths and weaknesses of existing laws and regulations, highlighting possible areas of improvement using the RSMs.*

- Virtual and in-person consultations with stakeholder (see Annex I) held in Addis Ababa.
- *Stakeholders' consultations and validation reinforced findings from the legal and regulatory assessment and highlighted issues that were not apparent from a review of the laws and regulations themselves.*

2

Stakeholders' Consultations

Draft and Develop Side by Side RSMs

3

- Produced an initial set of six RSMs. *Maps integrate bottlenecks and challenges stakeholders are facing along the six study dimensions.*
- Developed a second set of RSMs focused on the new proposed laws and regulations. *This added a comparative element to the Activity and highlights changes or improvements to the system.*

- The RSMs were validated by stakeholders at a virtual session on November 10, 2021.
- *The validation confirmed information in the RSMs and highlighted additional aspects and priorities.*

4

Validation Workshop

ENGAGEMENT & STAKEHOLDER CONSULTATIONS

- Consultation tools included questionnaires tailored to the different stakeholders and focused on the key dimensions.
- Private stakeholders consulted included seven local seed companies and dealers, two multinational seed companies, two nongovernmental organizations, one international development agency, and the Ethiopian Seed Association.
- Eleven public sector stakeholders were consulted from the Ministry of Agriculture (MoA), the Regional Bureaus of Agriculture (RBoA), the Ethiopia Seed Enterprises (national and regional), the Ethiopian Institute of Agricultural Research (EIAR), Regional Agricultural Research Institutes (RARI), and the Agricultural Transformation Agency (ATA).

OVERVIEW OF APPROACH

- **Six regulatory dimensions:** (1) Public varietal research, development, and transfer; (2) Seed dealer and venue registration (certificate of competence); (3) Seed variety registration and release; (4) Plant variety protection (PVP) or plant breeder's rights (PBR); (5) Seed certification and quality assurance; and (6) Anti-counterfeiting and consumer protection.
- **Two comparative RSMs for each dimension:**
 - One set focused on the seed regulatory system as it currently exists and is implemented
 - A second set focused on depicting the new rules and procedures that are currently under development (twelve maps in total)
- **Inclusivity and flexibility focus across current and proposed dimensions**
 - Study focuses on aspects of seed laws and regulations that incorporate flexibility and inclusivity. For example, this includes provisions and processes that integrate small farmers, women, private sector enterprises of all sizes, and public research organizations. (See Kuhlmann 2022 & Kuhlmann & Dey 2021)

Seed Regulatory Value Chain

International/ Regional



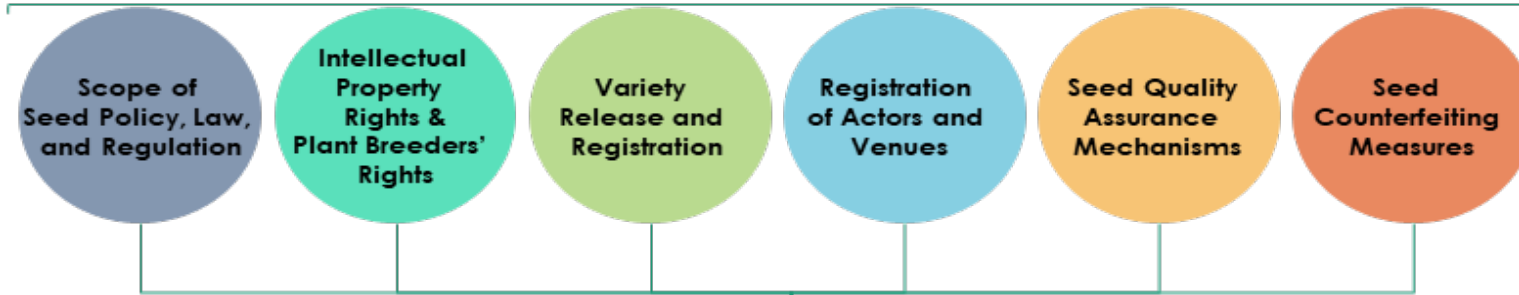
National



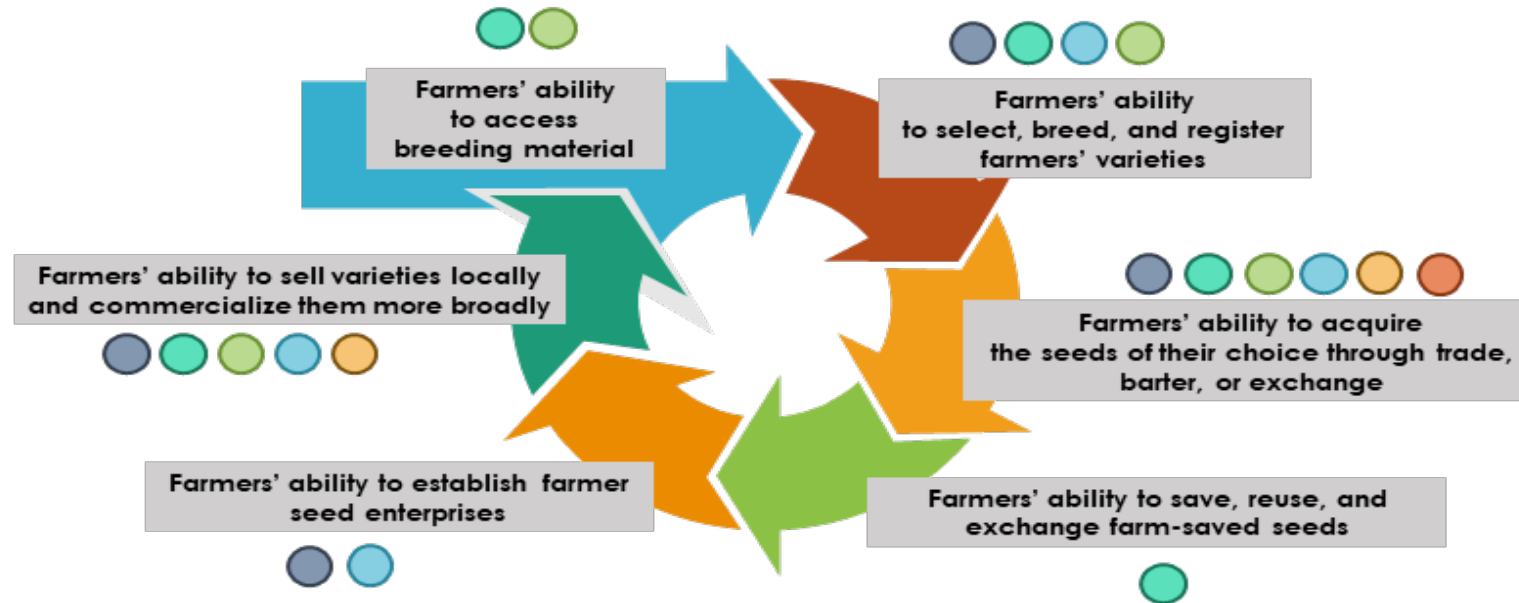
KEY ELEMENTS OF THE STUDY

- **The study highlights four key “dynamic” elements (with inclusivity and flexibility a focus across):**
 - Aspects/steps that are changing with the new Draft Seed Proclamation
 - Aspects/steps that changed with the new 2020 Seed Policy, but are not yet operational
 - Areas that require more detailed regulations, directives, guidelines to become operational
 - Areas written into law or regulation differs from stakeholder experience in practice

Regulatory Elements



How they bridge the gap between the formal and informal sectors



Kukhlmann & Dey (Agronomy, 2021)

Dimension: Varietal Research, Development, and Transfer

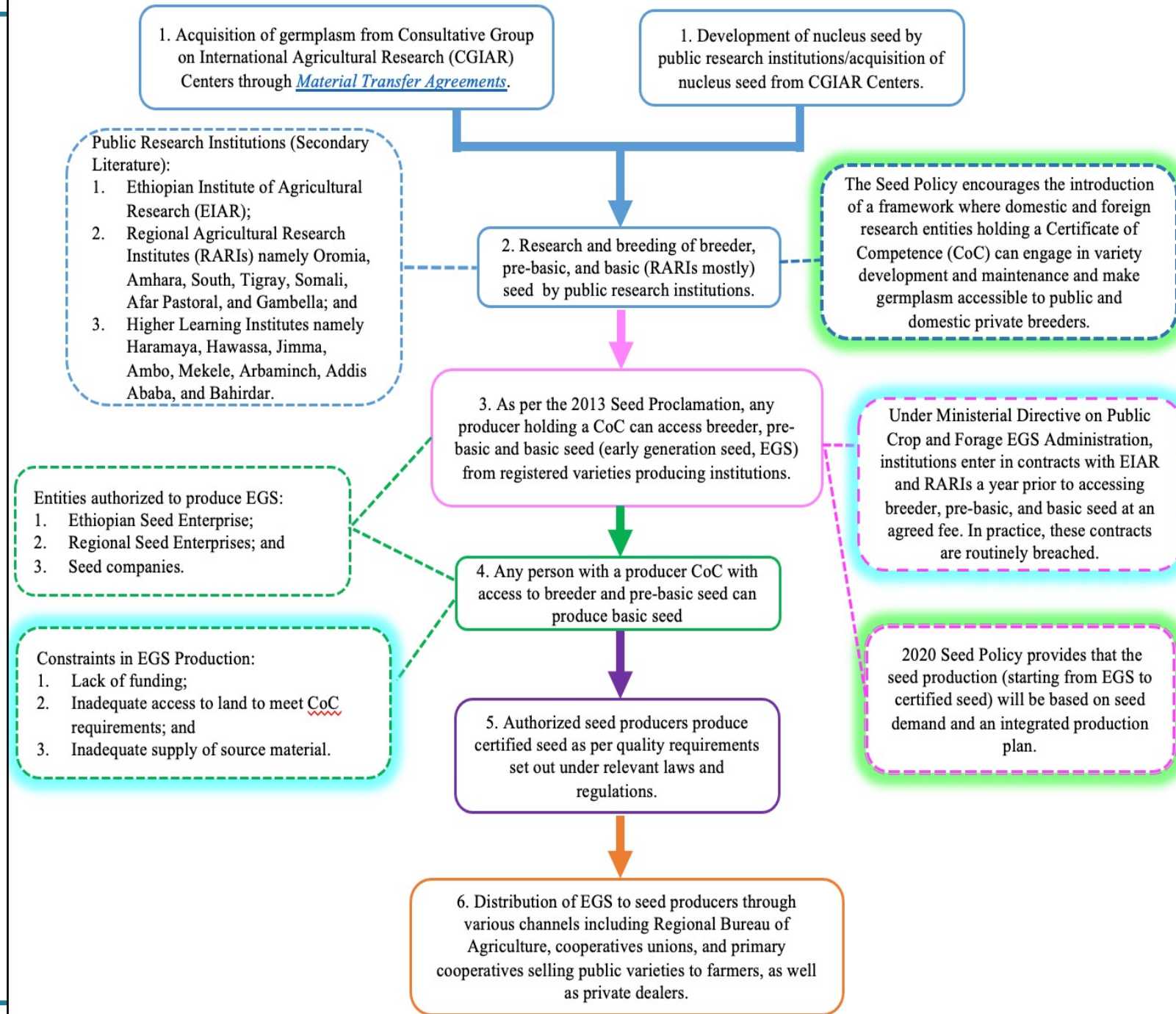
VARIETAL RESEARCH, DEVELOPMENT, AND TRANSFER

- For varietal research, development, and transfer, and the RSMs cover the following regulatory aspects: (a) genetic material or variety acquisition, development and research; (b) production of breeder, pre-basic, and basic seed (early generation seed); (c) production of certified seed; and (d) Early Generation Seed (EGS) distribution.
- Among these, engaging in varietal development and EGS production and distribution of EGS are particularly notable.

RSM: Varietal Research, Development, and Transfer in Ethiopia (Current System)

Key

- Varietal Research and Development
- Production of EGS
- Production of Certified Seed
- Distribution
- Notes
- Changes in 2020 Seed Policy that require further legal measures
- Stakeholder experience differs from law



KEY FINDINGS: CURRENT SYSTEM

Activity identified several implementation challenges in the legal framework for Varietal Research, Development, and Transfer in Ethiopia, as highlighted in the RSMs:

- Private seed companies do not engage directly in breeding, mainly because of challenges in accessing land and the lengthy processes in practice for obtaining an import permit for parent material (see blue shaded box attached to Step 4 in the RSM on the Current System).
- Unavailability of EGS is also an issue (see blue shaded box linked with Step 3 in both RSMs showing that practice does not match law). Reasons include (i) Public Research Institutions (PRIs) lack capacity and resources; (ii) Priority in EGS distribution given to Ethiopian Seed Enterprise (ESE) and farmer groups over private companies; and (iii) RBoAs interfere with setting price of seed.
- Absence of Legal Framework on Certificate of Competence for Varietal Research and Development.
- Absence of Flexibilities on Certificate of Competence Requirement for Small Seed Producers. Stringent producer CoC requirements effectively keep smallholder farmers operating within the informal sector.

KEY FINDINGS: PROPOSED SYSTEM

- Two important changes are proposed to increase the engagement of the private sector in varietal research, development and transfer:
 - A CoC on Variety Development & Research (Seed Policy 2020); however, no such CoC is provided in Draft Seed Proclamation
 - A CoC on pre-basic seed multiplication (Draft Seed Proclamation)
- Proposed institutional licensing framework to address EGS bottlenecks:
 - Framework awaiting ministerial approval that will allow for licensing of public varieties and sharing of genetic material.
 - Licensing is linked with other regulatory dimensions, such as PBR (PBR Proclamation and Directive), which enhances the legal effectiveness of licensing frameworks. However, regulations under the PBR Proclamation are not yet in place, which makes the PBR regulatory framework incomplete. Private sector stakeholders seem to be unaware that the PBR Directive had been passed.

RSM: Varietal Research, Development, and Transfer in Ethiopia (Proposed System)

Key

■ Varietal Research and Development

■ Production of EGS

■ Production of Certified Seed

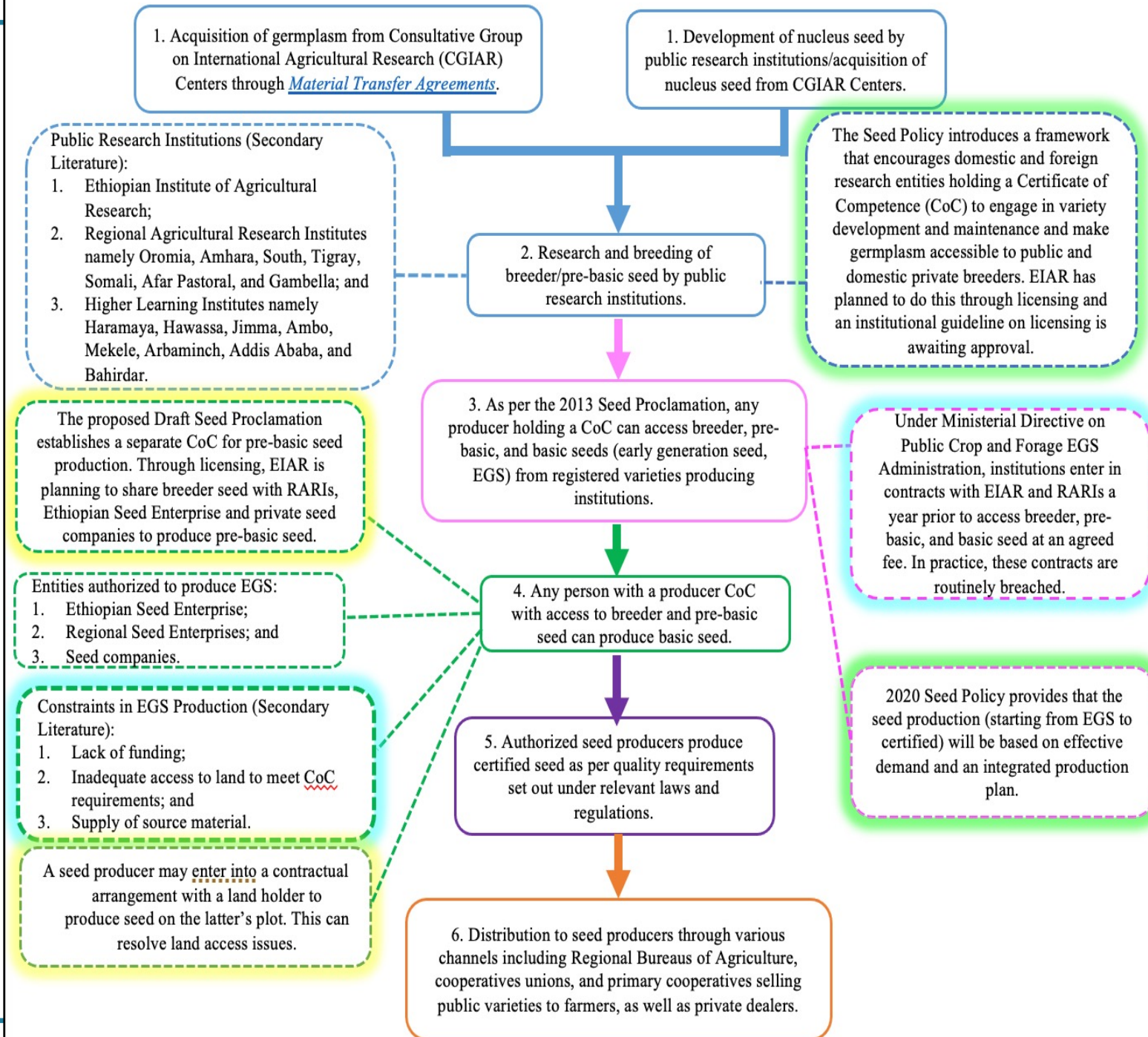
■ Distribution

--- Notes

--- Change proposed in new Draft Seed Proclamation

--- Changes in 2020 Seed Policy that require further legal measures

--- Stakeholder experience differs from law



Dimension: Seed Variety Registration and Release Process

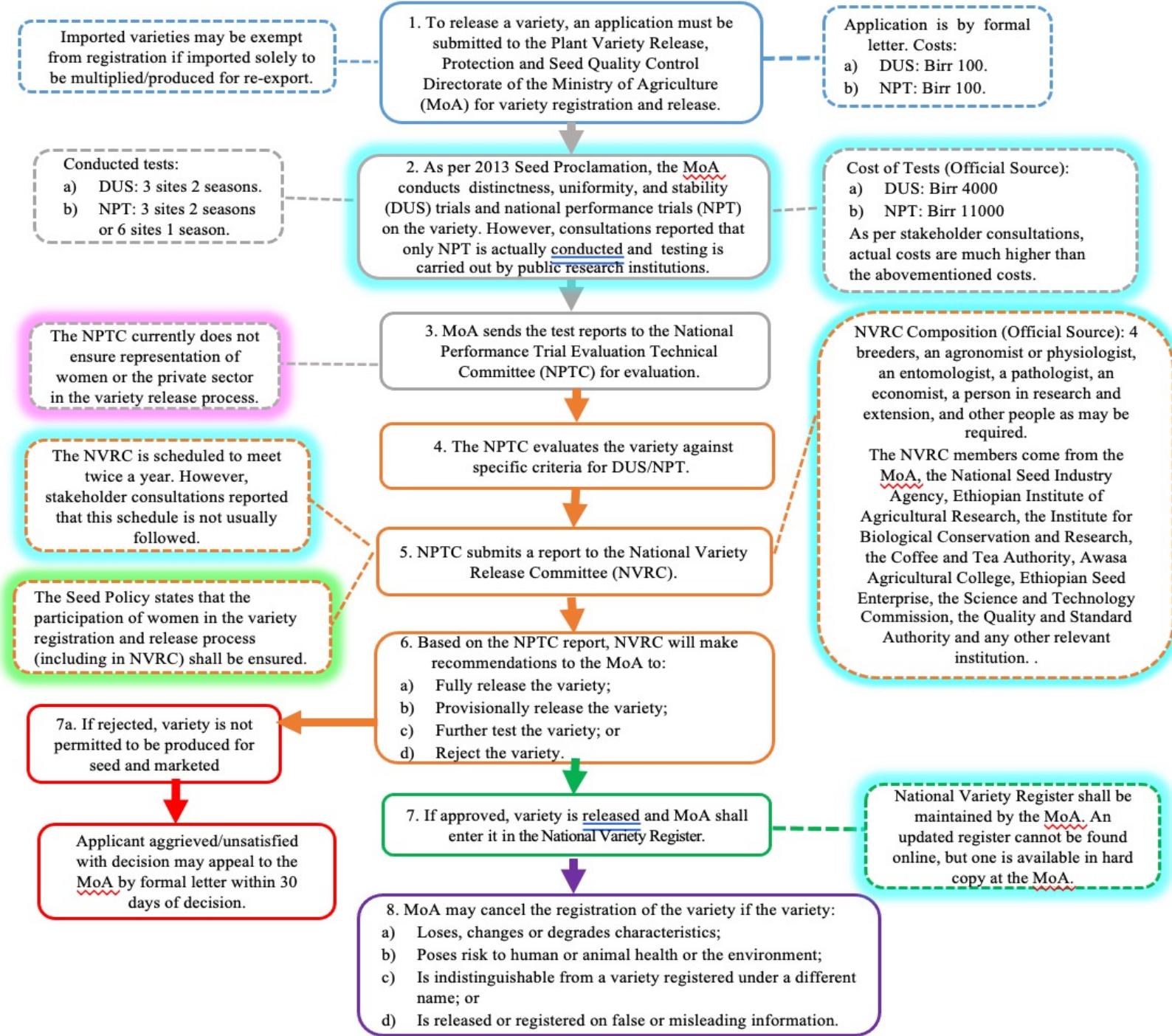
SEED VARIETY REGISTRATION AND RELEASE PROCESS

- The RSMs cover the following regulatory aspects: (a) application for variety release and registration; (b) testing of new varieties; (c) evaluation by regulatory authorities/committees; and (d) regulatory determination and post determination actions.
- In particular, the testing and evaluation stages contain important gaps and ambiguities.

RSM: Seed Variety Registration and Release Process in Ethiopia (Current System)

Key

- Application
- Testing
- Evaluation
- Regulatory determination
- Post Determination
- Notes
- Changes in 2020 Seed Policy that require further legal measures
- Stakeholder experience differs from law
- Areas require further detailed regulations, directives, or guidelines



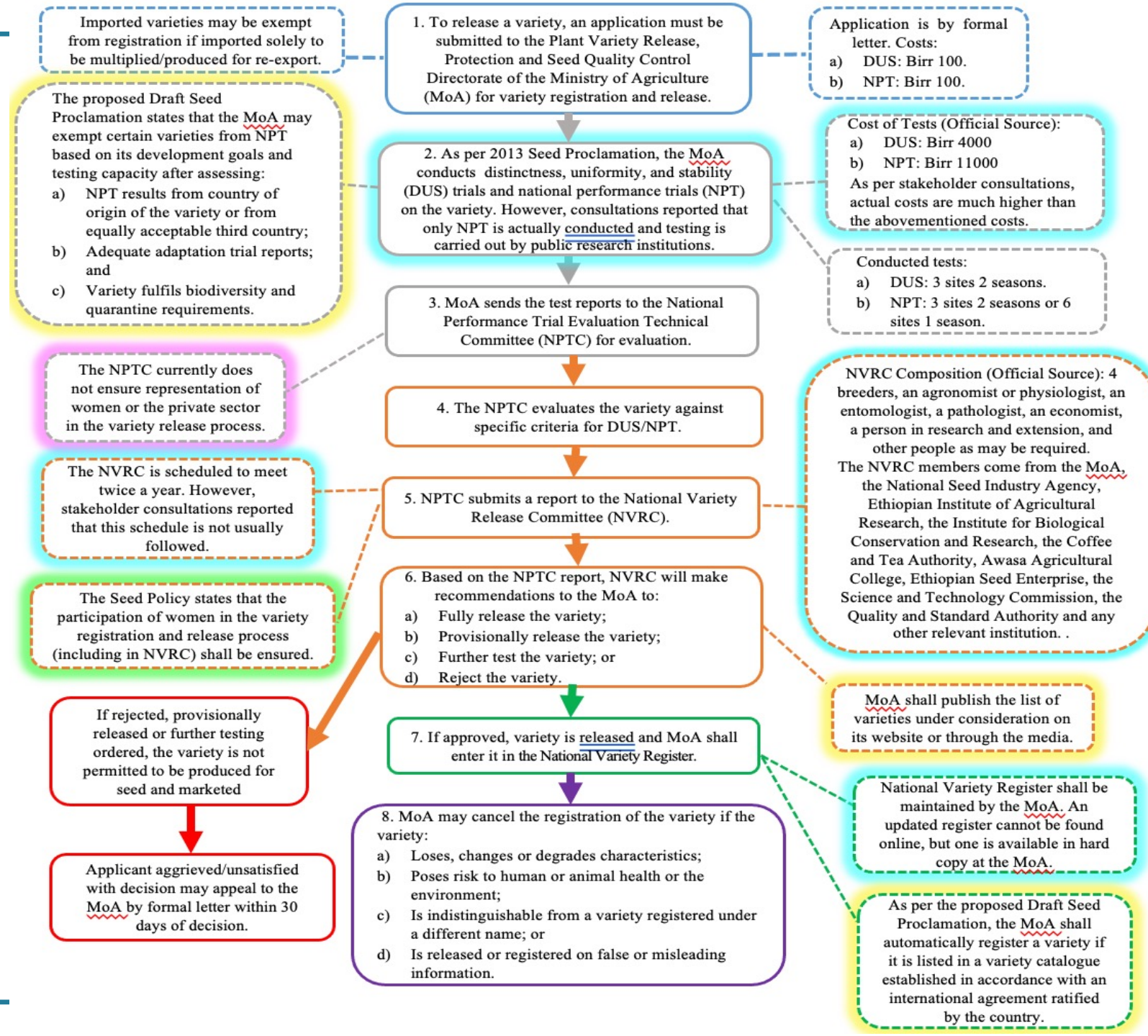
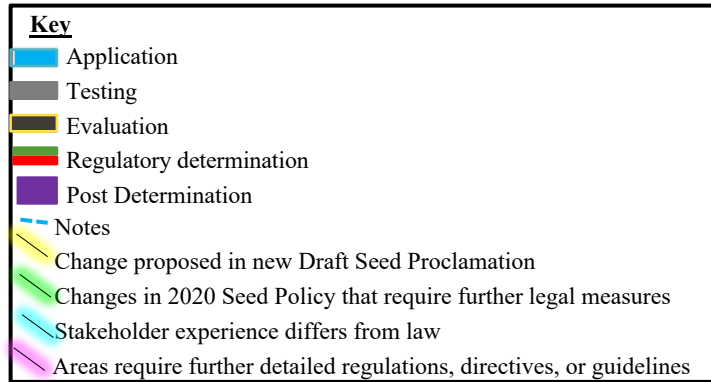
KEY FINDINGS : CURRENT SYSTEM

- Despite a requirement that MoA conduct both DUS and NPT testing, only NPT testing is reportedly done in practice (see blue shaded box attached to Step 2 in the RSM on the Current System).
 - NPT testing is conducted by public research institutions and not MoA as required.
 - Fees charged for variety evaluation are contrary to those in the Service Fee Regulation (and much higher) (see blue comment box off step 2 in the RSM on Current System).
- DUS protocols are absent, which is one reason that DUS testing is not conducted (this difference in stakeholder experience is noted by the shaded box, Step 2 in the RSM on the Current System).
- Women and farmers are not well represented on the National Variety Release Committee (NVRC), even though the 2020 Seed Policy calls for greater gender representation (see green comment box off step 5 in the RSM on the proposed System).

KEY FINDINGS : PROPOSED SYSTEM

- Draft Seed Proclamation calls for the creation of an independent entity responsible for variety registration and release (see yellow comment box attached to Step 2 in the RSM)
- System could be made more inclusive by expanding women's and farmers' representation on the NVRC (2020 Seed Policy) - by revising the Draft Seed Proclamation and/or Variety Release Policy and Mechanism Manual, 2001
- Simplify and streamline the process for variety release and registration:
 - Approval of DUS protocols for wheat and barley and development of DUS Protocols for other crops;
 - Revision of the Service Fee Regulation (include appropriate fees involved in the variety registration process, including DUS and VCU testing); and
 - Revision of the Draft Seed Proclamation to align with regional seed rules (COMESA Seed Trade Harmonisation Regulations) by defining “prioritized development goals”

RSM: Seed Variety Registration and Release Process in Ethiopia (Proposed System)



Dimension: Quality Assurance Process

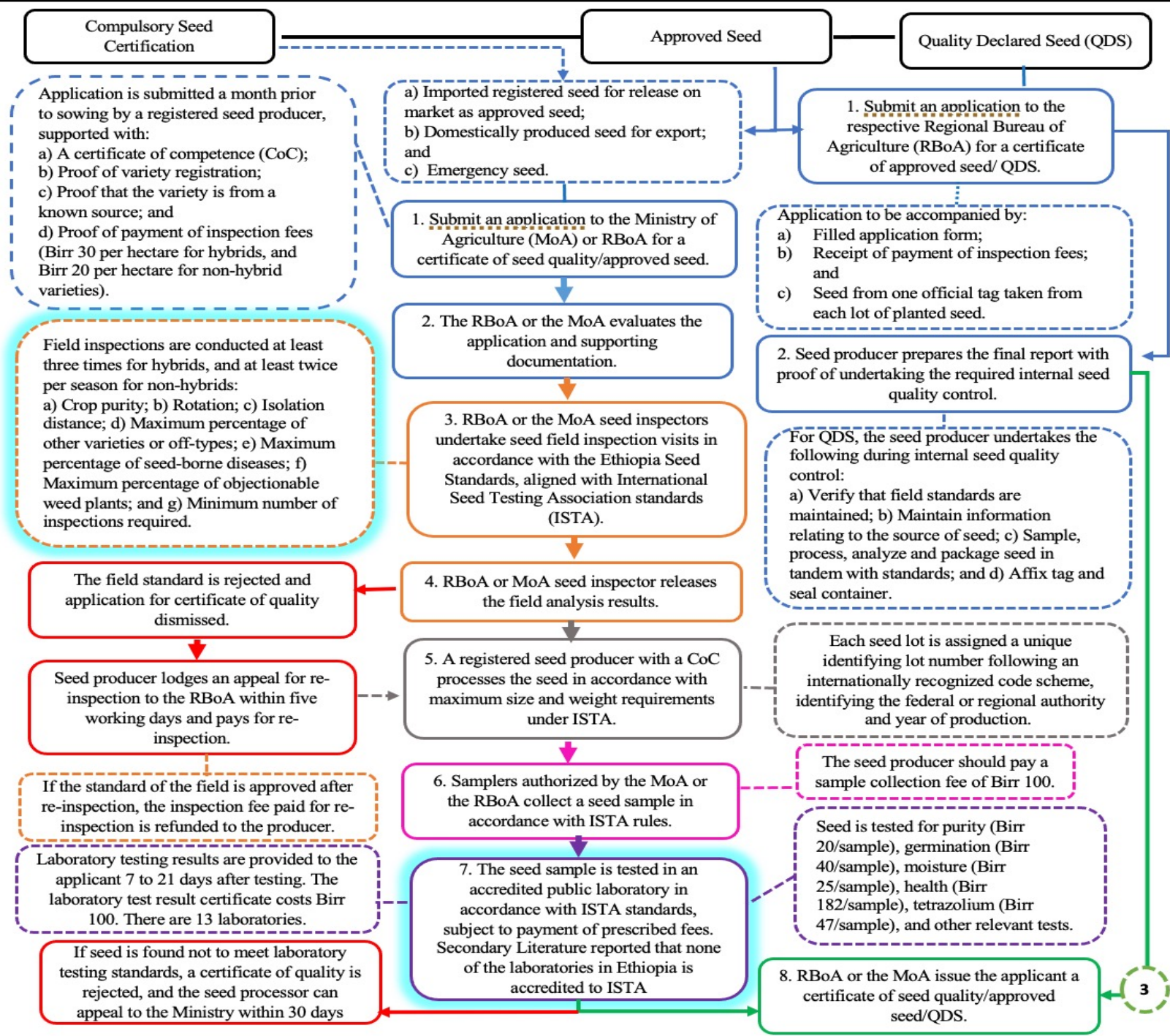
QUALITY ASSURANCE PROCESS

- The RSMs cover the following regulatory aspects: (a) seed quality assurance schemes; (b) application and evaluation; (c) field inspection and analysis; (d) seed processing; (e) seed sampling; (f) laboratory testing; (g) issuance of certificate of quality; and (h) rejection and appeal.
- Among these, seed quality assurance schemes, field inspection, and laboratory testing are particularly important and contain some notable gaps and ambiguities as highlighted in the RSMs.

RSM: Seed Quality Assurance Process in Ethiopia (Current System)

Key:

- Seed Quality Assurance Schemes
- Application and Evaluation
- Field Inspection and analysis
- Seed Processing
- Seed Sampling
- Laboratory testing
- Issuance of Certificate of Quality
- Rejections and Appeals
- Notes
- Stakeholder experience differs from law



KEY FINDINGS: CURRENT SYSTEM

- System currently carried out by public institutions, without private sector involvement. This causes delays for private seed companies and further postpones getting seed to farmers. This is an important area of focus for the Draft Seed Proclamation
- Both public and private sector stakeholders reported laboratory capacity gaps in terms of finance, human resource, and facilities (see Step 7 in the RSM on the Current System, which is shaded due to the difference in stakeholder experience).
- None of the laboratories has ISTA accreditation, which is called for under international seed testing standards and regional practices, and most laboratories at the regional level lack facilities to test additional seed quality parameters based on new protocols that address tests related to seed health, variety quality, and vigor, among other things.

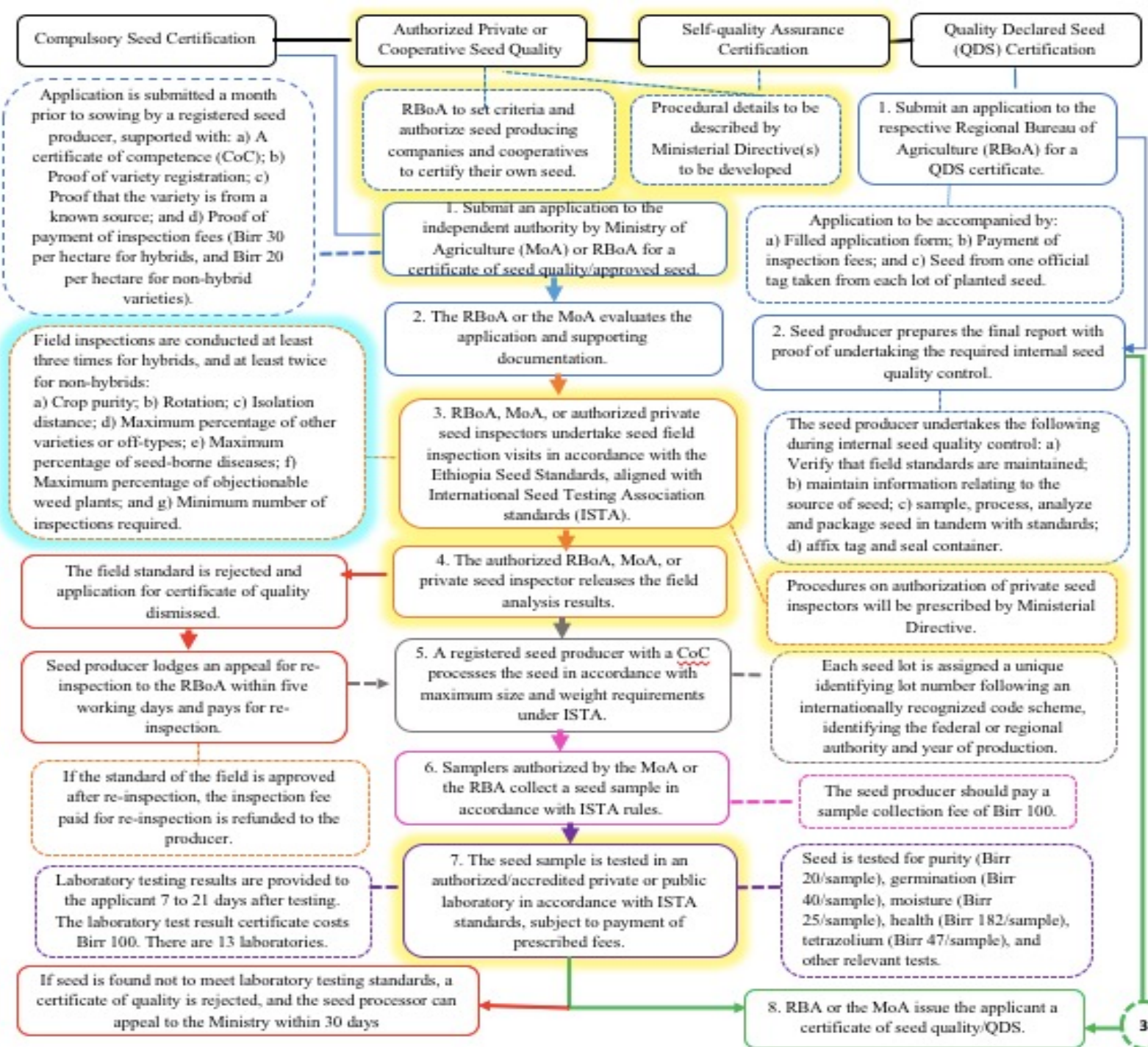
KEY FINDINGS: PROPOSED SYSTEM

- Creation of independent certifying authorities at the federal and national levels (this is depicted in Step 2 in the RSM on the Proposed System; these already exist in some regions)
- Authorization of private seed inspectors by the relevant federal and regional institutions to conduct field inspections (this is depicted in the yellow comment box attached to Step 3 in the RSM on the Proposed System)
- Authorization of private seed laboratories that meet international ISTA standards to conduct laboratory tests (this is depicted in Step 7 in the RSM on the Proposed System)
- Introduction of self-quality seed certification, with oversight by the relevant federal and regional institutions (details of this approach forthcoming in a Ministerial Directive)

RSM: Seed Quality Assurance Process in Ethiopia (Proposed System)

Key

- Application
- Testing
- Evaluation
- Regulatory determination
- Post Determination
- Notes
- Change proposed in new Draft Seed Proclamation
- Changes in 2020 Seed Policy that require further legal measures
- Stakeholder experience differs from law
- Areas require further detailed regulations, directives, or guidelines



KEY TAKEAWAYS: FOCUS ON INCLUSIVITY AND FLEXIBILITY

- We reviewed roles of farmers, women, private sector, and research organizations to assess and recommend ways in which the rules do – and could – incorporate flexibility and inclusivity
- The 2020 Seed Policy calls for greater gender representation in the NVRC, which is notable, but this is not yet operational under the law. Small farmers and farmers' associations should also be represented.
- Small farmers may have difficulty meeting CoC requirements - e.g., prior experience and education. Some countries have adopted more flexible approaches to recognize informal actors (Kuhlmann and Dey, 2021).
 - India's system is particularly noteworthy and maintains a separate registration system for small farmers and informal actors.
 - Peru exempts those engaged in the production, trade, and storage of traditional varieties from registration.

KEY TAKEAWAYS: FOCUS ON INCLUSIVITY AND FLEXIBILITY (CONTD.)

Ethiopia's rules on PBR allow for registration of farmers' varieties, but the rules confuse DUS standards with standards for Quality Declared Seed, making the flexibility inoperable.

- Ethiopia could consider something like an “identifiability test” (adopted in Malaysia) which modifies the DUS test, substituting “identifiability” for uniformity and stability and better tailoring the test to farmers' varieties (Kuhlmann and Dey, 2021).
- Use of an identifiability test could also make it easier for small farmers to register their varieties. Other countries have adopted approaches such as preferential schemes for traditional varieties or alternative seed catalogues (Kuhlmann and Dey, 2021).
- Some countries maintain more flexible approaches to PBR (e.g., India, Peru, Thailand and Vietnam) and variety registration (e.g., Peru, Brazil, and Benin).

MATRIX OF MEASUREMENTS

Dimensions	Issues	Proposed indicators
Varietal research dev and transfer	Include a CoC on variety development and research to enable private sector engagement	# of CoC issues to private sector per year; % share of applications renewed each year #of private entities commercializing production of EGS; Total amount (crop and variety disaggregated) in MT
Seed dealer registration	Seed producers contracting land holders	# of contractual arrangements made (per year – age and gender disaggregated)
Variety registration and release	Define “prioritized development goals”	Goals defined and shared with stakeholders for validation; # of stakeholders shared with; Digitized national variety register available on public domain and accessible free of cost
	To qualify for NPT exemption, an applicant seeking registration applies for an NPT waiver	# of applicants applying for and receiving the NPT waivers (gender, and age disaggregated)
	NVRC composition needs to be more inclusive and diverse	% of members that are women; youth; farmers; private sector entities #of times the NVRC convenes per year
PBR	Share PBR directive widely	#of stakeholders participated in the sensitization of the directive (age and sex disaggregated)
Seed quality assurance	Seed certification is delayed	Amount of time (in # of days) taken for seed certification (disaggregated by types of applicants)
Anti-counterfeiting	Some regional authorities have less capacity than others.	# of court cases filed; Guidelines established and shared in the public domain

FEEDBACK ON USE CASE

- How can the RSMs play a role in increasing awareness of the legal and regulatory system?
- How could the RSMs help facilitate engagement in legal and regulatory processes central to development of the seed system?
- Do you think digitization of the maps can raise awareness amongst all stakeholders and increase transparency?
- Other comments?

PRIORITIZATION OF GOALS

- **Short Term – Focus on “Gateway” Changes via Instruments in Draft (Including Seed Proclamation) or Directives:**
 - Establish CoC on Variety Development and Research to enable the private sector to more fully engage in EGS and align with the 2020 Seed Policy
 - Support licensing of public varieties by PRIs and move forward with Ministerial Directive on licensing of public varieties and corresponding guidelines to improve EGS
 - Clarify important issues related to DUS testing (DUS protocols and delink from QDS)
 - Formally include women in NVRC and incorporate flexible requirements for smallholder farmers to obtain a CoC to ensure their inclusion in the formal sector
- **Medium Term – Modify Other Legal/Regulatory Instruments:**
 - Simplify process for variety registration and release and PBR, with focus on inclusivity, through changes to related legal instruments
- **Long Term – Align with Regional Developments Underway:**
 - Revision of 2016 Seed Regulations to align with COMESA seed labels and seed classes

CONCLUDING REMARKS

- **Financial and operational planning and accountability** to execute many of the changes proposed in the new seed rules. For example, a new institutional structure has been proposed (Agricultural Inputs Regulatory Formation Authority) that will require dedicated resources and budgetary allocation, as will institutions like the NVRC. An M&E framework will also be important.
- **Flexibility and inclusivity in the rules** will be important for addressing the needs of small farmers, the private sector, and women and youth to make it a more pluralistic and inclusive seed sector.
- Legal and regulatory change can be an ambitious and costly undertaking, and it will be important to **prioritize short-, medium-, and long-term goals**.
- **Good practices from other countries** (like those highlighted in legal and regulatory takeaways), provide important options and would enhance Ethiopia's existing good practices.
- Given the different initiatives focused on Ethiopia's seed systems, **sectoral coordination and co-location** critical to raising awareness, engaging stakeholders, and building capacity as rules, institutions, and system overall evolve.

SPEAKER BIOS



Prof. Katrin Kuhlmann is President and Founder of the New Markets Lab and a Visiting Professor at Georgetown University Law Center. Her areas of expertise include law and development, comparative economic law, agricultural regulation and trade corridors, regional trade harmonization, and international trade and development. Professor Kuhlmann is also a Senior Associate with the Global Food Security Project of the Center for Strategic and International Studies (CSIS) and a member of the Trade Advisory Committee on Africa at the Office of the U.S. Trade Representative (USTR). Previously, she was a Lecturer on Law at Harvard Law School; Senior Fellow and Director at the Aspen Institute; Director at USTR; and international lawyer in private practice. J.D. Harvard Law School; BA Creighton University; Fulbright Scholar 1992.



Dr. Bhramar Dey (Senior Technical Advisor, S34D CRS) brings a unique blend of project design, management, and analytical skills focusing on country-led interventions (often through negotiations with governments) in data, policy, monitoring and evaluation, and agricultural input systems. She has over 18 years of experience in data and regulatory reform analyses, and designing, managing large client and stakeholder-oriented projects. Prior to joining CRS, Dr. Dey worked at the Bill and Melinda Gates Foundation (BMGF) - Agriculture initiative. Passionate about turning data into information, Dr. Dey focuses on institution strengthening, and bridging gaps between evidence and impact. Bhramar holds a Ph.D. in Applied Economics from Clark University.



Dr. Mulugetta Mekuria is an Ph.D. scholar in Agricultural Economics from Michigan State University and an international consultant specializing in African agricultural research and development. Dr Mulugetta contributed to the advancement of farming system research in Ethiopia as head of EIAR's Department of Agricultural Economics and Farming system Research. He was Professor, Head of Department of Agricultural Economics and Deputy Dean of Faculty of Agriculture of the University of the North, South Africa. He worked at CIMMYT for more than 20 years where he was Regional Representative and Head of the Diplomatic Mission for CIMMYT Southern Africa Regional Office based in Harare, Zimbabwe. Mulugetta was CIMMYT's Program Leader for the Sustainable Intensification of Maize-Legume Cropping Systems for Food Security in Eastern and Southern Africa.

THANK YOU!

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