



# FEED THE FUTURE

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



## DEVELOPMENT AND COMPARISON OF SEED REGULATORY SYSTEMS MAPS IN ETHIOPIA



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**Author's names:** Katrin Kuhlmann, Bhramar Dey, Mulugetta Mekuria, Adron Naggayi Nalinya, and Tara Francis

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**Technical office:** USAID/RFS/CA

**AOR name:** Daniel Bailey

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**Submitted by:** Nikaj van Wees, Chief of Party S34D activity  
Catholic Relief Services  
228 West Lexington Street, Baltimore, MD 21201  
Nikaj.vanwees@crs.org

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**Feed the Future Consortium Partners** in the Feed the Future Global Supporting Seed Systems for Development activity:



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## Acronyms and Abbreviations

<b>ATA</b>	Agricultural Transformation Agency
<b>CGIAR</b>	Consultative Group on International Agricultural Research
<b>CoC</b>	Certificate of Competence
<b>COMESA</b>	Common Market for Eastern and Southern Africa
<b>CRS</b>	Catholic Relief Services
<b>DUS</b>	Distinctness, Uniformity, and Stability
<b>EGS</b>	Early Generation Seed
<b>EIAR</b>	Ethiopian Institute for Agricultural Research
<b>ESE</b>	Ethiopian Seed Enterprise
<b>ISTA</b>	International Seed Testing Association
<b>MoA</b>	Ministry of Agriculture
<b>MTA</b>	Material Transfer Agreement
<b>NGO</b>	Non-Governmental Organization
<b>NML</b>	New Markets Lab
<b>NPT</b>	National Performance Trial
<b>NPTC</b>	National Performance Trial Evaluation Technical Committee
<b>NVRC</b>	National Variety Release Committee
<b>OECD</b>	Organization for Economic Co-operation and Development
<b>PBR</b>	Plant Breeders' Right
<b>PRI</b>	Public Research Institution
<b>PVP</b>	Plant Variety Protection
<b>QDS</b>	Quality Declared Seed
<b>RARI</b>	Regional Agricultural Research Institutes
<b>RBoA</b>	Regional Bureaus of Agriculture
<b>RSE</b>	Regional Seed Enterprises
<b>RSM</b>	Regulatory Systems Map
<b>S34D</b>	Feed the Future Global Supporting Seed Systems for Development
<b>SMTA</b>	Standard Material Transfer Agreement
<b>SNNPR</b>	Southern Nations, Nationalities and People's Region
<b>UPOV</b>	International Union for the Protection of New Varieties of Plants
<b>USAID</b>	United States Agency for International Development
<b>VCU</b>	Value for Cultivation and Use

## Executive Summary

Under the Feed the Future Global Supporting Seed Systems for Development (S34D) activity (hereinafter referred to as the “Activity”), NML and CRS collaborated to assess progress and dynamics in Ethiopia’s seed system by documenting the processes and procedures contained in Ethiopia’s current and proposed seed legal and regulatory systems. The objective was to compare current laws, regulations, policies, and directives with the changes contemplated under the Draft Seed Proclamation and other instruments, highlighting important changes and gaps, and building upon efforts by the Government of Ethiopia. This assessment contains the results of this comparative mapping of rules and regulations along six key dimensions of the seed systems regulatory value chain: (1) public varietal research, development, and transfer; (2) seed dealer and venue registration or certificate of competence (CoC); (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 (hereinafter referred together as “Key Regulatory Dimensions”; see **Figure 1**).

**Figure 1: Six Key Regulatory Dimensions of the Ethiopian Seed Value Chain Assessed under the Activity**



This assessment is particularly timely, as Ethiopia is currently in the process of making significant changes to its legal and regulatory framework for seed systems. A new seed policy was issued in February 2020 (2020 Seed Policy), and the 2013 Seed Proclamation No.782/2013 (2013 Seed Proclamation) is undergoing revision, with a Draft Seed Proclamation developed in 2018 that is reportedly at an advanced stage of enactment.

The current assessment also allows for establishment of a baseline scenario to measure any potential impact of the new laws under consideration. As the primary comparative tool, the assessment focused on development of Regulatory Systems Maps (RSMs), a legal and regulatory tool developed by NML in 2015, that visually depict regulatory systems, processes, procedures and their implementation in a step-by-step manner, highlighting gaps, bottlenecks, and good practices found in law and practice.<sup>1</sup> RSMs function as analytical instruments to highlight gaps, challenges (including with implementation), intervention points, proposed legal and regulatory changes, and systemic shifts over time.<sup>2</sup> Thus,

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<sup>1</sup> See Katrin Kuhlmann, “Mapping Inclusive Law and Regulation: A Comparative Agenda for Trade and Development”, 2 *African Journal of International Economic Law* (forthcoming), available at [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3912907](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3912907)

<sup>2</sup> *Id.*

RSMs serve as a regulatory tool that could raise awareness about policies, laws, and regulations that govern a regulatory domain and increase transparency of systems and processes amongst stakeholders. The current partnership between NML and CRS enhanced these RSMs further and provides indicative metrics to measure systemic progress over time. Furthermore, the RSMs were adapted and enhanced to encompass additional dimensions, including gender, cost, and links to forms.

Under this Activity, NML and CRS developed two sets of RSMs for each of the six key regulatory dimensions, providing a visual representation of the changes underway in Ethiopia's legal and regulatory system. For each Key Regulatory Dimension two comparative RSMs were created: (i) a set focused on the seed regulatory system as it *currently exists* and is implemented in practice (based on legal assessment and stakeholder consultations), and (ii) a set focused on the *new rules and procedures* that are currently under development.

In particular, the assessment focused on how the current and proposed legal and regulatory system could incorporate inclusion and flexibility, especially with regard to the needs of smallholder farmers.<sup>3</sup> Across RSMs, four dynamic elements are highlighted to illustrate intervention points for inclusion and flexibility, changes underway, and decision points public and private stakeholders should consider:

- ***Aspects/steps that are changing with the new law (Draft Seed Proclamation)*** to improve stakeholder awareness of the new processes and procedures being introduced under each Key Regulatory Dimension (these important changes are depicted in yellow shading in the RSMs).
- ***Aspects/steps that changed with the new 2020 Seed Policy but are not yet operational*** to highlight the gaps observed in implementation of the 2020 Seed Policy, some of which are expected to be addressed through the Draft Seed Proclamation (these changes are depicted in green shading in the RSMs).
- ***Areas that require more detailed regulations, directives, guidelines, etc. to become operational*** given that some of the processes set out under relevant seed laws and regulations are unclear (these gaps are depicted in pink shading in the RSMs).
- ***Areas in which what is written into law or regulation differs from stakeholder experience in practice*** to call to attention the challenges faced by stakeholders in complying with regulatory processes set out under seed laws (these discrepancies are depicted in blue shading in the RSMs).

Consultations on the ground were held with an array of stakeholders spanning across both public and private sectors to gather, compile data, and validate information (See Annex I for a list of stakeholders

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<sup>3</sup> See Kuhlmann & Bhramar Dey, *Using Regulatory Flexibility to Address Market Informality in Seed Systems: A Global Study*, 11 AGRONOMY 1, 16 (2021), <https://www.mdpi.com/2073-4395/11/2/377>. See also, Kuhlmann, *supra* note 1.

consulted). A validation workshop was held in November 2021 and a final dissemination through a global webinar was undertaken in January 2022. During these two webinars, stakeholders identified and validated a number of recommendations on policy, legal, and regulatory interventions that could be considered to streamline the legal and regulatory system along the seed value chain. These are summarized below and elaborated upon in **Table 1**. These recommendations are divided into short, medium and long-term to help prioritize interventions.

**Short Term Recommendations – 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 Early Generation Seed (EGS) and align with the 2020 Seed Policy
- Support licensing of public varieties by Public Research Institutions (PRIs) and move forward with Ministerial Directive on licensing of public varieties and corresponding guidelines to improve EGS
- Clarify important issues related to Distinctness Uniformity and Stability (DUS) testing (DUS protocols and delink from Quality Declared Seed (QDS))
- Formally include women in National Variety Release Committee (NVRC) and incorporate flexible requirements for smallholder farmers to obtain a CoC to ensure their inclusion in the formal sector

**Medium Term Recommendations – 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 Recommendations– Align with Regional Developments Underway:**

- Revision of Council of Ministers Seed Regulation No.375/2016 (2016 Seed Regulations) to align with Common Market for Eastern and Southern Africa (COMESA) seed labels and seed classes.

**Table 1: Summary of Existing Issues, Relevant Legal Provisions, Changes Introduced, Constraints, and Recommendations**

Existing Issue(s)	Existing Provisions	Draft Instruments	Challenges & Constraints	Possible Next Steps
<b>Dimension 1: Varietal Research, Development and Transfer</b>				
<p>Lack of private sector engagement in variety acquisition, development, and research and production of EGS.</p> <p>PRIs are under capacitated, and resource constrained. There are issues of funding and land access to produce EGS.</p>	<p>Agricultural and Rural Development Policy of 1994 vests varietal research and development in the PRIs.</p> <p>Under Proclamation No. 79/1997 establishing the Ethiopian Agricultural Research Organization, PRIs are mandated with conducting agricultural research and development.</p> <p>The 2020 Seed Policy sets out that the government will “Introduce a framework that encourages domestic and foreign research entities holding a CoC to engage in</p>	<p>The proposed Draft Seed Proclamation establishes a separate CoC for pre-basic seed production to improve private sector involvement.</p> <p>Under the Draft Seed Proclamation, a seed producer may enter into a contractual arrangement with a land holder to produce seed on landowner’s plot.</p>	<p>The 2020 Seed Policy will not be considered a national instrument until the revised Agricultural and Rural Development Policy is integrated.</p> <p>Under the draft and current Seed Proclamation, land need not be owned but accessible, for one to obtain a seed producer CoC. Access to land remains a challenge though, with fragmented plots, high costs of reimbursing or leasing smallholder farmer plots, and increasing cases of breach of contract by out grower farmers.</p>	<p>Draft Seed Proclamation could be revised to include a CoC on Variety Development and Research to enable private sector engagement and align with the 2020 Seed Policy (this aspect of the 2020 Seed Policy is dependent upon establishment of the CoC on Variety Development and Research through a binding legal instrument).</p> <p>The finalization of the Agricultural and Rural Development Policy should be prioritized, as this will operationalize the 2020 Seed Policy.</p> <p>Licensing of public varieties will depend upon approval of the Ministerial Directive on licensing of public varieties; the directive is currently before the Minister responsible for agriculture for endorsement.</p>

Existing Issue(s)	Existing Provisions	Draft Instruments	Challenges & Constraints	Possible Next Steps
	<p>variety development and maintenance of prioritized crops”</p> <p>Article 6.3 of the 2013 Seed Proclamation states that a seed producer holding a CoC may access EGS from one of these PRIs.</p>			
<b>Dimension 2: Seed Dealer Registration/Certification of Competence Process</b>				
<p>Seed producer CoC requirements are quite stringent for the private sector, especially regarding access to land.</p> <p>Stakeholder consultations revealed that the legal framework establishes no flexibilities regarding CoC requirements for smallholder farmers, who are usually incapable of meeting the CoC requirements.</p>	<p>As per Regulation 42 of the 2016 Seed Regulation, a person applying to obtain a seed producer CoC shall have: (a) a suitable and accessible farmland for seed inspection; and (b) is a sufficient professional with basic knowledge and experience in seed production. These requirements are further elaborated in the Ministerial Directive on Criteria</p>	<p>The Draft Seed Proclamation allows a seed producer to enter into a contractual arrangement with a land holder to produce seed on the latter’s plot.</p>	<p>Small holder farmers still face issues in meeting CoC requirements under the 2013 Seed Proclamation and 2016 Seed Regulation.</p>	<p>Legal instruments could be revised to include flexible requirements for smallholder farmers to obtain a CoC to ensure their inclusion in the formal sector. This could be done through the Ministerial Directive on Criteria and Implementation Procedures for Issuing CoC and could also be provided for under the Draft Seed Proclamation.</p> <p>The MoA is currently developing a digital platform to regulate activities along the seed value chain, which will include a seed production database. The</p>

Existing Issue(s)	Existing Provisions	Draft Instruments	Challenges & Constraints	Possible Next Steps
<p>No binding legal framework for CoC to the private sector for varietal research and development although provided for the 2020 Seed Policy.</p> <p>Consultations revealed the absence of a seed production database. This database would assist with projections for seed production for the upcoming season, setting out annual production targets, type of producers, and other relevant information. This would help in meeting demand for seed, especially EGS, in Ethiopia.</p>	<p>and Implementation procedures for issuing CoC.</p> <p>2020 Seed Policy recommends issuance of CoC to private sector to be involved in varietal research and development.</p>			<p>beta version of this platform is currently being tested.</p>
<b>Dimension 3: Variety Registration and Release Process in Ethiopia</b>				
<p>Conflict of interest in relation to PRIs conducting National Performance Tests (NPTs) and DUS testing.</p>	<p>Regulation 6 of the 2016 Seed Regulation sets out that the “Ministry shall perform both NPT and DUS and</p>	<p>Draft Seed Proclamation proposes setting up an independent and autonomous body that will be responsible for</p>	<p>Conflict of interest was recognized as a major challenge during the variety release process.</p>	<p>Creation of an independent authority was identified as a possible solution.</p>

Existing Issue(s)	Existing Provisions	Draft Instruments	Challenges & Constraints	Possible Next Steps
	<p>generate and provide the report to National Performance Trial Evaluation Technical Committee for evaluation”. However, the tests are conducted by PRIs on all varieties (i.e., those submitted by private as well a public sector). This means that they are also evaluating varieties that are competing in the market.</p> <p>The 2020 Seed Policy proposes that the variety release and registration process should be regulated by an autonomous public institution that operates according to international regulatory practices. It shall offer its services impartially</p>	<p>variety release and registration</p>		

Existing Issue(s)	Existing Provisions	Draft Instruments	Challenges & Constraints	Possible Next Steps
	to public and private variety developers and stakeholders.			
No DUS testing protocols in place; thus, DUS is not conducted.	Regulation 5 of the 2016 Seed Regulation requires MoA to conduct DUS and NPT before the varieties are released into the market.	None. This is an implementation gap.	The absence of DUS protocols is a major challenge to movement of seed across borders, because it does not comply with regional and international standards.	The MoA adopts DUS testing results conducted in other countries and is considering adopting DUS protocols for some crops from other countries. Incorporating DUS protocols into the Variety Release Policy and Mechanism Manual of 2001 could address this gap.
<p>NPT and DUS tests not fully aligned with regional seed trade rules.</p> <p>Incomplete alignment with regional trade rules affects development of the seed system and trade in seed within regional and international markets.</p> <p>Ethiopia is a Member State, of COMESA and the COMESA Harmonized Seed Trade Regulations</p>	Under the Variety Release Policy and Mechanism Manual of 2001, a variety that has been registered and released in one COMESA Member State need only undergo one additional season of confirmation testing (DUS and VCU/NPT) in order to be released in Ethiopia.	<p>The Draft Seed Proclamation provides for “registration of a variety in Ethiopia’s national variety register if such variety is listed in a variety catalog established in accordance with international agreements ratified by Ethiopia.”</p> <p>The Draft Seed Proclamation exempts mandatory testing of varieties that contribute to the “successful implementation of</p>	Cumbersome, time-consuming and costly testing process for variety registration and release in Ethiopia.	Revise the Draft Seed Proclamation to define “prioritized development goals” to include varieties that have been released in at least two countries with which Ethiopia shares membership in a Regional Economic Community.

Existing Issue(s)	Existing Provisions	Draft Instruments	Challenges & Constraints	Possible Next Steps
<p>exempts a variety from both NPT and DUS testing if it has been registered in at least two COMESA Member States, with a maximum of one season of DUS and NPT testing when a variety has been registered in one COMESA Member State. Ethiopia's Draft Seed Proclamation only exempts such varieties from NPT, and not DUS, testing.</p>		<p>prioritized development goals”, which is not defined, or are predetermined to be beyond the capacity of the regulatory authority to test their performance and quality.</p> <p>In order for a variety to qualify for the NPT exemption, the applicant seeking registration in Ethiopia may apply for a waiver of the NPT test from the MoA. The applicant must also submit any NPT and DUS trial results from the country of origin or a third country.</p>		
<p>Exorbitant testing costs.</p> <p>Private sector stakeholders mentioned that the costs are much higher, because the MoA does not conduct the</p>	<p>As per the Rates of Fees for Seed Competency and Related Services Fees Regulation, No. 361/ (Services Fees Regulation), cost of conducting NPT is Birr 11000 per</p>	<p>MoA noted that the Services Fees Regulation is not representative of the current economic situation, and it is considering revising it.</p>	<p>Seed companies noted payment of exorbitant and changing fees for NPT and DUS tests as a major challenge.</p> <p>Although the legally-mandated evaluation fees are reasonable in comparison with what is charged in other neighboring countries, in practice, applicants are charged much</p>	<p>Revision of the Services Fees Regulation was supported by the stakeholders.</p> <p>Private seed companies expressed that Ethiopia could possibly adopt best practices from other countries, such as Kenya, where the legally-</p>

Existing Issue(s)	Existing Provisions	Draft Instruments	Challenges & Constraints	Possible Next Steps
testing, and the PRI that do set their own testing fees, which can be more than Birr 250,000 depending upon the variety.	variety per season, and DUS is Birr 4000 per variety per season.	Under the Draft Seed Proclamation, the MoA will establish an independent authority to conduct testing as highlighted above.	more by public research institutions, because MoA does not actually conduct the tests. Moreover, bureaucracy and time delays were also reported, even when fees are paid.	mandated fees are applied in practice and quality service is offered that is commensurate with costs.
<p>Composition of NVRC is not well balanced with representation of women, and the private sector.</p> <p>Meeting of the NVRC is not regular.</p>	<p>According to the Variety Release Policy and Mechanism manual of 2001, the NVRC is comprised of four breeders, an agronomist or physiologist, an entomologist, a pathologist, an economist, a person in research and extension, and other people as may be required. The Variety Release Policy and Mechanism Manual requires NVRC members from various organizations (including the MoA, EIAR, ESE).</p>	<p>No proposed clauses in the Draft Seed Proclamation.</p> <p>MoA has recommended revision to the Variety Release Policy and Mechanism Manual of 2001 to align it with the Seed Policy and Draft Seed Proclamation, including balanced public and private sector and gender representation on the NVRC and National Performance Trial Evaluation Technical Committee (NPTC).</p>	<p>The law does not yet ensure the representation of women and private sector in the NVRC.</p> <p>The NVRC does not usually follow the prescribed schedule of at least twice a year, due to limited funds.</p>	<p>The omission of women and the private sector on the NVRC could be addressed by revising the Variety Release Policy and Mechanism manual of 2001 to include a more balanced NVRC representation.</p> <p>Development partners could provide support to the MoA to enable proper funding of the NVRC and facilitate regular meetings.</p>

Existing Issue(s)	Existing Provisions	Draft Instruments	Challenges & Constraints	Possible Next Steps
	<p>These organizations are not representative of the private sector, and the current composition does not include any women.</p> <p>The 2020 Seed Policy states that the participation of women and the private sector in variety registration and release process shall be ensured.</p> <p>The NVRC is mandated to meet at least twice a year but reportedly does not keep to this schedule.</p>			
Regularly updating the National Variety Register	Article 5 of the 2013 Seed Proclamation requires the MoA to enter varieties released in the National Variety Register.	Under the Draft Seed Proclamation, the MoA shall register a variety if is listed in a variety catalog established in accordance with an international agreement ratified by the country.		The MoA is currently developing a digital platform which should house the national variety release register online in line with the draft Seed Proclamation.

Existing Issue(s)	Existing Provisions	Draft Instruments	Challenges & Constraints	Possible Next Steps
	An updated national variety register is not available online, but one is available in hard copy at the MoA.			
<b>Dimension 4: Plant Breeders' Right</b>				
PBR System is not fully operational due to the absence of PBR Regulations, and limited popularization of the 2021 Plant Breeders' Rights Directive No. 765 of 2021 (PBR Directive).  Process for approving PBR applications and granting provisional PBR also not clear.	Article 5 of the PBR Proclamation No. 1068/2017 (PBR Proclamation) has criteria for grant of PBR.  Article 32 of the PBR Proclamation states that the Council of Minister may issue regulation for the implementation of this Proclamation.	None.	The PBR Directive is generally not known by stakeholders, yet there is a time limit on when one can claim PBR.	Clear institutional framework for PBR should be established through PBR Regulations.  The PBR Directive should be shared more widely.  The ATA is working with the MoA and other development partners to sensitize relevant actors about the PBR Proclamation.
Inaccurate DUS criteria for granting of PBR to farmers.	As per Article 6 of the PBR Directive, farmers can apply for grant of PBR, which is based on a more flexible application of DUS	None.	Basing the DUS criteria for farmer varieties on minimum QDS standards is inaccurate.	The DUS criteria should be revised to align with international standards and best practices and de-linked from QDS standards.

Existing Issue(s)	Existing Provisions	Draft Instruments	Challenges & Constraints	Possible Next Steps
	linked to minimum QDS standards, yet DUS and QDS standards are different in nature.			
<b>Dimension 5: Seed Quality Assurance</b>				
Inadequate staffing, limited staff mobility, inconsistency in implementing testing, and limitation in seed tracking systems in relation to field inspection for seed quality assessments.	As per Article 45 of the 2016 Seed Regulations, a seed inspector has the responsibility to conduct field inspection on seed and inspect whether it meets Ethiopian standard prescribed by the Ethiopia Standards Agency	The Draft Seed Proclamation proposes establishment of independent institutions at the federal and regional levels for seed quality assurance.	The independent seed quality assurance authorities already exist in some of the regions like Oromia.	The legal background for the creation of the independent quality assurance authorities is dependent upon enactment of the Draft Seed Proclamation.
Limited private sector involvement in the seed quality assurance process which causes delays for private seed companies and access to seed to farmers.	As per Regulation 18 of the 2016 Seed Regulation, the responsibility of seed quality control and certification rests with the MoA and regional authorities.	The Draft Seed Proclamation introduces alternate seed quality assurance processes including QDS, self-seed quality assurance and authorized private or cooperative seed quality assurance	Seed certification is delayed in some regions, especially in relation to applications made by private seed companies.	Creating a legal background for alternative seed certification schemes is dependent upon enactment of the Draft Seed Proclamation.

Existing Issue(s)	Existing Provisions	Draft Instruments	Challenges & Constraints	Possible Next Steps
		schemes with oversight by relevant federal and regional institutions.		
<p>Certification process is not yet fully aligned with regional trade rules and international seed certification standards, including seed classes, coloring requirements, labeling, and packaging.</p> <p>Incomplete alignment with regional trade rules affects seed system development and trade in seed within regional and international markets.</p>	<p>The MoA, in collaboration with the Ethiopian Standards Agency, develops field and seed standards.</p> <p>The following seed classes and coloring requirements are recognized: breeder seed (white with diagonal violet stripes), pre-basic seed (white with diagonal violet stripes), basic seed (white), certified seed 1<sup>st</sup> generation (blue), 2<sup>nd</sup> generation (red), 3<sup>rd</sup> generation (red), 4<sup>th</sup> generation (red), and quality declared seed (color determined by the RBOA).</p>	<p>The Draft Seed Proclamation provides that seed certification, including standards, should be aligned with international rules.</p>		<p>Fully aligning the seed certification process with internationally recognized seed classes and coloring requirements will depend upon revision of the Seed Regulations.</p> <p>For avoidance of ambiguity, the regulations would have to make specific recognition of seed labels issued by regional economic communities in which Ethiopia is a member.</p>

Existing Issue(s)	Existing Provisions	Draft Instruments	Challenges & Constraints	Possible Next Steps
<b>Dimension 6: Anti-Counterfeiting</b>				
<p>Gaps in enforcement of anti-counterfeiting rules.</p>	<p>Under the 2013 Seed Proclamation, Article 26, the seed standards enforcement bodies in the seed industry in Ethiopia are the MoA at the federal level and the RBAs at the regional level.</p>	<p>None.</p>	<p>MoA and RBoAs supervise companies to assess whether they have the appropriate CoCs and proper storage, and they also assess the quality of seed that is for sale. These inspections are only conducted in a few Woredas within selected regions, depending upon the capacity of the respective RBoA.</p> <p>Stakeholders noted that enforcement of counterfeit seed is primarily done at the regional level and depends on the resourcefulness of the respective regional authority, making enforcement inconsistent.</p> <p>Stakeholders noted court cases brought by the RBoA against alleged perpetrators, and enforcement by police through market surveillance.</p>	<p>Several important regulatory aspects of this dimension require more detailed provisions that could be made clearer under the Draft Seed Proclamation (for example, the process for filing a complaint is not clear in the legal framework, the process of informing seed dealers or conforming or non-conforming seed is not clear, and the appeal process is not clear).</p> <p>Process for filing a complaint is not clear in the legal framework, although consultations with MoA noted that a formal letter can suffice.</p> <p>Process of informing seed dealer of conforming or non-conforming seed not clear.</p> <p>Appeal process is not clear.</p>

## I. Introduction, Approach, Methodology, and Background on Legal and Regulatory Framework and RSMs

Ethiopia’s legal and regulatory framework for seed systems is in a state of significant transformation.<sup>4</sup> In addition to creating a foundation for the development of the seed industry, a well-designed policy, legal, and regulatory framework for the seed sector could facilitate effective private and public sector participation and inclusion,<sup>5</sup> which would impact the availability, accessibility, and affordability of improved seed varieties at the last mile.

Aside from the policy, legal, and regulatory instruments themselves, implementation is a challenge in any enabling environment, and there are often gaps in knowledge and understanding of the full system of rules and regulations that apply to stakeholders. These challenges are further exacerbated when the enabling environment is undergoing significant changes, as is the case in Ethiopia. As laws and regulations change, it is important to ensure awareness of the existing rules, pinpoint bottlenecks, and challenges, and help sensitize stakeholders to how the system will look once changes are fully implemented.

The RSMs are a helpful tool in this regard, as they visually depict the current and proposed legal and regulatory processes, along with aspects of their implementation, highlighting regulatory bottlenecks, tradeoffs, institutional roles and mandates, and good practices across the six Key Regulatory Dimensions. They can enable governments and enterprises to prioritize options for legal and regulatory reform and weigh appropriate interventions. They can also assist policy makers in formulating implementing regulations and procedures in an inclusive manner, incorporating feedback from public-private dialogue, and ensuring that the interests of smallholder farmers and other vulnerable groups are addressed.

### A. Approach and Methodology

Based on NML’s experience with RSMs,<sup>6</sup> and tailored to the Ethiopian context with support from CRS, development of RSMs in Ethiopia consisted of several interconnected steps, as depicted in **Figure 2**.

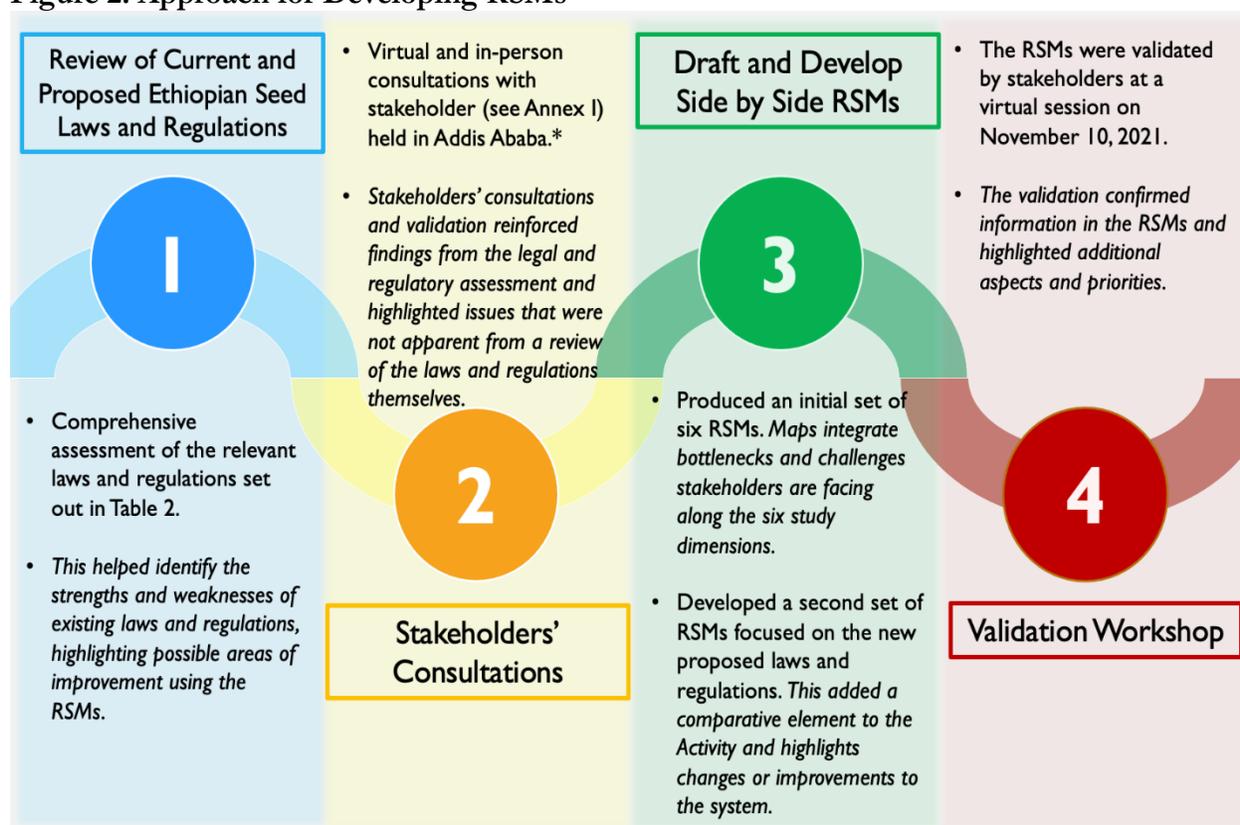
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<sup>4</sup> See “*Transforming the Ethiopian Seed Sector: Issues and Strategies*”, ETHIOPIAN MINISTRY OF AGRICULTURE (2019), [https://www.researchgate.net/publication/344401686\\_Transforming\\_the\\_Ethiopian\\_Seed\\_Sector\\_Issues\\_and\\_Strategies](https://www.researchgate.net/publication/344401686_Transforming_the_Ethiopian_Seed_Sector_Issues_and_Strategies).

<sup>5</sup> *Seed System Development Strategy, Vision, Systemic Challenges, and Prioritized Interventions*, MINISTRY OF AGRICULTURE AND NATURAL RESOURCES, ETHIOPIAN AGRICULTURAL TRANSFORMATION AGENCY, (2016).

<sup>6</sup> NML has been developing Regulatory Systems Maps since 2015, mapping economic rules and trade agreements, sector-focused regulation (including agricultural regulations, such as those related to seed and fertilizer), and steps involved in registering businesses. See NML & Southern Agricultural Growth Corridor of Tanzania Centre Ltd., *A Legal Guide to Strengthen Tanzania’s Seed and Input Markets*, Alliance for a Green Revolution (April 2016) [hereinafter, *Tanzania Legal Guide*] (made possible through support provided by the U.S. Agency for International Development, under the terms of Cooperative Agreement No. AID-OAA-A-13-00040, and managed by The Alliance for a Green Revolution in Africa (AGRA)).

Figure 2: Approach for Developing RSMs<sup>7</sup>



The assessment presents RSMs for six dimensions along the seed system regulatory value chain. The dimensions are: (1) public varietal research, development, and transfer; (2) seed dealer and venue registration or certificate of competence (CoC); (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 (see **Figure 1**).<sup>8</sup> RSMs are the primary

<sup>7</sup> At the start of the consultation period, the project team held a virtual meeting with eleven private seed companies to acclimatize them to the objectives of the Activity and obtain initial perspectives on key regulatory issues. The RSMs were shared with the seed companies who responded to targeted questions to understand the gaps in the seed value chain and identify any legal and regulatory implementation challenges. Separate virtual meetings were later held with each of the seed companies. In-person consultations were also held in Addis Ababa with eleven public sector stakeholders, two non-governmental organizations, one international development agency, two multinational seed companies, and the Ethiopian Seed Association (ESA). The non-governmental organizations consulted were One Acre Fund and the Ethiopia-Netherlands Partnership Programme (formally the Integrated Seed Development Programme - ISSD); the international development agency was the German Corporation for International Cooperation (GIZ); the multinational seed companies were Corteva Agriscience (formally Pioneer) and Bayer; and the public stakeholders were from MoA, RBoA, the Ethiopia Seed Enterprises (national and regional), EIAR, Regional Agricultural Research Institutes (RARI), and ATA.

<sup>8</sup> See Kuhlmann & Bhramar Dey, *Using Regulatory Flexibility to Address Market Informality in Seed Systems: A Global Study*, 11 AGRONOMY 1, 16 (2021), <https://www.mdpi.com/2073-4395/11/2/377> and Katrin Kuhlmann, "Mapping Inclusive Law and Regulation: A Comparative Agenda for Trade and Development", 2 African Journal of International Economic Law (forthcoming), available at [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3912907](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3912907), *supra* note 1.

comparative tool for the Report and are used across these six Key Regulatory Dimensions. RSMs are a legal and regulatory tool developed by NML in 2015 that visually depict regulatory systems, processes, procedures and their implementation in a step-by-step manner, highlighting gaps, bottlenecks, and good practices found in law and practice.<sup>9</sup> They serve as analytical instruments to highlight gaps, challenges (including with implementation), intervention points, proposed legal and regulatory changes, and systemic shifts over time.<sup>10</sup>

This Activity involved development of two sets of RSMs for each Key Regulatory Dimension, in order to provide a visual representation of the changes underway in Ethiopia’s legal and regulatory system. The comparative RSMs focus on: (i) the seed regulatory system as it *currently exists* and *is implemented in practice* (based on legal assessment and stakeholder consultations), and (ii) the *new rules and procedures* that are currently under development or may be needed to address gaps and ambiguities in the system.

Across the six sets of RSMs, four dynamic elements are highlighted to illustrate intervention points for inclusion and flexibility, changes underway, and decision points public and private stakeholders should consider. These elements pinpoint dynamic components of Ethiopia’s legal and regulatory system to highlight areas in which change is underway and could present opportunities for making the system more inclusive of small farmers, women, and other vulnerable stakeholders, namely:

- 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

In collaboration with CRS, the RSMs were adapted and enhanced to encompass additional aspects, including gender, cost, and links to forms. In particular, the Activity focused on how the current and proposed legal and regulatory systems incorporate inclusion and flexibility, especially with regard to the needs of small farmers.<sup>11</sup> For this aspect, the methodology applied to this Activity draws upon research by several of the Report authors (Kuhlmann and Dey 2021), as depicted in **Figure 3** below. It is important to note that the figure covers five of the Report’s six Key Regulatory Dimensions, with Varietal Research, Development, and Transfer incorporated in the context of farmers’ abilities. It is also important to note that one of the Key Regulatory Dimensions, the CoC, corresponds with the Registration of Actors and Venues dimension in the figure.

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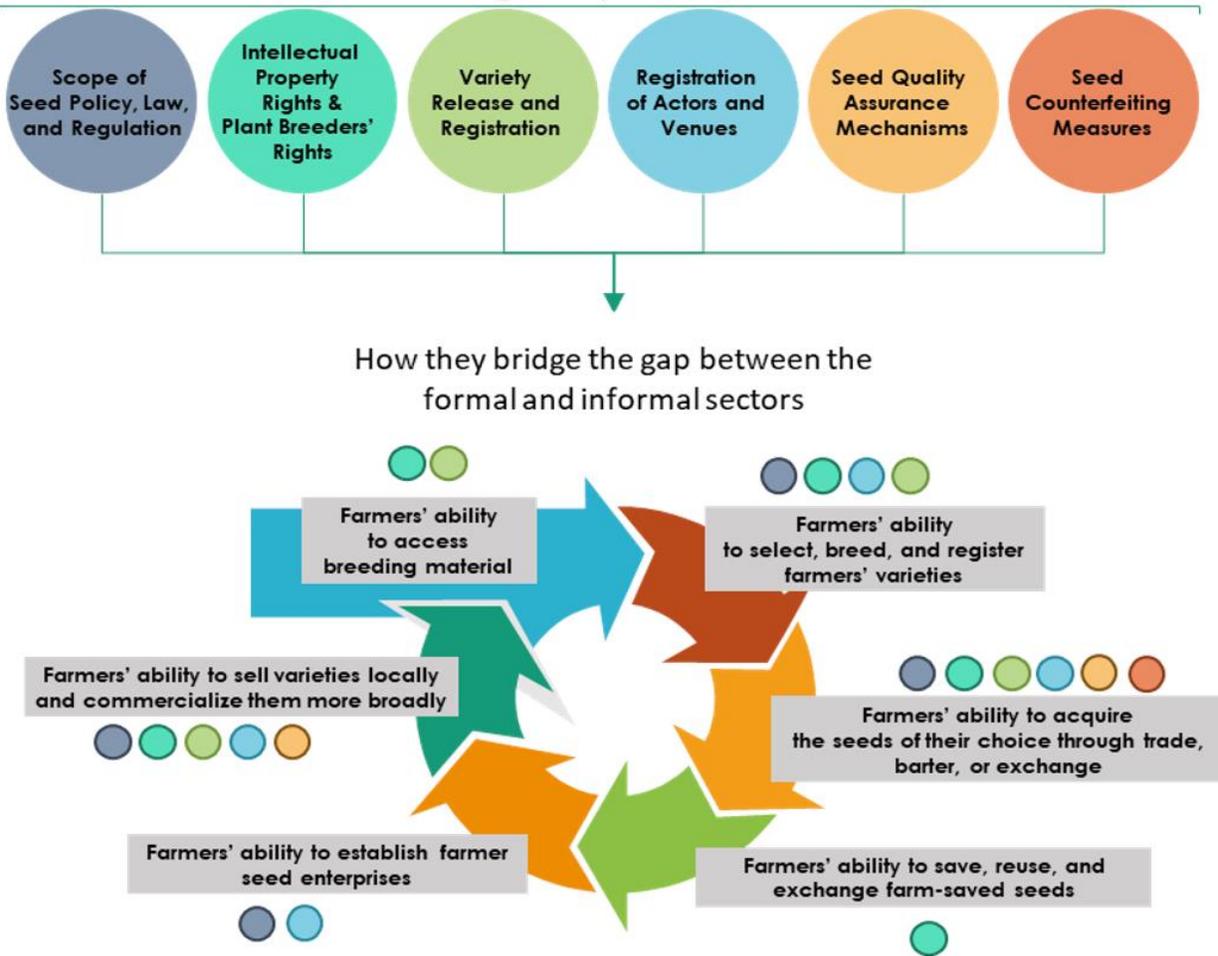
<sup>9</sup> See Katrin Kuhlmann, “Mapping Inclusive Law and Regulation: A Comparative Agenda for Trade and Development”, 2 African Journal of International Economic Law (forthcoming), available at [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3912907](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3912907)

<sup>10</sup> *Id.*

<sup>11</sup> See Kuhlmann & Bhramar Dey, *Using Regulatory Flexibility to Address Market Informality in Seed Systems: A Global Study*, 11 AGRONOMY 1, 16 (2021), <https://www.mdpi.com/2073-4395/11/2/377>. See also, Kuhlmann, *supra* note 1.

**Figure 3** below highlights the Key Regulatory Dimensions correspond with farmers’ needs. For example, variety release and registration, which is a key regulatory dimension for the RSMs, impacts farmers’ ability to access breeding material; select, breed, and register farmers’ varieties; acquire the seed of their choice through trade, barter, or exchange; and sell varieties locally and commercialize them more broadly. Similarly, other dimensions including seed quality assurance, intellectual property rights (plant breeders’ rights), and seed counterfeiting measures also correspond with farmers’ needs and can bridge the formal and informal sectors, responding to priorities of the Ethiopian government.

**Figure 3: Key Regulatory Dimensions Corresponding with Farmer’s Needs<sup>12</sup>**



<sup>12</sup> Kuhlmann & Dey, Using Regulatory Flexibility to Address Market Informality in Seed Systems: A Global Study, 11 *Agronomy* 1, 16 (2021), <https://www.mdpi.com/2073-4395/11/2/377>; and “Farmers’ Abilities” adapted from Visser, Bert, A Summary of the Impact of *National Seed Legislation on the Functioning of Small-Scale Farmers’ Seed Systems in Peru, Vietnam and Zimbabwe, December 2015 and A Study Into Seeds Laws in Selected Developing Countries?*, Oxfam, March 16, 2016.

## B. Background on Ethiopia’s Legal and Regulatory Framework

In Ethiopia, several instruments are used to regulate the seed industry, with each playing a distinct but interconnected role. Ethiopia’s system contains common elements, namely a seed policy; seed law, act, or proclamation (proclamations are used in Ethiopia's case); regulations; and subsidiary guidelines and other measures.<sup>13</sup> In Ethiopia’s case, directives are also a common instrument to support laws (proclamations) and regulations and set out further instructions on the implementation of these laws and regulations.

A seed policy is a nonbinding instrument that defines principles and strategies that guide government actions in the regulation of the seed industry.<sup>14</sup> A seed policy does not create rights and obligations unless its provisions are reiterated in either a seed legal or regulatory instrument. The seed law or proclamation and seed regulations function as the primary binding legal measures. The seed law or proclamation creates legal rights and obligations, with the seed regulations detailing provisions on how to operationalize the seed proclamation or law. While the seed law or proclamation is enacted through a legislative or parliamentary process, the regulations are usually adopted through an administrative process, which makes them more flexible and easier to change. Other instruments commonly used are guidelines, directives, and manuals, all of which are soft law, non-binding instruments that include guidance and instructions on how to implement provisions of either the law or regulations. Ethiopia’s seed sector is currently regulated by several instruments including a policy, proclamations, regulations, ministerial directives, and manuals, governing various aspects of the seed industry. **Table 2** summarizes instruments governing Ethiopia’s seed sector.

**Table 2: Instruments Governing the Seed Sector in Ethiopia**

No.	INSTRUMENT
<b>Policy</b>	
1.	2020 Seed Policy
<b>Laws</b>	
2.	Seed Proclamation No.782/2013 (amendments pending)
3.	Proclamation No. 79/1997 establishing the Ethiopian Agricultural Research Organization
4.	Plant Breeders’ Rights Proclamation No.1068 of 2017
5.	Plant Quarantine Proclamation of 1992
6.	Biosafety (Amendment) Proclamation No. 896/2015
<b>Regulations</b>	
7.	Seed Regulation No.365/2016
8.	Rates of Fees for Seed Competency and Related Services Regulation, No. 361/2015

<sup>13</sup> *Seed System Development Strategy, Vision, Systemic Challenges, and Prioritized Interventions*, MINISTRY OF AGRICULTURE AND NATURAL RESOURCES, ETHIOPIAN AGRICULTURAL TRANSFORMATION AGENCY, (2016).

<sup>14</sup> New Markets Lab, *Economic Impact Assessment and Legal Review and Analysis of the East African Community Seed and Fertilizer Legislation*, study prepared for Emerge Centre for Innovations-Africa (ECI-Africa) for the East African Community (EAC) Secretariat Under the Partnership Toward Catalyzing the Implementation of Comprehensive Africa Agriculture Development Programme (CAADP)-Malabo 2017-2020, ALLIANCE FOR A GREEN REVOLUTION IN AFRICA (AGRA) (2019).

9.	Plant Quarantine Regulations No.4/2002 (undergoing revision)
<b>Directives</b>	
10.	Ministerial Directive on Public Crop and Forage EGS Administration, No. 005/782/2012
11.	Ministerial Directive on Import and Multiplication of Unregistered Varieties Exclusive for Re-Export
12.	Ministerial Directive for Certificate of Competence to engage in the Seed Business
13.	Ministerial Directive on Criteria and Implementation Procedures for issuing Certificate of Competence
14.	Seed standards by Ethiopia Standards Agency
15.	Ministerial Directive on Quality Declared Seed (QDS)
16.	Ministerial Directive to Administer Seed Marketing
17.	Ministerial Directive for Tracking, and Utilization of Rejected Fields
18.	Ministerial Directive for Exclusive Import and Multiplication and Export of Unregistered Varieties.
19.	Plant Breeders Rights Directive No. 769 of 2021
<b>Guidelines</b>	
20.	National Variety Release Policy and Mechanism, 2001

Considering the relevance of a well-designed legal and regulatory framework for seed, Ethiopia's system is undergoing a period of important change, with the 2020 Seed Policy recently passed and several laws and regulations either under development or in draft form. The 2020 Seed Policy was introduced with the vision of modernizing the Ethiopian seed sector and creating an enabling environment for seed to encourage greater private sector involvement. The 2013 Seed Proclamation is currently being revised, and the new Draft Seed Proclamation contemplates changes to rules and procedures relating to plant variety research, development and transfer, variety registration and release, and seed certification. PBR Regulations for implementing the 2017 PBR Proclamation are in draft form and awaiting approval, and the Plant Quarantine Regulations No.4 of 2002 are also currently undergoing revision to align them with regional and international rules.

## II. Regulatory Systems Maps and Legal and Regulatory Assessment

The sub-sections below present issues, innovations, and gaps in the six dimensions included in the assessment. Each section uses RSMs as a guiding tool to assess relevant rules and procedures. Shading is used to depict important proposed and needed changes to laws and regulations, as well as areas in which stakeholder experiences differ from the rules and regulations on the books. The RSMs for each dimension set out relevant procedures, gaps, and areas of change; additional detail is included in Annexes II, III, IV, V, and VI.

### A. Dimension One: Public Varietal Research, Development, and Transfer

Varietal research, development, and transfer constitute the earliest step in the seed value chain and one of the most fundamental aspects of a well-functioning seed system.<sup>15</sup> This dimension has immense influence on the quality and quantity of seed that is made available in the market, and stakeholder consultations highlighted that access to ESG is a pressing issue.

**Figure 4** below shows the RSM depicting the current system for varietal research, development, and transfer in Ethiopia, which highlights some of the key issues and decisions points. Box 1 summarizes the key findings for the current system on varietal research, development, and transfer.

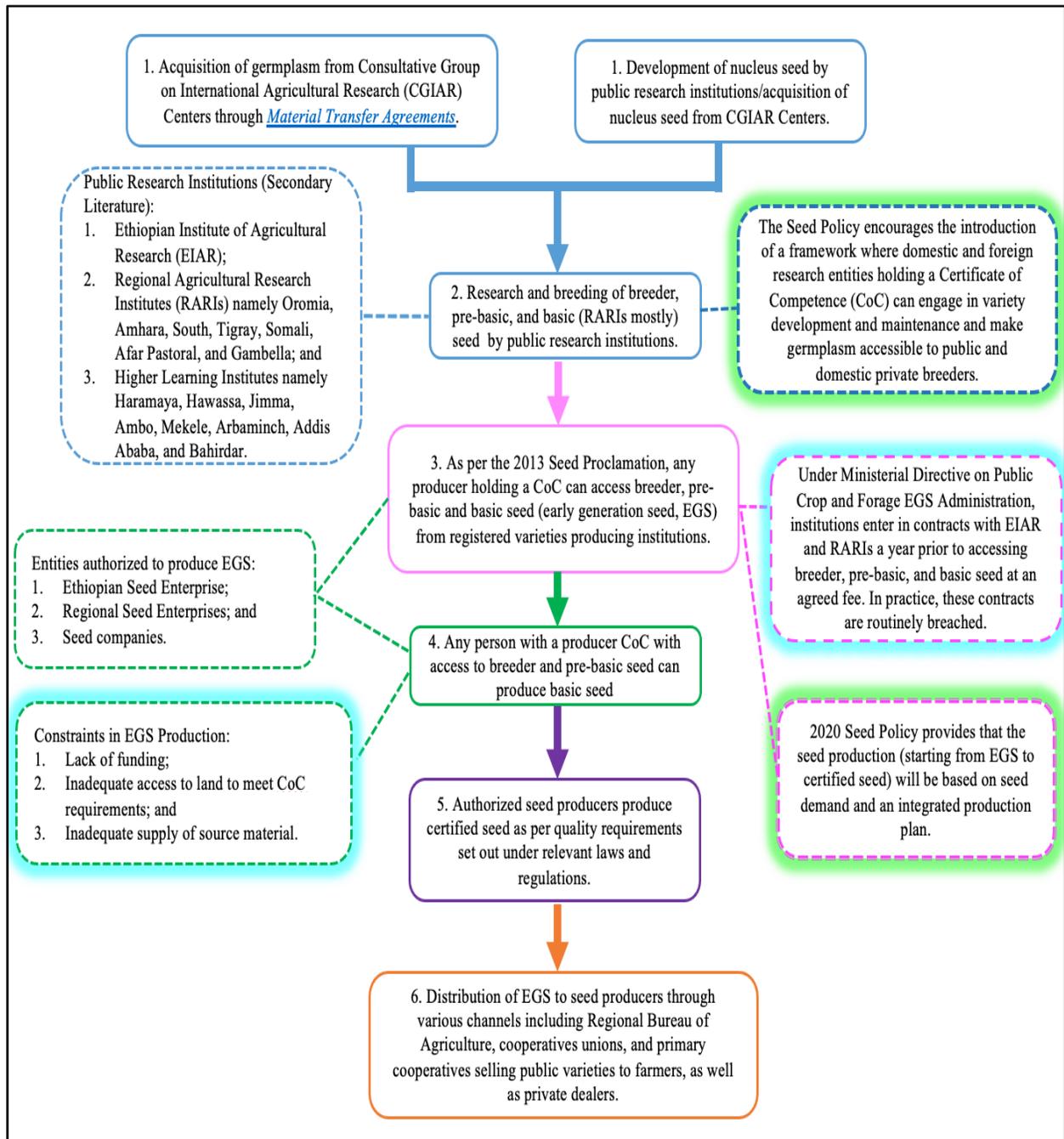
#### Box 1. Key Findings: Current System on Varietal Research, Development, and Transfer

Gaps and implementation challenges exist 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) 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 CoC for Varietal Research and Development.
- Absence of Flexibilities on CoC Requirement for Small Seed Producers. Stringent producer CoC requirements effectively keep smallholder farmers operating within the informal sector.

<sup>15</sup> Katrin Kuhlmann, Tara Francis, and Indulekha Thomas, Seed Laws and Regulation Affecting the Development of the Private Vegetable Seed Sector in Sub-Saharan Africa, World Vegetable Center, (2021), <https://worldveg.tind.io/record/74189?ln=en>.

**Figure 4: RSM on Varietal Research, Development, and Transfer in Ethiopia (Current System)**



**Key**

- Variety 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

## 1. Current System and Key Issues in Varietal Research, Development, and Transfer

Under Ethiopia's current system, several issues are illuminated by the maps. These include private sector participation in breeding, unavailability of EGS, and the absence of legal flexibilities and instruments for varietal research and development and requirements for small producers to engage in the market. Several legal and regulatory instruments are relevant, including the 2020 Seed Policy, the 2013 Seed Proclamation, the 2016 Seed Regulation, Seed Proclamation No. 79/1997 establishing the Ethiopian Agricultural Research Organization, and Ministerial Directive on Public Crop and Forage EGS Administration, No. 005/782/2012.

### *a) Varietal Acquisition, Development, and Research*

To develop new varieties, PRIs,<sup>16</sup> which are the primary entities involved in agricultural research in Ethiopia, breed or obtain germplasm from the Consultative Group on International Agricultural Research (CGIAR) Centers and develop it further or procure nucleus seed from other PRIs or CGIAR Centers to evaluate its national performance and have it registered on the national variety register.<sup>17</sup> Transfer of germplasm or nucleus seed from CGIAR Centers is generally executed through a Material Transfer Agreement, which is based on the terms of the Standard Material Transfer Agreement, as shown in **Step 1** of **Figure 4**.

Among the private seed companies in Ethiopia, none is locally involved in varietal research and development. The multinational seed companies trading seed in Ethiopia mainly import their varieties for multiplication and do not engage in breeding directly in the country. This is partly because the Agricultural and Rural Development Policy of 1994 vests varietal research and development in PRIs. This was changed under the 2020 Seed Policy, which introduces a framework that encourages domestic and foreign research entities holding a CoC to engage in varietal development and maintenance and provides for the PRIs to make germplasm accessible to public and domestic private breeders. This is highlighted in the green shaded box attached to **Step 2** in **Figure 4**. However, this important change under the 2020 Seed Policy still requires an additional instrument to become operational. This could be done through a policy, legal, or regulatory instrument, such as a directive, or it could be achieved through licensing agreements.

Difficulty accessing sufficient land was another constraint noted by the private sector, as shown in the blue shaded box attached to **Step 4** in **Figure 4** (current system for varietal research, development

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<sup>16</sup> Public Research Institutions (PRIs) include the EIAR; RARIs, namely, Oromia Agricultural Research Institute, Amhara Regional Research Institute, Southern Agricultural Research Institute (SARI), Tigray Agricultural Research Institute, Somali Pastoral and Agro-pastoral Research Institute, Afar Pastoral and Agro-pastoral Research Institute, and Gambella Agricultural Research Institute; and higher learning institutions, namely Haramaya University, Hawassa University, Jimma University, Ambo University, Mekele University, Arbaminch University, Bahirdar University, and Addis Ababa University.

<sup>17</sup> Germplasm is living tissue from which new plants can be grown, whereas nucleus seed is the purest form of a new plant variety. (See *Germplasm*, SEED BIOTECHNOLOGY CENTER, UNIVERSITY OF CALIFORNIA, DIVISION OF AGRICULTURE AND NATURAL RESOURCES, [http://sbc.ucdavis.edu/About\\_US/Seed\\_Biotechnologies/Germplasm/](http://sbc.ucdavis.edu/About_US/Seed_Biotechnologies/Germplasm/)).

and transfer). EGS production is inherently resource- and capital-intensive, requiring significant land, a high level of technical expertise, and the appropriate infrastructure and equipment.<sup>18</sup> While many of these challenges reportedly impact the private sector (see the blue shaded box attached to **Step 4** in **Figure 4**), they can be issues for public sector production of EGS as well. Finally, while not covered under this dimension, the lengthy and bureaucratic processes in practice for obtaining an import permit for parent material is also a factor in the lack of private sector engagement.

Under Seed Proclamation No. 79/1997 establishing the Ethiopian Agricultural Research Organization, PRIs are mandated with conducting agricultural research and development. The EIAR executes this mandate at the federal level, while RARIs and research universities conduct research at the regional levels.<sup>19</sup> Reportedly, there is not a clear mandate related to production of pre-basic seed and basic seed; under the Ethiopian establishment laws for each PRI, only the Southern Agricultural Research Institute has been given a clear mandate to produce basic seed. This is a notable gap that will affect access and availability of EGS.

#### *b) Production of EGS*

EIAR and RARIs produce breeder and pre-basic seed based on a demand assessment conducted in collaboration with the MoA and RBoA.<sup>20</sup> In most cases, RARIs obtain their germplasm from EIAR to develop varieties and produce breeder and pre-basic seed, or sometimes obtain breeder and pre-basic seed from EIAR to produce basic seed.<sup>21</sup>

Under the 2013 Seed Proclamation, a seed producer holding a CoC may access EGS from one of the PRIs. This is reflected in **Step 3** of **Figure 4**.<sup>22</sup> The process for accessing EGS is elaborated under the Ministerial Directive on Public Crop and Forage EGS Administration, No. 005/782/2012 (see Annex II and the blue shaded box attached to **Step 3** of **Figure 4**). A contract is then entered into between the PRI and the applicant that sets forth the terms for the PRI to produce the described classes of seed in a prescribed time and for the applicant to pay for the seed once produced. In some

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<sup>18</sup> See Katrin Kuhlmann, Yuan Zhou, Adron Nalinya Naggayi, and Heather Lui, *Seed Policy Harmonization in ECOWAS: The Case of Nigeria*, SYNGENTA FOUNDATION FOR SUSTAINABLE AGRICULTURE (SFSA) AND NML, 10 (2018), [https://www.syngentafoundation.org/sites/g/files/zhg576/f/seed\\_policy\\_harmonization\\_in\\_ecowas\\_the\\_case\\_of\\_nigeria\\_2019.pdf](https://www.syngentafoundation.org/sites/g/files/zhg576/f/seed_policy_harmonization_in_ecowas_the_case_of_nigeria_2019.pdf).

<sup>19</sup> RARIs have 63 corresponding research centers in Ethiopia, namely, Oromia Agricultural Research Institute (with 17 research centers), Amhara Regional Research Institute (with 9 research centers), South Agricultural Research Institute (with 6 research centers), Tigray Agricultural Research Institute (with 9 research centers), Somali Pastoral and Agro-pastoral Research Institute (with 4 research centers), Afar Pastoral and Agro-pastoral Research Institute (with 5 research centers), and Gambella Agricultural Research Institute (with 3 research centers).

<sup>20</sup> Abebe Atilaw, Dawit Alemu, Zerdie Bishaw, and Tekeste Kifle, *Early Generation Seed Production and Supply in Ethiopia Status Challenges and Opportunities* (2017), [https://www.researchgate.net/publication/312530797\\_Early\\_Generation\\_Seed\\_Production\\_and\\_Supply\\_in\\_Ethiopia\\_Status\\_Challenges\\_and\\_Opportunities](https://www.researchgate.net/publication/312530797_Early_Generation_Seed_Production_and_Supply_in_Ethiopia_Status_Challenges_and_Opportunities).

<sup>21</sup> Entities operating in more than one region can obtain breeder and pre-basic seed from EIAR, while in specific regions they can access it from the RARIs in the respective regions to produce basic and certified seed.

<sup>22</sup> Seed Proclamation No.782/2013 (2013 Seed Proclamation), A 6.3.

cases, contracts for EGS are reportedly finalized late, which delays production and affects the planting season. EIAR mentioned that production of pre-basic seed is not inherently in their mandate but instead falls under the RARIs and that demand further stretches already over-strained capacity.

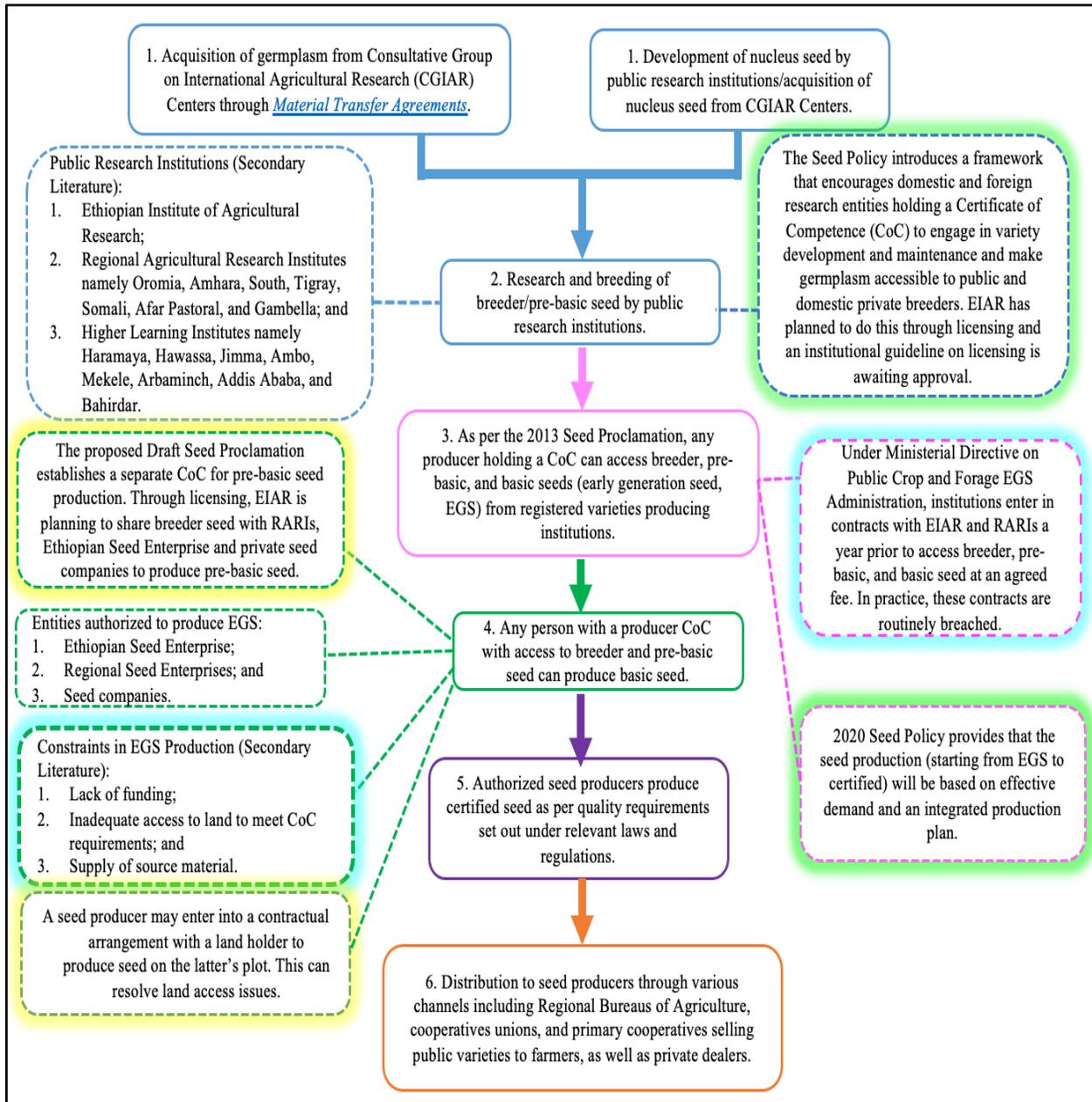
Entities that access breeder and pre-basic seed from PRIs include the ESE, Regional Seed Enterprises (RSEs), farmers unions and co-operatives, non-governmental organizations, and seed companies. This is depicted in the green dotted box attached to **Step 4** of **Figure 4**.

According to stakeholder consultations, the price paid for EGS is determined by a board comprised of the EIAR, RARIs, MoA, and the seed enterprises at the national and regional levels. This is shown by the blue shaded box to the right of Step 3 of the RSM on the Current System for Varietal Research, Development and Transfer, which indicates that stakeholder experience differs in practice from the legal and regulatory instruments. Price is based on the cost of production, the kind of variety (maize and wheat are, for instance, in high demand so their prices might be a bit higher), market demand, and smallholder farmer willingness and ability to pay, among other factors. At the regional level, the RARIs or RSEs may decide to set a different (but lower) price from that agreed upon, based on the farmers' ability to pay in the respective region or in accordance with the direction of political influences.

## 2. Proposed System and Remaining Gaps and Ambiguities

The Draft Seed Proclamation introduces important changes to address some of these challenges and gaps. **Figure 5** below on the RSM for the proposed system for varietal research, development, and transfer highlights important changes under the Draft Seed Proclamation (these appear in yellow highlighted boxes associated with **Step 4** in **Figure 5**).

Figure 5: Varietal Research, Development, and Transfer in Ethiopia (*Proposed System*)



**Key**

- Variety 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

Box 2 below summarizes key findings for the proposed system on varietal research, development, and transfer, which are elaborated upon below.

**Box 2. Key Findings: Proposed System for Varietal Research, Development, and Transfer**

- 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.

One important development is the move towards greater involvement of the private sector in varietal research and development. To an extent, this shift is underway as a result of the 2020 Seed Policy, and further changes will occur with passage of the Draft Seed Proclamation. Relevant changes made in the 2020 Seed Policy are noted in the green shaded box attached to **Steps 2 and 3** of **Figures 4 and 5**. However, in order for this policy to be enforceable, there must be a binding framework supporting it either under a Proclamation, Regulation, or Ministerial Directive, none of which is yet in place. Moreover, the 2020 Seed Policy will remain a ministerial instrument instead of a national policy until the Agriculture and Rural Development Policy, under which the 2020 Seed Policy falls, is finalized and approved by the Council of Ministers, which would give full effect to the 2020 Seed Policy.

In order to increase private sector involvement in EGS, the Draft Seed Proclamation introduces a CoC for pre-basic seed production, as seen in the yellow shaded box attached to **Step 4** in **Figure 5**. However, stakeholder consultations highlighted that this is a helpful but not sufficient change, and additional steps could be taken to address gaps and areas of ambiguity to enable legal inclusion of the private sector in the varietal research, development and transfer processes. The Draft Seed Proclamation could, for instance, incorporate provisions on a CoC on Variety Development and Research to enable private sector engagement, as called for by the 2020 Seed Policy. It could also streamline the import permitting process for parent material so that interested multinational companies could engage in domestic varietal research and development.

Another way of including the private sector in varietal research and development and improving EGS availability would be through licensing of public varieties by the PRIs and possibly sharing of genetic material. Licensing can be done under the current system, although it will encompass broader legal protection if rooted in an effective legal framework for PVP or PBR which is not yet fully operational, drawing a connection between two regulatory dimensions. While a PBR Proclamation and PBR Directive exist, the latter of which was recently approved by the Minister of Agriculture in February of 2021, regulations under the PBR Proclamation are not yet in place, which makes the PBR regulatory framework incomplete. The PRIs also lack institutional frameworks guiding licensing and intellectual property, and, in this regard, guidelines for how germplasm can be accessed by the private sector by PRIs would be beneficial.

EIAR is considering licensing as a way of getting breeder seed into the hands of RARIs, ESEs, and private companies in order to enable them to produce their own EGS. EIAR has developed an institutional guideline on licensing that is awaiting ministerial approval, as shown the yellow shaded box attached to **Step 4** in **Figure 5**. The guideline includes parameters to be followed by EIAR in licensing their varieties to parastatals and private companies, along with conditions of how to maintain the varieties. EIAR hopes that this will cover some of the EGS delivery gaps, as well as get more public varieties out to farmers. The licensing of public varieties by PRIs is contingent upon approval of the Ministerial Directive on Licensing of Public Varieties and corresponding guideline. During consultations, none of the companies consulted knew of EIAR's intention to license their varieties, although they were very receptive to the idea. RARIs, ESEs, and private companies all opined that licensing of public varieties would ensure improved access and availability of EGS. Most local companies were, however, concerned that private sector capacity gaps must also be addressed in order to meet the licensing terms. For example, most companies cannot meet the requirements to obtain a producer CoC, as discussed below.

Responding to the challenges of access to land, the Draft Seed Proclamation provides that a seed producer may enter into a contractual arrangement with a land holder to produce seed on the latter's plot, as depicted in the yellow shaded box attached to step 4 of the RSM for the proposed system on varietal research, development, and transfer. stakeholder consultations revealed that this has already happened in practice and that the current legal requirement is for a seed producer to have access to land and not necessarily own it, highlighting an area of misinterpretation by many private sector stakeholders. Nonetheless, a legal provision explicitly allowing contractual arrangements between a seed producer and land-owners would streamline the requirements on access to land and strengthen the contractual relationship.

MoA has stressed that the Ministerial Directive on Direct Seed Marketing will be implemented to ensure quality of EGS and reduce the cases of sale of fake seed. This will involve the RBoAs' supervision of companies to assess whether they have CoCs and proper storage, as well as assessing the quality of the seed for sale. These inspections are conducted either prior to sale or during the sale

of the seed. However, at the moment, these inspections are only conducted in a few Woredas within selected regions.

## **B. Dimension Two: Seed Dealer Registration/Certificate of Competence Process**

Ethiopia's system reflects an ex-ante approach to market regulation, which is common across sub-Saharan Africa. Under an ex ante system, market participants must obtain government approval in order to operate and engage in various activities along the seed value chain.<sup>23</sup> While the ex ante aspects of Ethiopia's system appear across the Key Regulatory Dimensions, the CoC dimension encompasses this approach. A seed producer, wholesaler, processor, distributor or retailer (or seed dealer) has to obtain a CoC before undertaking corresponding activities in the sector. The regulated process for the CoC follows several steps, as depicted in **Figure 6**: (a) application, (b) evaluation, and (c) regulatory evaluation and post determination.

As noted in the preceding section, the 2020 Seed Policy recommends issuance of a CoC to involve the private sector in varietal research and development; however, no such CoC is provided for either in the existing laws or the Draft Seed Proclamation.

Box 3 summarizes key issues related to the current CoC system.

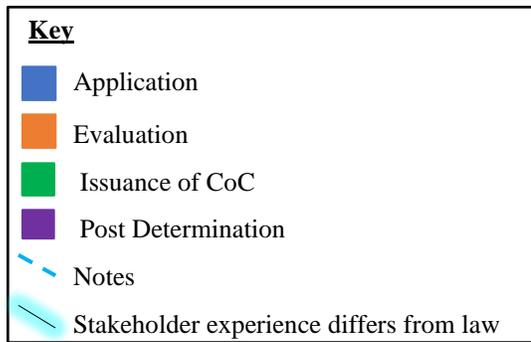
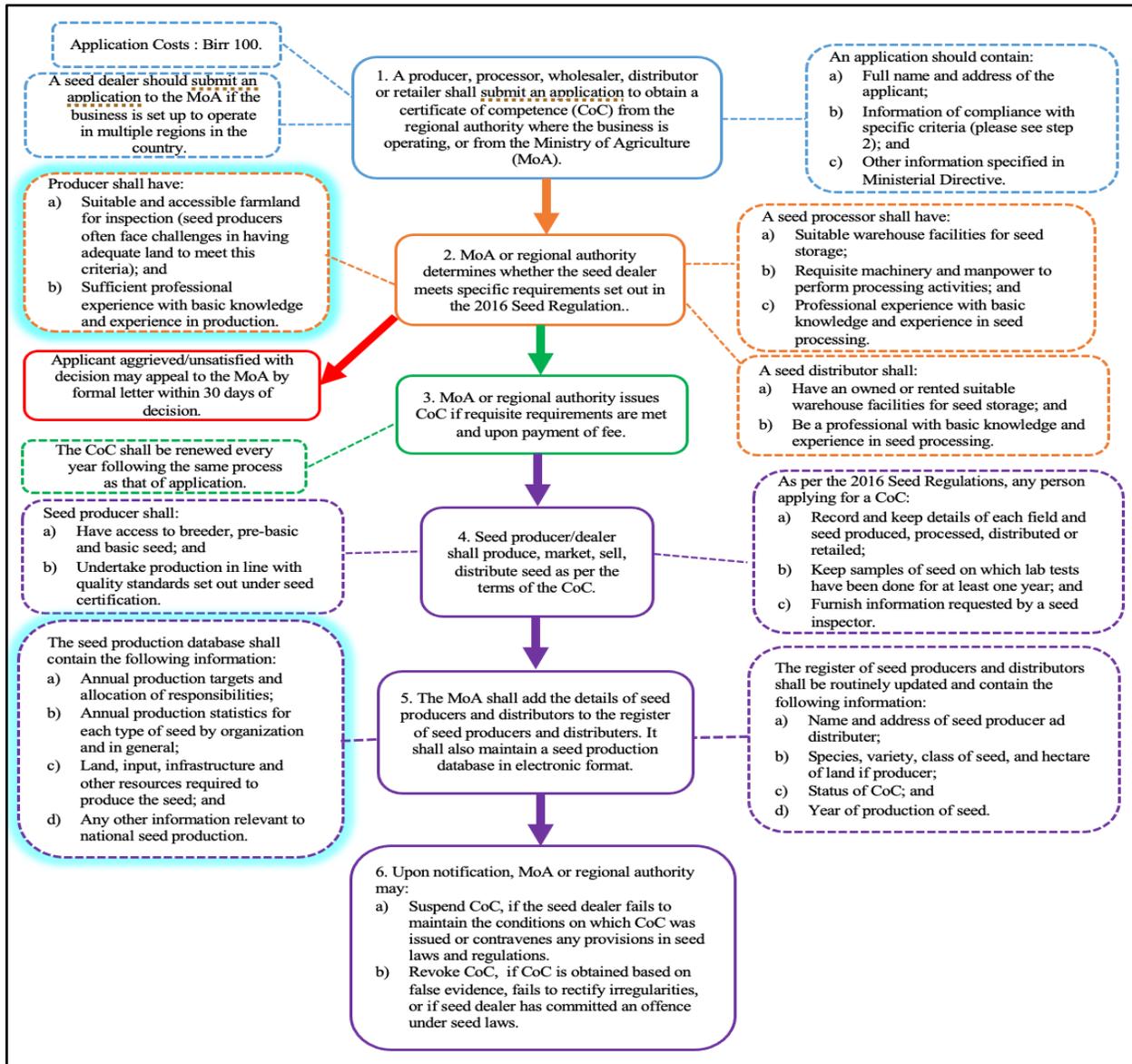
### **Box 3. Key Takeaways: Current System for Certificate of Competence**

- Consultations highlighted concerns that the requirements for a producer CoC are quite stringent, especially regarding access to land (this is depicted in the blue shaded box attached to **Step 2** in **Figure 6**).
- Professional experience requirements (also shown in **Step 2**) can also be a challenge, particularly for small farmers.
- While the 2020 Seed Policy recommends issuance of a CoC to the private sector for varietal research and development, no such CoC is provided for either in the existing laws or the Draft Seed Proclamation. This gap is linked to the regulatory dimension on varietal research, development, and transfer covered in the preceding section (it is depicted in the green shaded box attached to **Step 2** in **Figure 6**).

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<sup>23</sup> See Katrin Kuhlmann, *Planning for Scale Brief #6: Enabling Environment*, AGPARTNER XCHANGE, 2013

Figure 6: RSM on Certificate of Competence Process in Ethiopia (*Current System*)



## 1. Current System and Key Issues in Seed Dealer Registration/Certificate of Competence Process

The procedure for obtaining a CoC for seed dealers is covered under the 2020 Seed Policy, 2013 Seed Proclamation, 2016 Seed Regulation; Services Fees Regulation, Ministerial Directive for CoC to engage in the Seed Business, and Ministerial Directive on Criteria and Implementation Procedures for issuing CoC.

### *a) Application*

Anyone who wants to engage in Ethiopia's seed system has to apply for a CoC. This process differs based on whether an actor will operate in one region or multiple regions. Stakeholder consultations confirmed that overall the application process for obtaining a CoC is quite clear. The MoA is working to further improve the system by rolling out a digital platform through which applications can be made and processed. The beta version of the platform is currently undergoing trial.

### *b) Evaluation*

In contrast, the evaluation process for a CoC reportedly presents challenges. The 2016 Seed Regulation<sup>24</sup> and the Ministerial Directive on Criteria and Implementation procedures for issuing CoC set out criteria for seed producers, dealers, processors and distributors to obtain a CoC. Seed producers need to have suitable and accessible farmland for seed inspection and sufficient professional experience, with basic knowledge and experience in seed production (this is depicted in the blue shaded box attached to **Step 2** of **Figure 6**). This provision has been made clearer in the Draft Seed Proclamation, which allows a seed producer to enter into a contractual arrangement with a landholder to produce seed on the latter's plot.

Similar criteria are set out for seed processors and distributors (**Step 2** of **Figure 6**, with additional detail in Annex III). Consultations with private sector stakeholders revealed that most were incapable of meeting these CoC requirements. For example, most local companies cannot fulfill the minimum professional requirement for a diploma in agricultural sciences or a related field, and the failure to meet this professional requirement affects who can participate in the sector and sets a high bar for inclusivity. Public sector stakeholders proposed that the diploma requirement be changed in the Draft Seed Proclamation in order to ensure that those involved in seed production and distribution have the requisite capacity in order to produce better quality seed.

Notably, the legal framework includes no flexibilities regarding CoC requirements for small seed producers, such as smallholder farmers who are usually incapable of meeting strict professional requirements. Private sector stakeholders noted that smallholder farmers in general have less education, request relatively small quantities of seed, live in remote areas, and have very limited

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<sup>24</sup> 2016 Seed Regulation, r 43.

budgets for seed purchases, so the producer CoC requirements are beyond their capacity. Smallholder farmers can organize in seed primary cooperatives or make contractual agreements with the seed enterprises,<sup>25</sup> but additional options could exist to allow small farmers to produce on their own. Stringent producer CoC requirements effectively keep smallholder farmers operating within the informal sector, affecting both opportunity within the sector and the quality of seed they produce, since this seed is not monitored by the regulatory institutions.

This is an important intervention point at which flexibility and inclusion could be enhanced. Some countries have adopted more flexible approaches to recognize informal actors, such as India's system which maintains a separate registration system for small farmers and informal actors and Peru's system, which exempts those engaged in the production, trade, and storage of traditional varieties from registration.<sup>26</sup> These good practices could be considered in Ethiopia's case, building upon other flexibilities in Ethiopia's seed system.

### *c) Regulatory Determination and Post Determination*

A seed dealer can begin operations in the market once the relevant federal or regional body issues a CoC (**Steps 3 and 4** of **Figure 6** and Annex III).<sup>27</sup> For example, a registered seed producer could access EGS and produce seed for commercialization.<sup>28</sup> Seed producers, specifically, have the responsibility to hold a valid CoC throughout production, undertake production in accordance with the quality standards established for seed certification, participate in integrated seed production activities, and comply with requirements set out in the relevant ministerial directives.

## 2. Proposed System and Remaining Gaps and Ambiguities

The Draft Seed Proclamation introduces changes to address some of the challenges with the CoC process. To clarify CoC requirements and improve access to land, the Draft Seed Proclamation allows a seed producer to enter into a contractual arrangement with a landholder to produce seed on the latter's plot, as depicted in yellow shaded box attached to **Step 2** of the RSM for the proposed CoC process in Ethiopia (**Figure 7**). Implementation of this provision, however, will depend upon enactment of the Draft Seed Proclamation.

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<sup>25</sup> Seed producer cooperatives play an important role in Ethiopia's seed sector with respect to opportunities for small farmers, seed supply, and seed security. See Dawit Tsegaye Sisay, Frans J. H. M. Verhees & Hans C. M. van Trijp, *Seed Producer Cooperatives in the Ethiopian Seed Sector and Their Role in Seed Supply Improvement: A Review*, JOURNAL OF CROP IMPROVEMENT 31:3, 2017.

<sup>26</sup> Katrin Kuhlmann & Bhramar Dey, *Using Regulatory Flexibility to Address Market Informality in Seed Systems: A Global Study*, 11 AGRONOMY 1, 10-11 (2021), <https://www.mdpi.com/2073-4395/11/2/377>.

<sup>27</sup> Ministry of Foreign Affairs Ethiopia, *IM&NA Ethiopia Public Seed Sector Services*, 12 (2020), <https://www.rvo.nl/sites/default/files/2020/03/IMNA-Ethiopia-Public-Seed-Sector-Services.pdf>.

<sup>28</sup> 2013 Seed Proclamation, A 6.

Flexible requirements for smallholder farmers to obtain a CoC and to ensure their inclusion in the formal sector are also important,<sup>29</sup> and these will be dependent upon revision of the Draft Seed Proclamation or Ministerial Directive on Criteria and Implementation Procedures for Issuing CoC. The definition of requirements for a CoC on varietal research and development provided for in the 2020 Seed Policy will also be dependent upon revision of the Draft Seed Proclamation to include this instrument, or this could be established through amended seed regulations. Approval of the Agriculture and Rural Development Policy will also be needed in order to give full effect to the Seed Policy.

Important changes are shown in the shaded areas in **Figure 7** below on the RSM for the proposed CoC process in Ethiopia, and key findings are include in Box 4 and elaborated upon below.

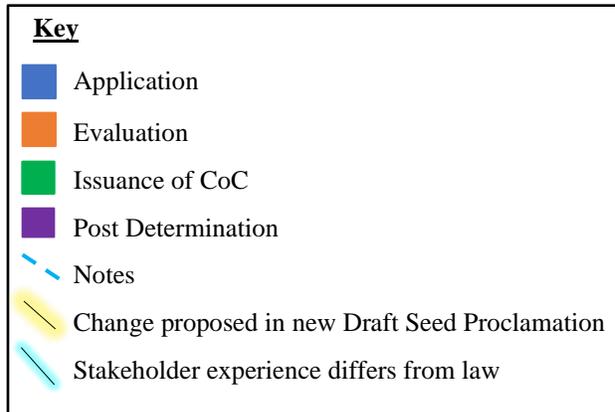
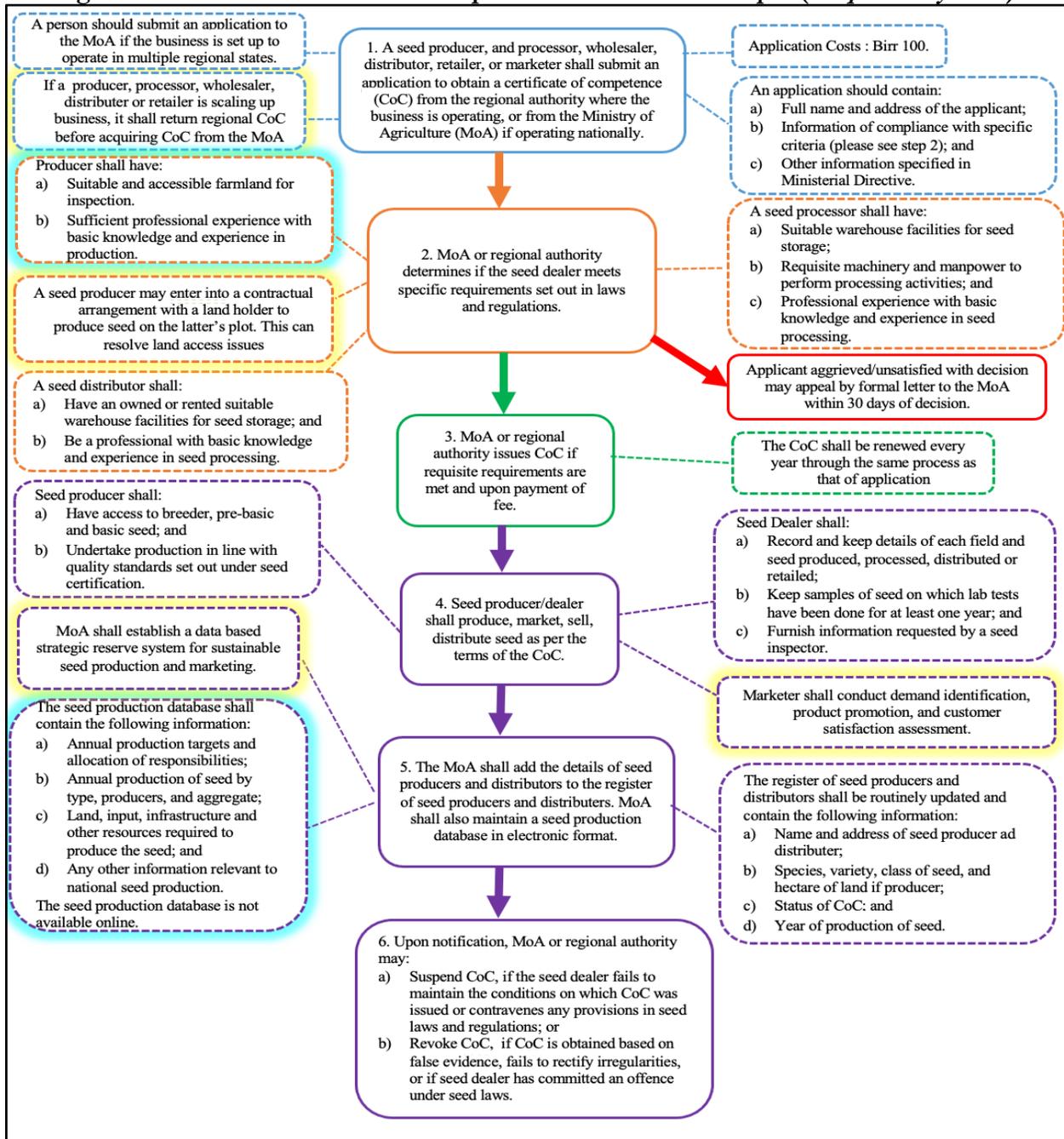
#### **Box 4: Key Findings Proposed Certificate of Competence Process**

- The Draft Seed Proclamation includes provisions to allow seed producers to enter into contractual relationships with a landholder to produce seed on the latter's plot, addressing a significant gap.
- Stakeholder consultations revealed that the legal framework makes no exemptions regarding CoC requirements for smallholder farmers, who are usually incapable of meeting the CoC requirements.
  - This could be addressed through the Draft Seed Proclamation or Ministerial Directive on Criteria and Implementation Procedures for Issuing CoC, which could be revised to include flexible requirements for smallholder farmers to obtain a CoC to ensure their inclusion in the formal sector.
- The Draft Seed Proclamation could be revised to implement provisions in the 2020 Seed Policy that call for a CoC on varietal research and development (regulations could also be drafted).

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<sup>29</sup> See Katrin Kuhlmann & Bhramar Dey, *Using Regulatory Flexibility to Address Market Informality in Seed Systems: A Global Study*, 11 AGRONOMY 1, 16 (2021), <https://www.mdpi.com/2073-4395/11/2/377>.

Figure 7: RSM on Certificate of Competence Process in Ethiopia (*Proposed System*)



To address challenges associated with under and over production of seed, the Draft Seed Proclamation requires a marketer to conduct demand identification, product promotion, and customer satisfaction assessment (see yellow shaded box linked with **Step 4** of **Figure 7**). Implementation of this provision will depend upon enactment of the Draft Seed Proclamation.

Consultations also revealed that while a seed production database is provided for in the 2013 Seed Proclamation, one does not exist in practice (see blue shaded area linked to **Step 6** of **Figure 7**). The Draft Seed Proclamation provides for the MoA to establish a data-based strategic reserve system for sustainable seed production and marketing (see yellow shaded box linked with **Step 2** of **Figure 7**). In line with this, MoA is currently developing a digital platform for the seed value chain, which will include a seed production database. The beta version of this platform is currently being tested. In addition, information on a seed production database could be used to project demand and address issues of over- or under-production of EGS and certified seed.

### **C. Dimension Three: Variety Registration and Release Process in Ethiopia**

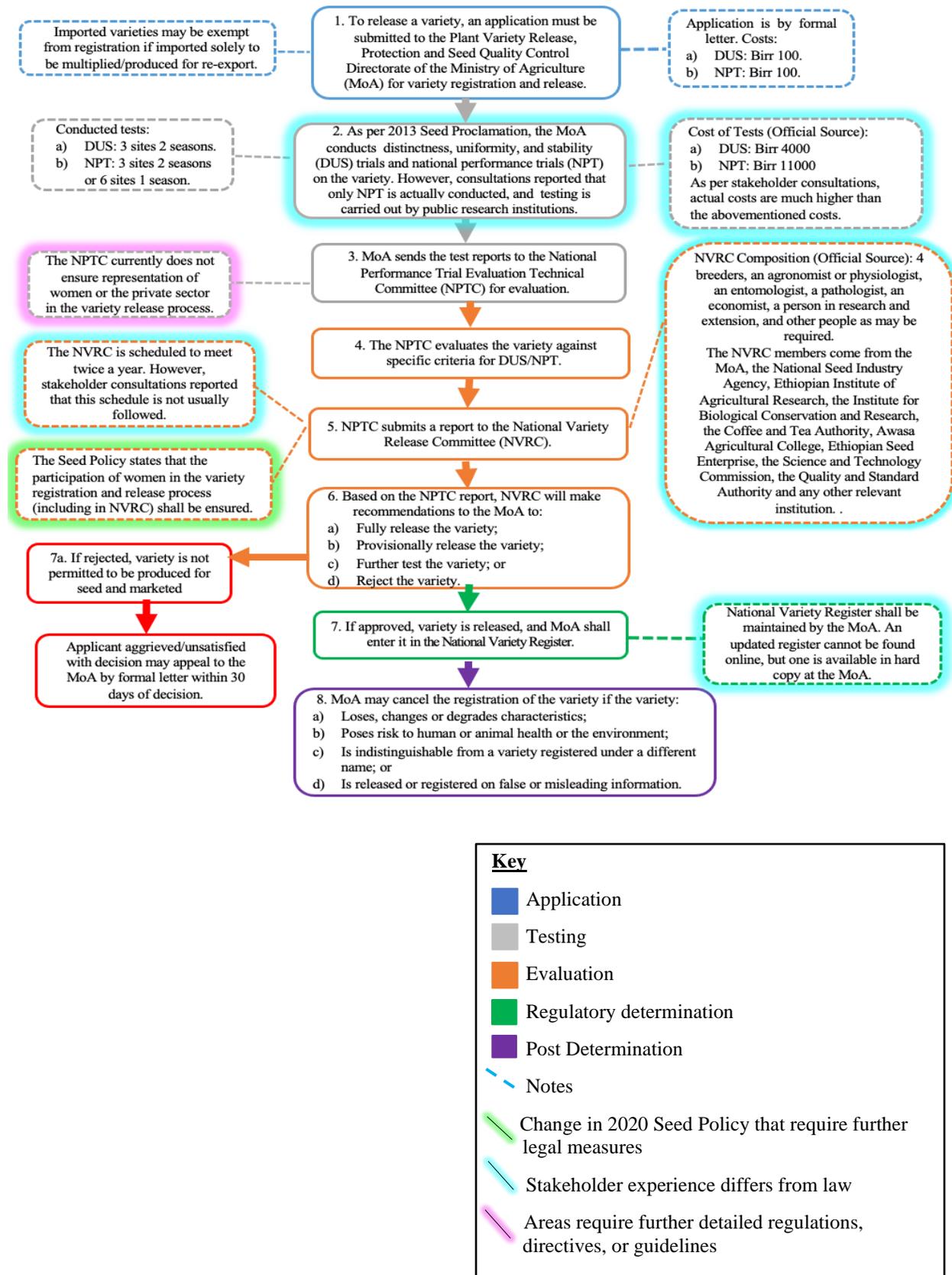
In most African countries, including Ethiopia, plant varieties must undergo a formal process of variety registration and release before a variety can be commercialized. All varieties must be evaluated and registered on the national variety list prior to commercialization.<sup>30</sup> Even though Ethiopia's system requires that these be conducted by the MoA, in practice, the PRI evaluate new varieties with MoA oversight.

The variety registration and release process in Ethiopia is governed by a number of instruments, including the 2020 Seed Policy; 2013 Seed Proclamation; 2016 Seed Regulation; Services Fees Regulation; Variety Release Policy and Mechanism Manual of 2001; and Ministerial Directive on Import and Multiplication of Unregistered Varieties Exclusive for Re-Export. The variety release process contains four steps: (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, which are discussed below. The RSM on the current process for variety registration and release is included in **Figure 8** below.

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<sup>30</sup> Seed System Development Strategy, Vision, Systemic Challenges, and Prioritized Interventions, MOA ETHIOPIA ETHIOPIAN AGRICULTURAL TRANSFORMATION AGENCY, (2016).

**Figure 8: RSM on Seed Variety Registration and Release Process in Ethiopia (*Current System*)**



## 1. Current System and Key Issues in Variety Registration and Release Process

Anyone who wishes to release a variety locally or export it to a foreign market from Ethiopia has to go through the process of variety registration and release managed by the Plant Variety Release, Protection and Seed Quality Control Directorate of the MoA.<sup>31</sup> The process does have some gaps and ambiguities, as noted in Box 5 below and described in the sections that follow.

### Box 5. Key Findings Current System for Variety Registration and Release

- 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 PRIs 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 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).

#### a) Variety Testing

Ethiopian seed laws and regulations require DUS and NPT tests before a variety can enter the market,<sup>32</sup> which MoA has the mandate for overseeing (depicted in **Step 2** of **Figure 8**).<sup>33</sup> Stakeholders reported that, in practice, the NPIC oversees the trials on behalf of the MoA, which appoints the NPIC members.<sup>34</sup> In addition, stakeholders report that testing is actually conducted by the PRIs in practice and not the MoA,<sup>35</sup> contrary to the 2013 Seed Proclamation. These differences between rules on paper and the process reported by stakeholders are depicted in the blue shaded boxes in **Figure 8**. Private seed companies noted a conflict of interest with PRIs conducting variety testing, since they also engage in varietal research and development and their varieties compete in the market with private seed companies. Some companies alleged that PRIs will not recommend a variety for release if it is likely to be in competition with a similar variety and that there have been instances in which the recommended research institute declines to conduct the trials, citing limited human resource, capacity, and time. Seed companies also noted that the process for getting the respective PRIs to include private sector varieties in trials is rather bureaucratic and tedious.

<sup>31</sup> IM&NA Ethiopia Public Seed Sector Services, MINISTRY OF FOREIGN AFFAIRS ETHIOPIA, 30 (2020) <https://www.rvo.nl/sites/default/files/2020/03/IMNA-Ethiopia-Public-Seed-Sector-Services.pdf>.

<sup>32</sup> 2013 Seed Proclamation, A 4.1.

<sup>33</sup> 2016 Seed Regulation, r 5

<sup>34</sup> 2013 Seed Proclamation, A 4.

<sup>35</sup> IM&NA Ethiopia Public Seed Sector Services, MINISTRY OF FOREIGN AFFAIRS ETHIOPIA, 12 (2020) <https://www.rvo.nl/sites/default/files/2020/03/IMNA-Ethiopia-Public-Seed-Sector-Services.pdf>.

The costs associated with relevant testing for evaluation are set out in the Services Fee Regulations (Birr 100 per test); however, these fees differ from the application fees reported by stakeholders, as depicted in the blue shaded box off of **Step 2** of **Figure 8**, which puts the cost of conducting NPT at Birr 11000 Birr per variety per season (approximately USD 250) and the cost of conducting DUS tests at around Birr 4000 (approximately USD 90) per variety per season. However, in practice, there are no clear and specific charges for the field trials. In principle, the Services Fees Regulation would apply; however, because the MoA does not conduct evaluations as it is mandated to do, the PRIs set their own costs, with which companies must comply. This is depicted in the blue shaded box attached to **Step 2** of **Figure 8**. This is a significant reason that variety testing ends up being so expensive. Some companies noted, for instance, that NPTs could cost at least USD 10,000, which also varies depending upon the crop. The cost can be much higher for vegetables and varieties that are not so common.

Consultations also revealed that, in practice, DUS tests are not actually conducted as required due to the absence of DUS protocols (see blue shaded box associated with **Step 2** of **Figure 8**). This was cited as a factor that negatively impacts the effectiveness of the varietal evaluation process. The lack of DUS testing can affect the trade of locally produced seed in regional and international markets, because Ethiopian varieties will be unable to meet provisions under the COMESA Seed Trade Harmonisation Regulations of 2014,<sup>36</sup> International Seed Testing Association (ISTA) rules, and rules under the International Union for the Protection of New Varieties of Plants (UPOV) Conventions.

Ethiopia also currently has a fast-track process for varieties that are registered in other countries, which are subject to one season of NPT on six sites after submission of DUS and NPT test results from the other country (or countries).

#### *b) Evaluation*

Under the 2016 Seed Regulation, once the variety tests are completed, the MoA sends the trial results to the NPTC for evaluation (see **Step 3** of **Figure 8** and Annex IV).<sup>37</sup> Once the NPTC reaches a decision, it will submit a report to the NVRC with the results (see **Step 5** of **Figure 8**). According to the Variety Release Policy and Mechanism Manual of 2001, the NVRC is comprised of four breeders, an agronomist or physiologist, an entomologist, a pathologist, an economist, a person in research and extension, and others as may be required (the composition of the NVRC is depicted in the blue shaded box off of **Step 5** of **Figure 8**).<sup>38</sup> Although the 2020 Seed Policy calls for greater representation of women on the NVRC, as shown in the green shaded box attached to **Step 5** of the RSM, this is not

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<sup>36</sup> COMESA Seed Trade Harmonisation Regulations, A27.

<sup>37</sup> 2016 Seed Regulation, r 5.

<sup>38</sup> The Variety Release Policy and Mechanism Manual requires that the NVRC members come from the MoA, the National Seed Industry Agency, EIAR, the Institute for Biological Conservation and Research, the Coffee and Tea Authority, Awasa Agricultural College, ESE, the Science and Technology Commission, the Quality and Standard Authority, and any other relevant institution.

yet the case in practice. Small farmers are also not well represented, highlighting another gap in inclusion within Ethiopia's system.

### *c) Regulatory Determination*

Based on the NVRC's recommendation, the MoA will make a decision regarding whether to release or reject a variety. If a variety is released, it will be registered under the National Variety Register (see blue shaded box off of **Step 7** of **Figure 8**).<sup>39</sup> MoA has the obligation to maintain the Register. An aggrieved applicant can also appeal if the variety has been rejected by the MoA. Relevant procedures for these steps are described in greater detail in Annex III.

The NVRC is not very diverse, as shown in the pink shaded box attached to **Step 3** of **Figure 8**, and the current NVRC has two representatives from public universities, seven representatives from RARIs, and two members from the MoA. Yet, the NVRC plays an important role and makes recommendations on whether or not to release a variety. Consulted stakeholders stressed that it is important that the NVRC composition is representative of all key stakeholders in the seed system. In practice, however, both public and private stakeholders revealed that the NVRC is entirely composed of male public-sector members, even though the 2020 Seed Policy calls for greater gender representation, as shown in the green shaded box attached to **Step 5** in **Figure 8**. Small farmers and farmers' associations should also be better represented,<sup>40</sup> which could be addressed alongside greater gender balance.

This is an example of an intervention point where flexibility and inclusion could be enhanced to the benefit of small farmers. For example, Ethiopia could consider more flexible approaches to DUS testing, such as the "identifiability" test maintained by Malaysia that allows for consideration of more heterogeneous qualities in the context of variety registration and PBR or approaches of other countries, such as preferential schemes for traditional varieties or alternative seed catalogues.<sup>41</sup>

## 2. Proposed System and Remaining Gaps and Ambiguities

The variety registration and release process remains one of the more challenging among the Key Regulatory Dimensions. Issues include conflicts of interest with PRIs conducting public testing, higher costs for variety testing in practice than established under law, the absence of DUS protocols,

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<sup>39</sup> 2016 Seed Regulation, r 9.

<sup>40</sup> See Marcelin Tonye Mahop, "African Seed Laws and Policies: An Exploration of the Space for Farmers' Seed Systems in Africa" Expert Meeting on the Impact of Seed Laws on Smallholder Farming Systems in Africa: Challenges and Opportunities (ISSD, March 2016). See also Kuhlmann & Bhramar Dey, *Using Regulatory Flexibility to Address Market Informality in Seed Systems: A Global Study*, 11 AGRONOMY 1, 16 (2021), <https://www.mdpi.com/2073-4395/11/2/377>.

<sup>41</sup> Katrin Kuhlmann & Bhramar Dey, *Using Regulatory Flexibility to Address Market Informality in Seed Systems: A Global Study*, 11 AGRONOMY 1, 7-14 (2021), <https://www.mdpi.com/2073-4395/11/2/377>.

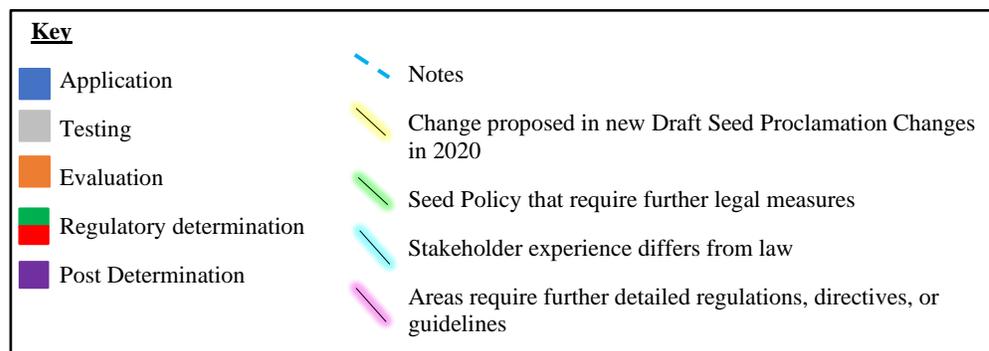
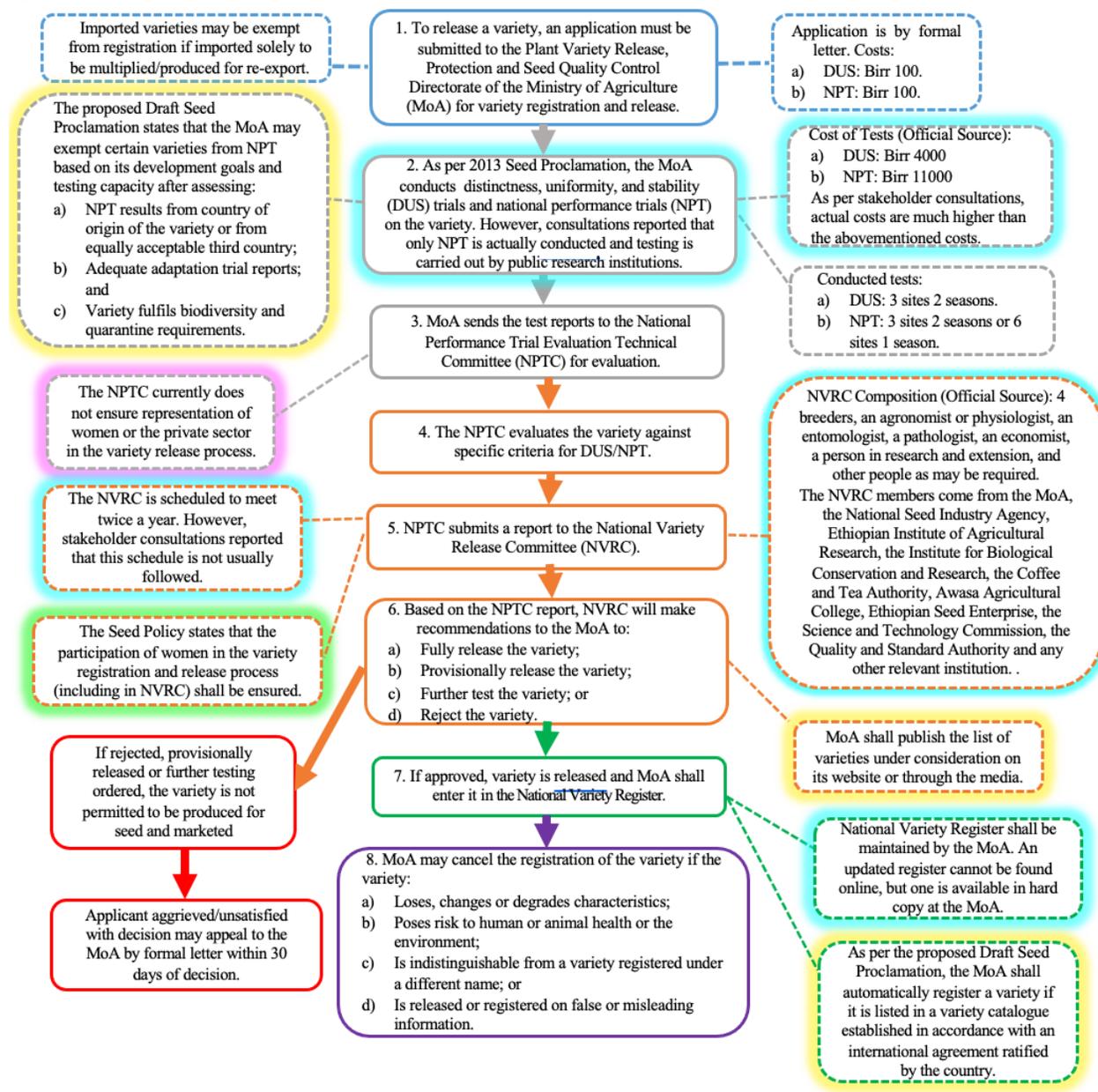
and a lack of diversity within the NVRC, particularly with respect to representation of women, which is called for by the Seed Policy.

**Figure 9** below with the RSM for the proposed system for variety registration and release depicts important changes under the Draft Seed Proclamation in yellow highlighted boxes. Key findings from the proposed system in this regulatory dimension are summarized in Box 6 and discussed in greater detail below.

#### **Box 6. Key Findings Proposed System for Variety Registration and Release**

- Draft Seed Proclamation calls for the creation of an independent entity responsible for variety registration and release (see yellow shaded 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”

**Figure 9: RSM on Seed Variety Registration and Release Process in Ethiopia (*Proposed System*)**



As noted, the Draft Seed Proclamation introduces changes to address some key challenges with respect to variety registration and release, namely:

- Creation of an independent seed authority;
- Provisions to streamline the variety testing process; and
- Provisions to align Ethiopia’s variety registration and release process more fully with COMESA regional rules.

For example, the Draft Seed Proclamation proposes that the MoA establish an independent and autonomous body responsible for the variety release and registration process. This is depicted in the yellow shaded box attached to **Step 2** of **Figure 9**. The creation of an independent entity responsible for variety release and registration could address issues of conflict of interest, as highlighted above, and will depend upon enactment of the Draft Seed Proclamation.

The Draft Seed Proclamation proposes exemption from testing of varieties that are listed in a variety catalogue established in accordance with international agreements ratified by Ethiopia. It follows that varieties listed in regional variety catalogues such as the COMESA Plant Variety Catalogue will be exempt from variety testing, since Ethiopia is a COMESA Member State. The Draft Seed Proclamation mentions that varieties listed in such regional variety catalogues will directly become part of the national variety list, which is an important development (this is shown in the yellow shaded box off of **Step 7** in **Figure 9**).

In an attempt to align with regional seed rules under COMESA for instance, the Draft Seed Proclamation exempts mandatory testing of varieties that contribute to the “successful implementation of prioritized development goals” but does not define what amounts to “prioritized development goals,” which leaves room for ambiguity and misinterpretation (depicted in the yellow shaded box attached to **Step 2** of **Figure 9**).

Simplifying and streamlining the process for variety release and registration will be dependent upon: (a) revision of the Variety Release Policy and Mechanism Manual of 2001 to legally mandate the inclusion of women and private sector in the NVRC; (b) approval of DUS protocols for wheat and barley and development of DUS Protocols for other crops; (c) revision of the Service Fee Regulation to include fees involved in the variety registration process, including DUS and VCU testing, that is reflective of the current economic status; and (d) revision of the Draft Seed Proclamation to fully align with regional seed rules like the COMESA Seed Trade Harmonisation Regulations by defining “prioritized development goals” to include varieties that have been released in at least two countries within a REC of which Ethiopia is a member.

#### **D. Dimension Four: Plant Variety Protection**

Ethiopia’s system contains both some innovative aspects and new developments with respect to PBR, including elements that reflect the needs of small farmers, although the legal and regulatory system

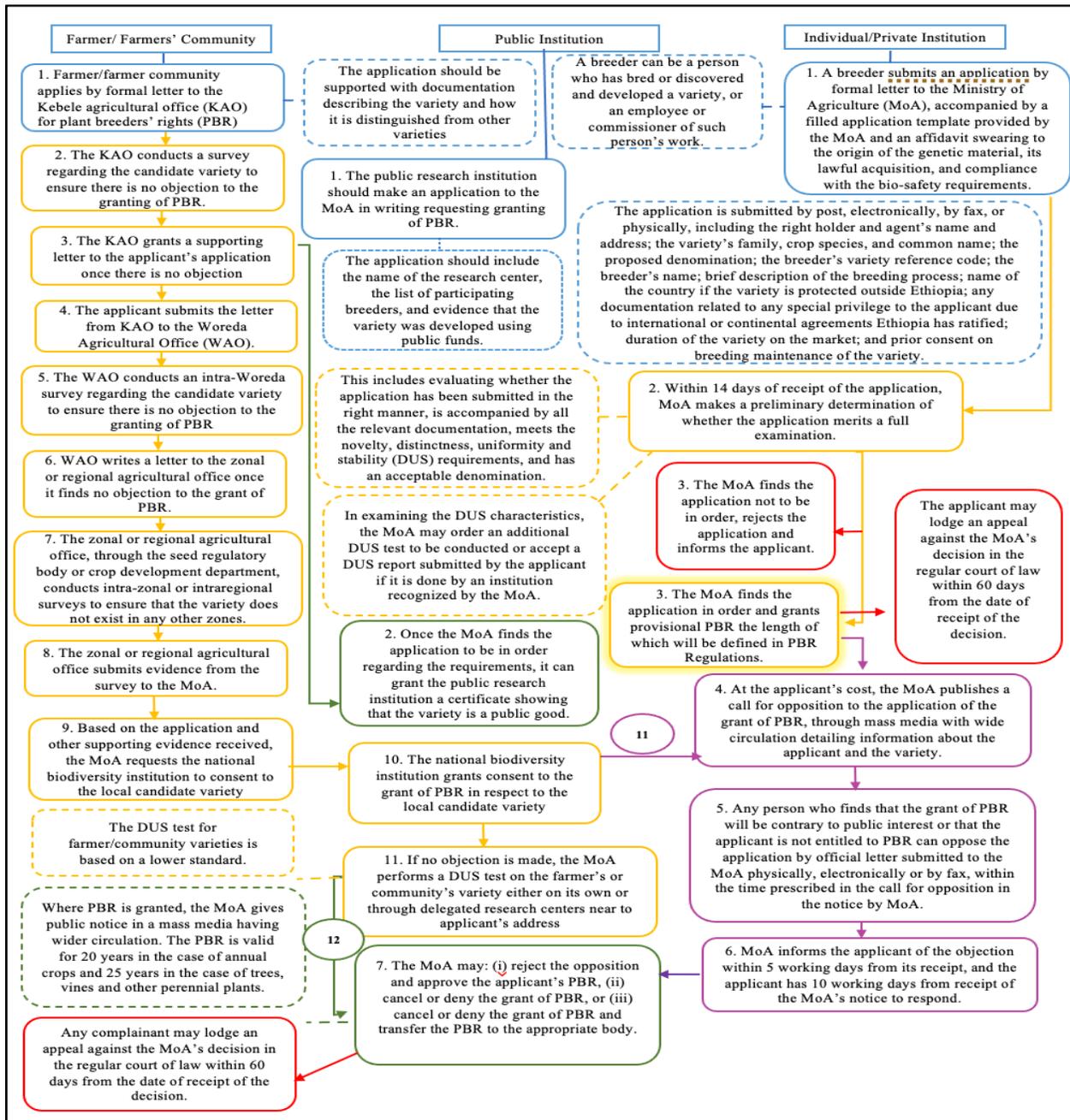
for PBR still contains gaps as well. The main PBR legal and regulatory instruments include the PBR Proclamation and PBR Directive. As one notable aspect of Ethiopia's PBR system, PBR is differentiated based upon whether the applicant is: (a) an individual (applies to private institutions too); (b) a farmer as an individual or as a community; or (c) a public research institution.

**Figure 10** below shows the RSM for the current system on plant breeders' rights in Ethiopia. Box 7 summarizes key findings for the current system, which are elaborated upon below.

#### **Box 7. Key Findings: Current System for Plant Breeder's Rights**

- The PBR system is not fully operational due to the absence of PBR Regulations and limited popularization of the PBR Directive.
  - There is a new PBR Directive aimed at implementing the PBR Proclamation, but it is yet to be popularized.
- A clear institutional framework for PBR is also not yet in place (this is highlighted in the shaded **Box 3** in **Figure 10**).
- The PBR Directive was commended for protecting farmers' rights, and the DUS test for farmers' varieties is also based on a more flexible standard.
  - The overall process, however, is long and could be better streamlined.

Figure 10: RSM on Plant Breeder's Rights in Ethiopia (*Current System*)



## 1. Current System and Key Issues in Plant Variety Protection

Under Ethiopia's current system, which was recently strengthened through the PBR Directive, varieties that are new, distinct, uniform, and stable,<sup>42</sup> with an acceptable denomination,<sup>43</sup> can be protected through PBR. The variety is new if the seed or harvested material had not been available on the commercial market for more than one year in the territory of Ethiopia, more than six years for varieties of trees or vines, or more than four years for any other species in the territory of any other country.<sup>44</sup> Although the PBR Directive strengthened the system, the legal framework on PBR/PVP remains incomplete, since regulations have not yet been issued.

The PBR Directive and 2013 Seed Proclamation do contain notable provisions relevant to small farmers. In the case of the 2013 Seed Proclamation, these include exceptions for (i) the use of farm-saved seed, (ii) the exchange or sale of farm-saved seed among smallholder farmers of agro-pastoralists, (iii) seed to be used for research purposes, and (iv) forestry seed.<sup>45</sup> Some provisions in the PBR Directive, however, require further clarification in this regard, including a provision suggesting that DUS for farmers' varieties be based on minimum QDS standards, which are qualitatively different than DUS standards. QDS standards are part of a seed quality control system, while DUS relates to the characteristics of the variety and its difference from other varieties and ability to be replicated with the same traits (see pink shaded box linked to **Step 11** of **Figure 10**).

Under the PBR Proclamation, a breeder can be a person who has bred or discovered and developed a variety, or an employee or commissioner of such person's work.<sup>46</sup> A breeder is entitled to apply for PBR with respect to a variety that meets prescribed criteria. The application process is set out in **Figure 10** and further elaborated in Annex IV. As depicted in **Figure 10**, under Article 6 of the PBR Directive farmers and farmers' associations/communities can also apply for PBR, along with public research institutions and individuals/private institutions. This is an important flexibility for small farmers,<sup>47</sup> but it is complicated by the provisions that conflate DUS and QDS standards, as referenced above.

PBR is one regulatory dimension in which inclusion and flexibility are particularly important. Although Ethiopia's system is notable in that it provides differentiation for small farmers and farmers' varieties, it both contains ambiguities (such as the confusion around DUS and QDS) and gaps. Other

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<sup>42</sup> PBR Proclamation, A 4.

<sup>43</sup> PBR Proclamation, A 12 and 13.

<sup>44</sup> PBR Proclamation, A 4.1(d).

<sup>45</sup> *Views, Experiences, and Best Practices as an Example for Possible Options for the National Implementation of Article 9 of the International Treaty*, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS AND INTERNATIONAL TREATY ON PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE, 2021.

<sup>46</sup> Plant Breeders' Rights Proclamation No.1068 of 2017 (PBR Proclamation), A 2.

<sup>47</sup> See Kuhlmann & Bhramar Dey, *Using Regulatory Flexibility to Address Market Informality in Seed Systems: A Global Study*, 11 AGRONOMY 1, 16 (2021), <https://www.mdpi.com/2073-4395/11/2/377>.

countries' rules and regulations do provide some good practices which could be considered in Ethiopia. For example, 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; use of an identifiability test could also make it easier for small farmers to register their varieties.<sup>48</sup> Other countries maintain more flexible approaches to PBR (e.g., India, Peru, Thailand and Vietnam) and variety registration (e.g., Peru, Brazil, and Benin).<sup>49</sup>

The new PBR Directive is also yet to be popularized, so most stakeholders are not aware of what it contains. Only one foreign company had applied for PBR with respect to some strawberry varieties, but the applications have not yet been processed.

## 2. Proposed System and Remaining Gaps and Ambiguities

Although the PBR Directive is new (2021), there are no PBR Regulations in place, and some gaps do remain that would need to be addressed through regulations. Reportedly, PBR Regulations will be introduced soon, which could address some of processes that are currently unclear in the PBR Proclamation, and need further explanation, as shown in **Figure 11** which contains the RSM for the proposed system for PBR. Box 8 contains key findings for the proposed PBR system.

### **Box 8. Key Findings: Proposed System for Plant Breeders' Rights**

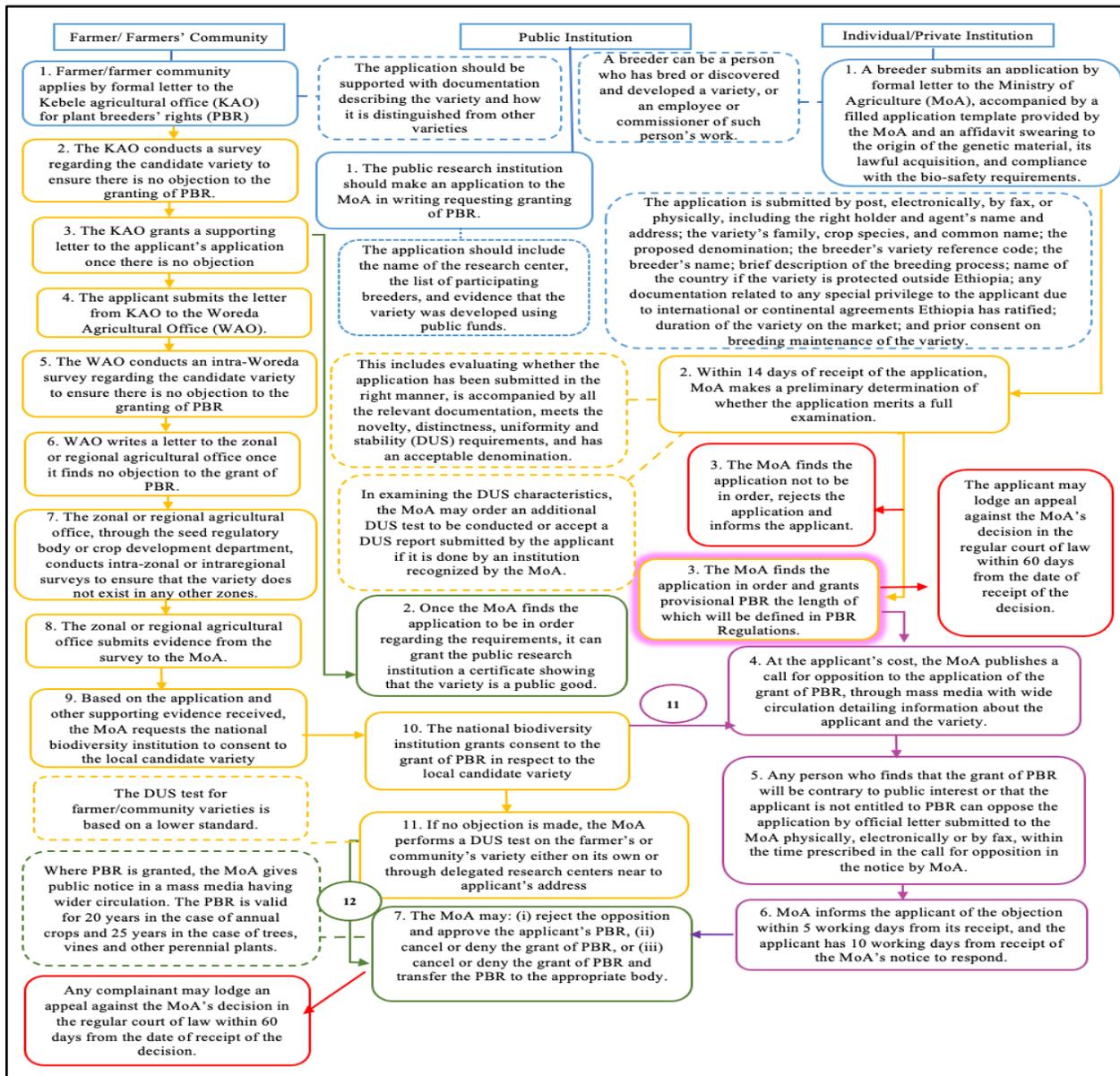
- Ethiopia has made great strides in closing gaps in the PBR system, in particular due to the 2021 PBR Directive, yet PBR Regulations will be needed in order to fully operationalize the PBR system.
  - For example, the process for provisional PBR will need to be laid out in the regulations.
- Awareness creation will be important, and the 2021 PBR Directive should be shared more widely.
- While it is notable that Ethiopia's PBR system provides flexibilities for small farmers, DUS for farmers' varieties is linked with minimum QDS standards, which is an error that needs to be revised through a binding legal instrument.

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<sup>48</sup> Kuhlmann & Dey, *Using Regulatory Flexibility to Address Market Informality in Seed Systems: A Global Study*, 11 AGRONOMY 1, 13-15 (2021), <https://www.mdpi.com/2073-4395/11/2/377>.

<sup>49</sup> *Id.*

Figure 11: RSM on Plant Breeder's Rights in Ethiopia (*Proposed System*)



In particular, implementation will be dependent upon approval of PBR Regulations that will define the length of provisional PBR, as depicted in the pink shaded box attached to **Step 3 of Figure 11**, and clarify provisions under the PBR Directive to align the DUS criteria for granting farmers' rights with international standards and best practices and de-link DUS from QDS standards (see pink shaded box linked attached to **Step 11 of Figure 11**).

According to stakeholder consultations, different key stakeholders, including MoA and ATA, have committed to popularizing PBR rules using different platforms. Institutions in both the private and public sectors saw the value of using the RSMs to help make regulatory processes known to key stakeholders.

### 3. Dimension Five: Seed Quality Control

In Ethiopia, the current seed quality control system is already somewhat diverse and differentiated, albeit government-controlled, and allows for compulsory seed certification (national level), approved seed (regional level), and QDS (regional level). The Draft Seed Proclamation will expand upon this system to incorporate more market-driven approaches. **Figure 12** below contains the RSM on the current system for seed quality assurance in Ethiopia. Box 9 contains key findings, which are elaborated upon in the sections that follow.

#### Box 9. Key Findings: Current System for Seed Quality Assurance

- 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 Figure 12**, 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.

Figure 12: RSM on Seed Quality Assurance Process in Ethiopia (*Current System*)



## 1. Current System and Key Issues in Seed Quality Assurance

Ethiopia's current system provides for three quality assurance schemes: compulsory certification, approved seed, and QDS, as shown in **Figure 12**. The RBoAs in Tigray, Oromia, Amhara, and the Southern Nations, Nationalities and People's Region (SNNPR) are responsible for seed quality control and assurance for all seed produced in the respective regions for the domestic market, while the MoA is responsible for verifying the seed quality of all imported and exported seed and seed sold throughout the country.<sup>50</sup> All seed must meet the quality standards set by the Ethiopian Standard Agency, based on ISTA, OECD, and regional standards, including under COMESA.<sup>51</sup> Any seed producer, importer, or exporter is required to have a certificate of seed quality issued by the RBoA for certified, QDS<sup>52</sup> or approved seed<sup>53</sup> at the regional level, and by the MoA for certified seed at the federal level. The QDS requirements are less demanding than those for formal seed certification and are thus often viewed as being less cumbersome for small seed producers and farmers.<sup>54</sup>

The following regulatory aspects are related to quality assurance schemes; (a) application and evaluation; (b) field inspection and analysis; (c) seed processing; (d) seed sampling; (e) laboratory testing; (f) issuance of certificate of quality; and (g) rejection and appeal. These steps are covered in Annex V, with several aspects relevant to obtaining a certificate of seed quality and field inspection and laboratory testing highlighted below. Gaps and ambiguities in these areas are also highlighted in the RSMs.

### *a) Application for a Certificate of Seed Quality*

For an applicant to be eligible to apply for a certificate of seed quality, the seed must be of a registered variety, the producer must hold a CoC, and the seed must be from a known source as depicted in the dotted box attached to **Step 1** (middle process) in **Figure 12**.<sup>55</sup> Applications are handled by the MoA or RBoA, as shown in **Figure 12** and further elaborated upon in Annex V. The RBoA or the MoA evaluates the application based on this supporting documentation as depicted in **Step 2** of **Figure 12**.

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<sup>50</sup> 2016 Regulation, r 18. *See also*, Karta K Kalsa, et al., *Status of Seed Quality Control and Assurance in Ethiopia: Required Measures for Improved Performance*, ETHIOPIAN INSTITUTE OF AGRICULTURAL RESEARCH, July 2020.

<sup>51</sup> Karta K Kalsa, et al., *Status of Seed Quality Control and Assurance in Ethiopia: Required Measures for Improved Performance*, ETHIOPIAN INSTITUTE OF AGRICULTURAL RESEARCH, 37 (2020), Available at: <https://www.researchgate.net/publication/343135414>.

<sup>52</sup> QDS is a viable alternative to formal certification, with set crop-specific requirements for field standards, facilities, field inspections, and seed quality, including those that follow the guidelines set by the Food and Agriculture Organization of the United Nations (FAO), (*See* Katrin Kuhlmann, *Planning for Scale Brief #6: Enabling Environment*, AGPARTNER XCHANGE, 2013).

<sup>53</sup> Approved seed means seed that is domestically produced or imported seed certified as conforming to the Ethiopian Seed Standards (see 2013 Seed Proclamation, A 2).

<sup>54</sup> Katrin Kuhlman, et al, *Seed Policy Harmonization in COMESA and SADC: The Case of Zambia*, NML AND SFSA (2019), [https://www.syngentafoundation.org/sites/g/files/zhg576/f/zambia\\_case\\_study\\_final\\_edit\\_8\\_march\\_2019\\_clean.pdf](https://www.syngentafoundation.org/sites/g/files/zhg576/f/zambia_case_study_final_edit_8_march_2019_clean.pdf).

<sup>55</sup> 2016 Seed Regulation, r 19.

Prior to issuance of the certificate of seed quality, the seed must undergo field inspection, processing, sampling, testing in an accredited laboratory, and affixation of a tag and seal on the seed packaging.<sup>56</sup> The certification process must be in alignment with ISTA requirements. This is highlighted in **Step 3** of **Figure 12**. Although Ethiopia is an ISTA member, there is not yet an ISTA-accredited laboratory.<sup>57</sup>

At the regional level, a seed producer may apply to the RBoA for a certificate of QDS.<sup>58</sup> This is set out in shaded box attached to **Step 1** on the right-hand side of **Figure 12** and Annex V. A 2015 Directive on QDS signaled the importance of QDS in terms of supplying quality seed to farmers and its role in covering agro-ecology and crop types which are not covered by the formal seed system. Key provisions in the QDS directive include: (i) coverage in terms of crop varieties; (ii) actors that may engage in QDS production; (iii) QDS quality assurance; (iv) procedures and requirements for variety registration, CoCs, packaging, labeling, and distribution; and (v) roles and responsibilities of relevant stakeholders in local variety registration, QDS production, and marketing. In this analysis, the basic provisions covering procedures and requirements to obtain a CoC, quality assurance, and marketing were considered.

QDS applies to local varieties, excluding hybrids, forest seed, and any seed to be sold in the formal seed sector.<sup>59</sup> Only farmer groups or farmer cooperatives are eligible to produce QDS, and they should have the sufficient land, equipment, storage, farm equipment, hired professionals or those assigned by the woreda office, and an internal quality control system in place to ensure that field standards are maintained during production.<sup>60</sup> Marketing of QDS is limited to designated areas. Relevant aspects of QDS are depicted in Step 2 of the right-hand side of the RSM on the current system for seed quality assurance. Additional detail on QDS is included in Annex V.

#### *b) Field Inspection, Analysis, and Laboratory Testing*

Seed must meet field and laboratory standards prior to certification. Field inspection is aimed at assessing genetic purity and ascertaining that contamination does not occur during any stage of production. After field inspections, samples are collected for laboratory testing,<sup>61</sup> which is done in accordance with ISTA rules. Seed that does not comply with the field and laboratory standards will be rejected. Sub-steps within seed quality assessment (including field inspection and seed processing, sampling, and testing) are described in greater detail in Annex V, as is the process for issuance of a certificate of quality, rejection and appeal.

Stakeholder consultations revealed challenges in the current quality control process, particularly with respect to field inspections, where inadequate staffing is an issue both in terms of number and capacity. Other issues include limited staff mobility due to shortage of vehicles, inconsistency in implementing

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<sup>56</sup> 2016 Seed Regulation, r 22 to 30.

<sup>57</sup> *IMENA Ethiopia Public Seed Sector Services*, MINISTRY OF FOREIGN AFFAIRS ETHIOPIA, 15 (2020) <https://www.rvo.nl/sites/default/files/2020/03/IMENA-Ethiopia-Public-Seed-Sector-Services.pdf>.

<sup>58</sup> 2016 Seed Regulation, r 22.

<sup>59</sup> 2015 Directive on QDS, article 5.2.

<sup>60</sup> 2015 Directive on QDS, article 9.1.

<sup>61</sup> 2016 Seed Regulation, r 124, 26, 27, and 28.

a grow-out test, and limitations in seed tracking systems, as depicted in the blue shaded box attached to **Step 3** in **Figure 12**.<sup>62</sup> EIAR has, for instance, stated that the field inspector to farm size ratio in Ethiopia was 1:3224 ha in 2020, which is bleak compared with other countries like Zambia where the inspector to area ratio per season is 1:400 ha or India, where it is 1:320 ha per season.<sup>63</sup>

Consultations also revealed that some of the laboratory testing is not based on new protocols by ISTA, which affects seed quality, as depicted in the blue shaded box to **Step 7** in **Figure 12**. Moreover, efficiency and efficacy of laboratory services varies across the different regions. For instance, at the regional level, only Oromia, SNNPR, and Tigray have laboratories at almost all of their offices. However, these are not fully equipped. For instance, seed laboratories tend to have facilities to conduct testing activities for the exiting testing protocols: purity, moisture, and germination tests; however, they lack facilities to test additional seed quality parameters based on new protocols related to seed health, variety quality, and vigor, among other things.<sup>64</sup>

## 2. Proposed System and Remaining Gaps and Ambiguities

The Draft Seed Proclamation will address a number of gaps in the seed quality assurance system and usher in important changes. These changes are shown in the yellow shaded areas in **Figure 13** which contains the RSM on the proposed seed quality assurance process.

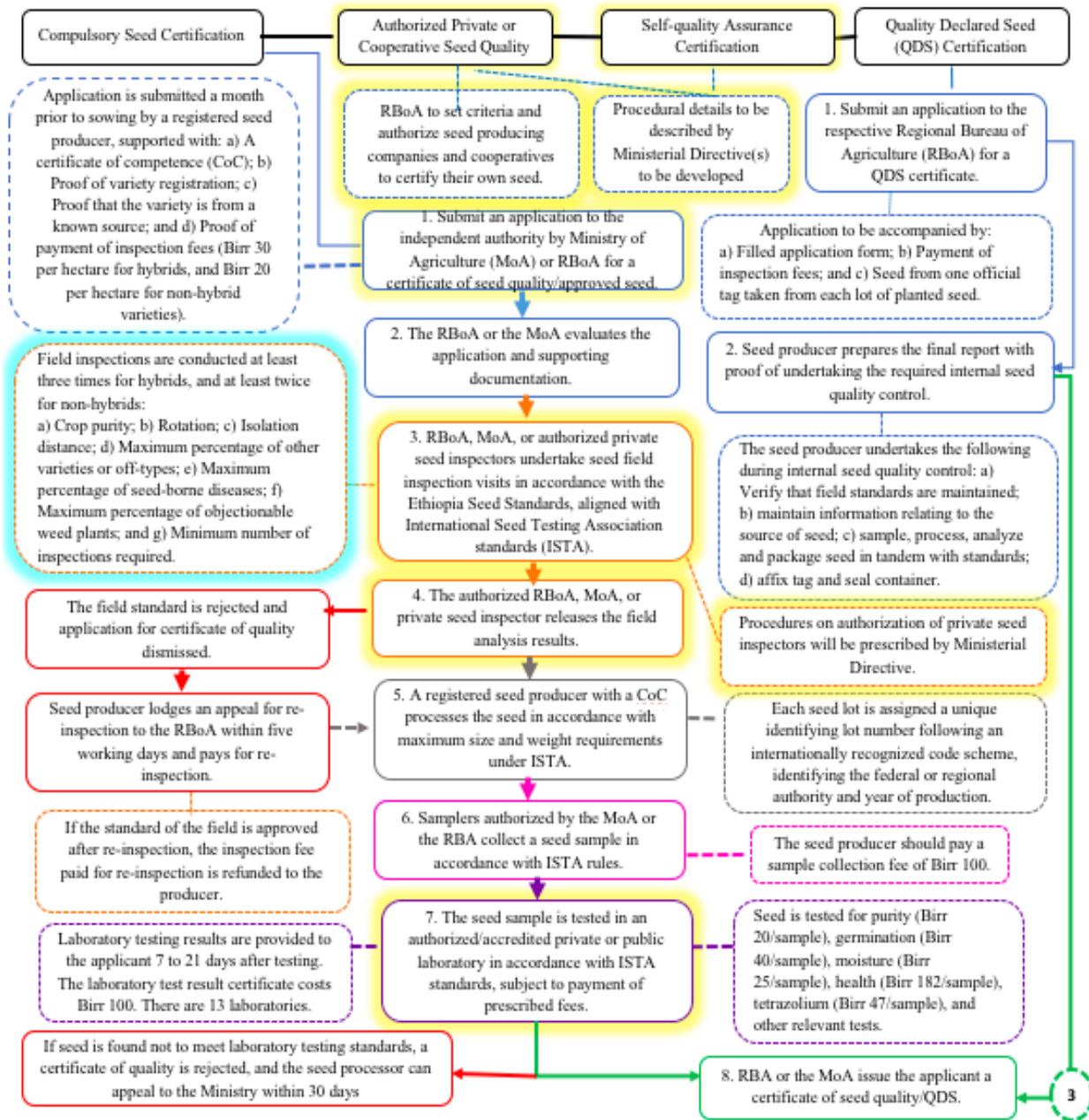
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<sup>62</sup> See also, Karta K Kalsa, et al., *Status of Seed Quality Control and Assurance in Ethiopia: Required Measures for Improved Performance*, ETHIOPIAN INSTITUTE OF AGRICULTURAL RESEARCH, 33 (2020), <https://www.researchgate.net/publication/343135414>.

<sup>63</sup> Karta K Kalsa, et al., *Status of Seed Quality Control and Assurance in Ethiopia: Required Measures for Improved Performance*, ETHIOPIAN INSTITUTE OF AGRICULTURAL RESEARCH, 33 (2020), <https://www.researchgate.net/publication/343135414>

<sup>64</sup> Karta K Kalsa, et al., *Status of Seed Quality Control and Assurance in Ethiopia: Required Measures for Improved Performance*, ETHIOPIAN INSTITUTE OF AGRICULTURAL RESEARCH, 33 (2020), <https://www.researchgate.net/publication/343135414>

Figure 13: RSM on 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

As shown in **Figure 13**, the Draft Seed Proclamation will significantly change the legal/regulatory and institutional landscape at the federal and regional levels for seed quality assurance. This is depicted in the yellow shaded boxes in the RSM. Box 10 below contains key findings for the proposed system.

#### **Box 10. Key Findings: Proposed System for Quality Assurance**

- The Draft Seed Proclamation introduces additional alternate mechanisms for seed quality assurance, including self-quality assurance and private sector involvement.
  - Self-quality seed certification will be introduced, with oversight by the relevant federal and regional institutions (details of this approach forth coming in a Directive)
  - Private seed inspectors will be authorized to conduct field inspection by the relevant federal and regional institutions (this is depicted in the yellow shaded box attached to **Step 3** in **Figure 13**)
  - Private seed laboratories that meet international ISTA standards will also be eligible for authorization to conduct laboratory tests (this is depicted in **Step 7** in **Figure 13**).
- Independent certifying authorities will be expanded at the federal and national levels (this is depicted in **Step 2** in **Figure 13**; these already exist in some regions)

As one important change, the Draft Seed Proclamation also proposes the authorization of private seed inspectors by the relevant federal and regional institutions to conduct field inspections (see yellow shaded box associated with **Step 3** in **Figure 13**). Self-quality seed certification is also included in the Draft Seed Proclamation, which will have the effect of vesting seed quality assurance in private seed companies and farmer’s cooperatives, with oversight by the relevant federal and regional institutions.

The Draft Seed Proclamation also proposes the authorization of private seed laboratories that meet international ISTA standards to conduct laboratory testing, as depicted in the yellow shaded box for **Step 7** in **Figure 13**. It further aligns the certification process with internationally-recognized standards, including testing, seed classes, and coloring requirements, which are also requirement under regionally aligned rules like the COMESA Seed Trade Regulations. These changes will be dependent upon the enactment of the Draft Seed Proclamation and revision of the 2016 Seed Regulations to make specific recognition of seed labels issued by RECs of which Ethiopia is a member.

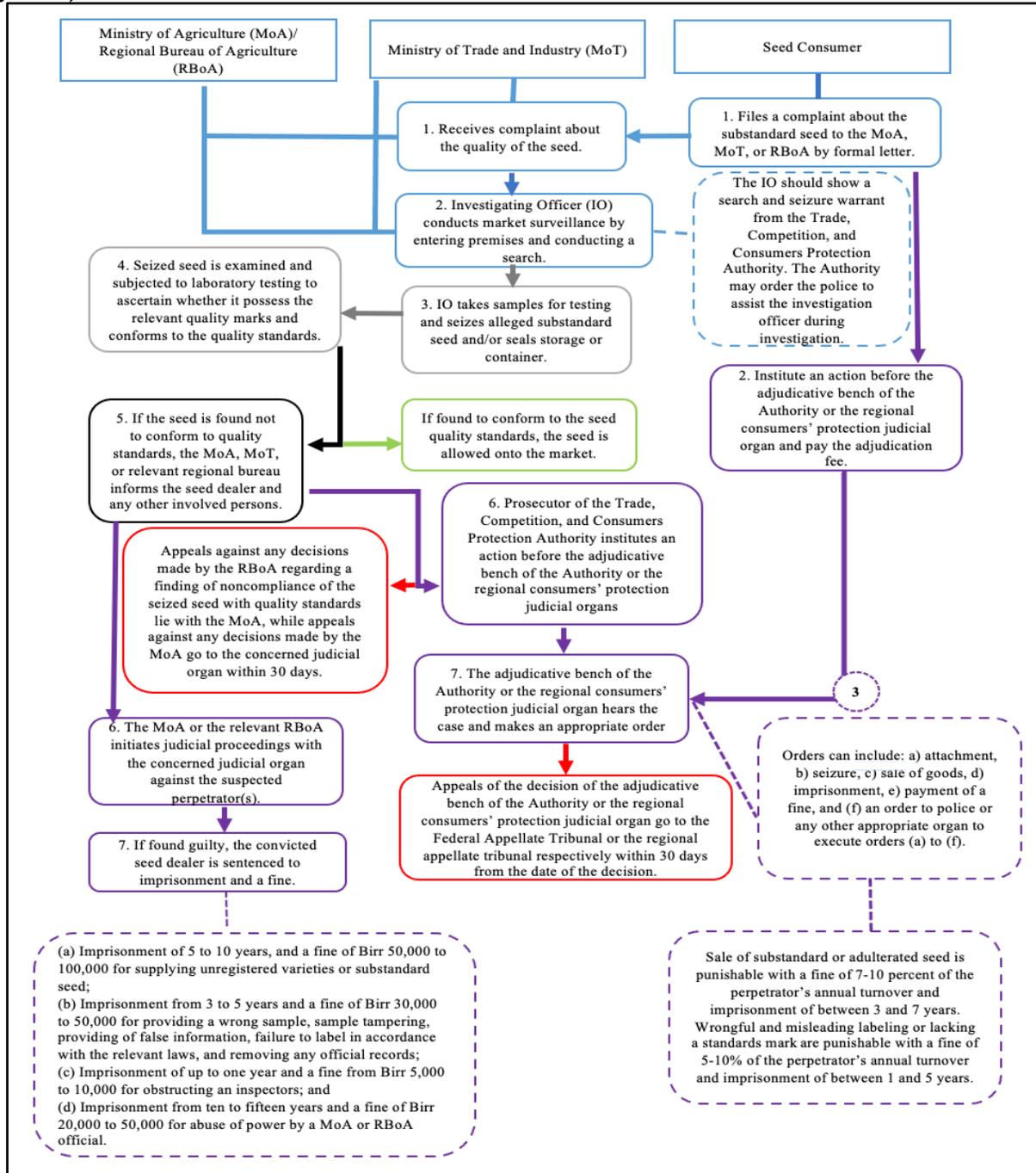
#### **4. Dimension Six: Anti-Counterfeiting and Consumer Protection**

The quality of seed can be affected at any stage throughout the seed value chain. To ensure seed quality, RBoAs enforce anti-counterfeiting measures at the regional level, and the MoA enforces them at the national level. Anti-counterfeiting measures include prosecution, fines, damages, imprisonment, impromptu searches, and seizures, among others. Despite these processes, stakeholders noted that the level of enforcement in practice depends upon the capacity of the RBoA. **Figure 14** below contains the RSM on the current system for enforcement of anti-counterfeiting measures in Ethiopia. Box 11 below contains key findings on the current system for anti-counterfeiting, which are elaborated upon below.

**Box 11. Key Findings: Current System for Anti-Counterfeiting**

- Legal framework provides for three ways in which counterfeit seed can be addressed:
  - Enforcement by the MoA and RBoAs under seed and standards laws;
  - Enforcement by Ministry of Trade and Industry under the laws on consumer protection;
  - Enforcement by the seed consumer under laws on consumer protection.
- Legal framework lacks provisions in key areas, such as the process for filing a complaint against trade in counterfeit seed, process of informing seed dealers of conforming or non-conforming seed, and the appeal process, although stakeholder consultations with MoA clarified these processes do exist in practice.

Figure 14: RSM on Enforcement of Anti-counterfeiting Measures in Ethiopia (*Current System*)



## 1. Current System and Key Issues in Anti-Counterfeiting Enforcement

Addressing challenges with counterfeit and adulterated seed is a pressing challenge for many governments, and Ethiopia's current system both provides some structure and contains gaps in this area. Because of the importance of ex-post controls in anti-counterfeiting (i.e., enforcement measures and institutions), the sections below and RSMs focus in particular on this aspect across institutional stakeholders.

The legal framework for addressing counterfeit seed in Ethiopia is contained in the 2013 Seed Proclamation, Ethiopian Standards Agency Establishment Council of Ministers Regulation No. 193/2010, and Proclamation No. 813/2013 on Trade, Competition and Consumer Protection (Consumer Protection Proclamation). Relevant provisions are presented below and in Annex VI.

### *a) Enforcement by the MoA and RBoAs*

Under the Ethiopian Standards Agency Establishment Council of Ministers Regulation No. 193/2010, relevant federal and regional law enforcement bodies are given powers to: (a) prohibit the import or export of products that do not meet the national standards; (b) undertake market surveillance and take control measures to ensure conformity of products with the relevant standards requirements; (c) seize products that do not conform with the standards and only authorize their re-introduction to the market after taking the necessary corrective measures or to decide the manner of their disposal where corrective measures are not possible and that they may entail a threat to the health or safety of consumers; and (d) to engage the services of reliable conformity assessment bodies to ascertain whether or not products and services available in the market conform to the standard requirements declared by their suppliers or to the quality marks of conformity assessment bodies they are using.<sup>65</sup> The seed standards enforcement bodies are the MoA at the federal level and the RBoAs at the regional level, as shown in the blue square boxes on the left-hand side of **Figure 14**.<sup>66</sup>

MoA or RBoA can receive a complaint about the quality of the seed from a consumer, as depicted in the left-hand box for **Step 1** of **Figure 14**. An authorized investigation officer (IO) in MoA or the respective RBoA can undertake market surveillance or receive complaints from seed users about seed suspected not to conform to seed standards and carry out an investigation to assess the truth of the allegations as per **Step 2** of **Figure 14**. Following market surveillance and investigation of customers' complaints, the inspector may seize seed that is suspected not to be in conformity with the seed standards, as highlighted in **Step 3** of **Figure 14**. Seized seed will be examined and laboratory tested to ascertain whether it possess the relevant quality marks and conforms to the standards, as set out in **Step 4** of **Figure 14**. If found to conform, the seed is allowed to enter the market (see green box attached to **Step 5** of **Figure 14**). If the seed is found not to conform to the quality standards, the

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<sup>65</sup> Article 15 of the Ethiopian Standards Agency Establishment Council of Ministers Regulation No. 193/2010

<sup>66</sup> Seed System Development Strategy, Vision, Systemic Challenges, and Prioritized Interventions, MOA ETHIOPIA ETHIOPIAN AGRICULTURAL TRANSFORMATION AGENCY, 47 (2016).

MoA or the relevant RBoA informs the seed dealer and any other involved persons, as highlighted in the box attached to **Step 5** of **Figure 14**.

The 2013 Seed Proclamation prohibits trade in substandard seed in Ethiopia, providing different penalties for various offenders, as set out in the dotted pink box attached to **Step 7** of **Figure 14**; If found guilty, a convicted seed dealer is sentenced to imprisonment and a fine. Appeals against any decisions made by the RBoA regarding the findings about the compliance of the seized seed with the quality standards should be lodged with the MoA within thirty days; while appeals against any decisions made by the MoA must be lodged with the concerned judicial organ within thirty days (see box attached to **Step 5** of **Figure 14**).<sup>67</sup> The MoA or the relevant RBoA may initiate judicial proceedings against the perpetrator(s), which could result in their imprisonment and payment of the prescribed fines listed above. The MoA or relevant RBoA can dispose of seed that is found to be non-compliant.

To ensure the quality of marketed seed and reduce cases of counterfeit and fake seed, the MoA and RBoAs reported that under the Ministerial Directive on Direct Seed Marketing, they supervise companies to assess whether they have the appropriate CoCs and proper storage, as well as evaluate the quality of seed for sale. Currently, however, these inspections are only conducted in a few Woredas within selected regions.

Consulted stakeholders noted that while some court cases have been brought by RBoAs against alleged perpetrators, in addition to enforcement by police through market surveillance, enforcement against counterfeit seed generally depends upon the resourcefulness of the respective regional authority, and some have less capacity than others.

#### *b) Enforcement by the Ministry of Trade and Industry*

There are also rules on consumer protection under the Consumer Protection Proclamation, which aim to safeguard market stakeholders against substandard goods. The Consumer Protection Proclamation also creates a Trade, Competition, and Consumers Protection Authority (Authority) responsible for protecting consumers from defective goods on the market, among other things. Where goods are defective or likely to cause damage, an individual or entity may file a complaint with the Ministry of Trade and Industry, any of its regional Bureaus, or any other appropriate regional organ, which can include the RBoA, as depicted in blue box associated with **Step 1** of **Figure 14**.<sup>68</sup> The Authority has the power to conduct investigations and searches and seizures, as set out in **Step 3** of **Figure 14** and Annex VII.<sup>69</sup> The relevant authority may enlist the police at the federal or regional level to assist in investigation activities. Based on a hearing, the adjudicative bench of the Authority or the regional consumers' protection judicial organ could decide and make an order of: (i) attachment, (ii) seizure, (iii) sale of goods, (iv) imprisonment, and/or (v) payment of a fine (this is shown by the pink

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<sup>67</sup> 2013 Seed Proclamation, 25.

<sup>68</sup> Consumer Protection Proclamation, A 20.

<sup>69</sup> Consumer Protection Proclamation, A 36(4).

dotted box attached to **Step 7** of **Figure 14**).<sup>70</sup> These bodies can also order the police or any other appropriate organ to execute their orders.

Under the Consumer Protection Proclamation, sale of substandard or adulterated seed is an offence punishable with a fine of 7-10 percent of the perpetrator's annual turnover and imprisonment from three to seven years.<sup>71</sup> Wrongful and misleading labeling or selling product without a standards mark<sup>72</sup> are also offences punishable with a fine of 5-10 percent of the perpetrator's annual turnover and imprisonment from one to five years.<sup>73</sup> This is depicted in the pink dotted box attached to **Step 7** of **Figure 14**.

An appeal of the decision of the adjudicative bench of the Authority or the regional consumers' protection judicial organ goes to the Federal Appellate Tribunal or the regional appellate tribunal respectively within 30 days from the date of the decision.<sup>74</sup> The decisions of the appellate bodies are final, except where the appellant claims the existence of mistake on question of law regarding a decision passed by the appellate body, in which case a further appeal will be lodged with the Federal Supreme Court within 30 days from the date of the decision.<sup>75</sup> The appeal process is set out in the pink shaded box attached to **Step 7** of **Figure 14**.

#### *c) Enforcement by the Seed Consumer*

The consumer may demand a refund or replacement of defective seed within fifteen days of purchase.<sup>76</sup> Where the consumer has suffered damage from the use of such substandard seed, the consumer could claim compensation from the persons who have participated in the supply of such substandard seed, including the manufacturer, importer, wholesaler, and retailer for damage suffered as a result of purchase or use of the seed.<sup>77</sup> The claim for compensation is made by instituting an action before an adjudicative bench of the Authority in the case of a transaction conducted in the Addis Ababa or the Dire Dawa city administrations or before the regional consumer protection judicial organ in the case of a transaction conducted in a region,<sup>78</sup> subject to payment of an adjudication fee.<sup>79</sup> If dissatisfied with the decision of the adjudicative bench of the Authority or the regional consumers' protection judicial organ, the consumer could lodge an appeal.

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<sup>70</sup> Consumer Protection Proclamation, A 38.

<sup>71</sup> Proclamation No. 813/2013 on Trade, Competition and Consumers Protection (Consumer Protection Proclamation), s 43(2).

<sup>72</sup> Consumer Protection Proclamation, A 22.

<sup>73</sup> Consumer Protection Proclamation, A 43(2).

<sup>74</sup> Consumer Protection Proclamation, A 39.

<sup>75</sup> Consumer Protection Proclamation, A 39.

<sup>76</sup> Consumer Protection Proclamation, A 20.

<sup>77</sup> Consumer Protection Proclamation, A 14(5) and 20.

<sup>78</sup> Consumer Protection Proclamation, A 37(3).

<sup>79</sup> Consumer Protection Proclamation, A 40.

## 2. Proposed System and Remaining Gaps and Ambiguities

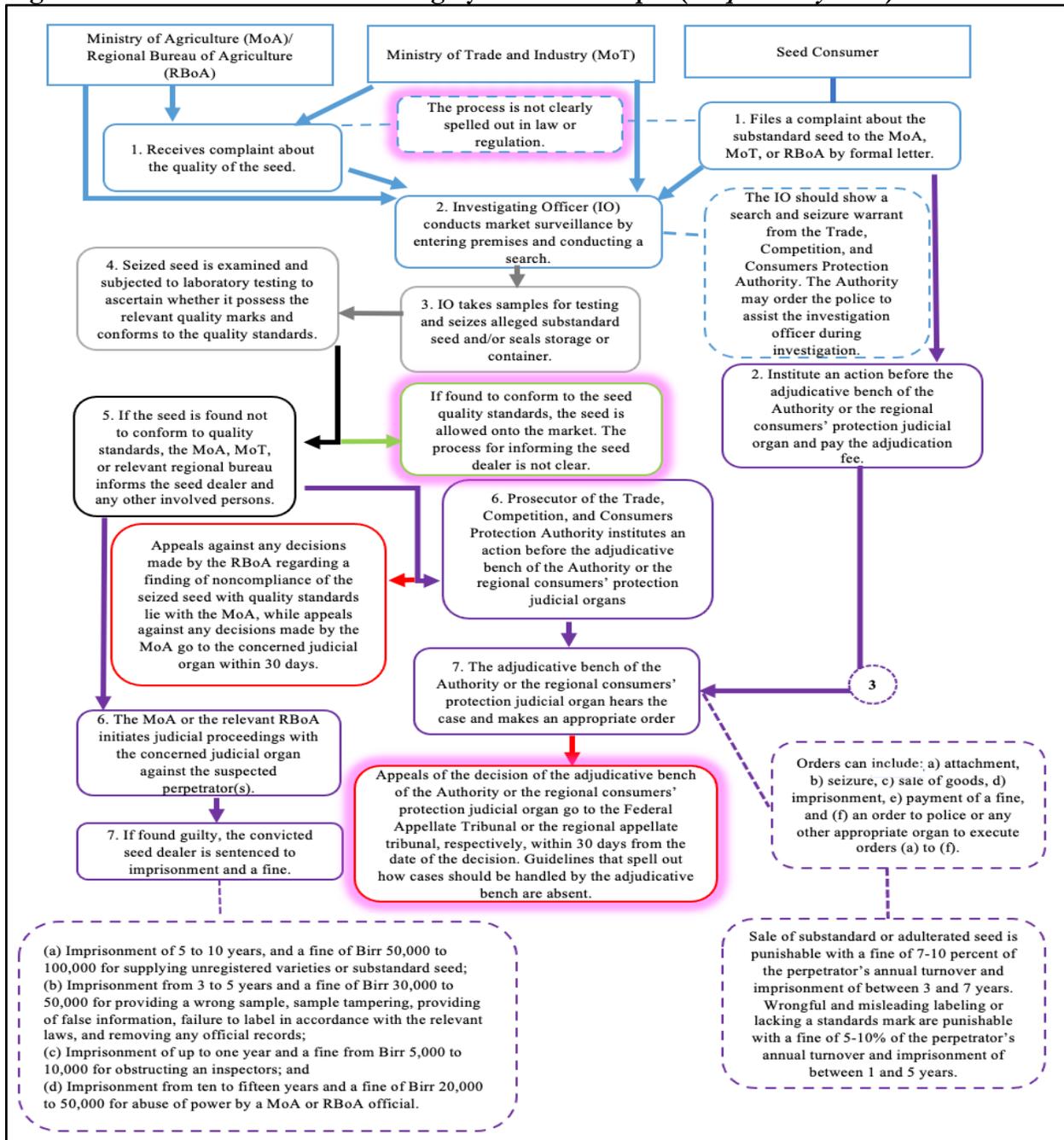
While the Draft Seed Proclamation is largely silent on anti-counterfeiting measures, several important aspects of anti-counterfeiting need to be clarified, as discussed in the preceding section. In particular, the current legal framework lacks provisions on the process for filing a complaint against trade in counterfeit seed, the process of informing seed dealers of conforming or non-conforming seed, and the appeal process, although stakeholder consultations with MoA clarified that these processes do exist in practice, as depicted in the pink shaded boxes in the RSM on the Current System for Enforcement of Anti-Counterfeiting Measures.

The RSM on the proposed anti-counterfeiting system, which highlights key gaps, is shown in **Figure 15**. Box 12 contains key findings, which are elaborated upon below.

### **Box 12: Key Findings: Proposed System for Enforcement of Anti-Counterfeiting Measures**

- MoA and RBoAs supervise companies to assess whether they have the appropriate CoC and proper storage, and they also assess the quality of seed that is for sale. These inspections are only conducted in a few Woredas within selected regions and could be expanded.
- Stakeholders noted that enforcement of counterfeit seed is primarily done at the regional level and depends on the resourcefulness of respective regional authority, making enforcement consistent.
  - Stakeholder noted some court cases were brought by the RBoA against alleged perpetrators, in addition to enforcement by police through market surveillance.
- Several important regulatory aspects of this dimension require more detailed provisions. These are depicted in the pink shaded steps in the RSM on the Proposed System.
  - Process for filing a complaint is not clear in the legal framework, although consultations with MoA noted that a formal letter can suffice.
  - Process of informing seed dealer of conforming or non-conforming seed not clear.
  - Appeals process not clear.

Figure 15: RSM on Anti-counterfeiting System in Ethiopia (*Proposed System*)



**Key**

- Complaint, Inspection and Seizure
- Testing and Investigation
- Compliant Seed
- Noncompliant Seed
- Judicial Proceeding
- Appeal
- Notes
- Areas require further detailed regulations, directives, or guidelines

While changes are not included in the Draft Seed Proclamation related to anti-counterfeiting measures, it would still be possible to clarify ambiguities in the system related to the process for filing a complaint, the process of informing seed dealers whether seed conforms to standards or not, and the appeal process. These could be clarified through additional changes to the Draft Seed Proclamation or through another legal and regulatory instrument.

Inspections are also reportedly an issue, as they are only conducted in a few Woredas within selected regions, making country-wide enforcement a challenge. Expanding inspection capacity and making it consistent across regions deserves greater focus as Ethiopia's seed system continues to grow. Nevertheless, however, stakeholders did report some cases against perpetrators and policy enforcement through market surveillance, signaling that the system is beginning to work.

### III. Recommendations and Conclusion

Validation and discussions of findings have led to recommendations that are prioritized based on priorities for the short term, medium term and finally, priorities for the longer-term.

The following recommendations focus on interventions that could be taken to improve Ethiopia's regulatory framework and seed industry by extension. Since all recommendations cannot be implemented at once, they have been classified into short-, medium-, and long-term interventions, beginning with those that are already in the pipeline, followed by those that would require additional work to be undertaken. Implementation of these recommendations will require collective stakeholder involvement, including public-private partnerships, and support from development partners. Across the recommendations, and as highlighted in the RSMs, opportunities arise for making the seed system more inclusive and building needed capacity.

#### A. Short-Term Recommendations – Focus on “Gateway” Changes vis Instruments Already in Draft (Including Seed Proclamation and Directives):

1. Priority gaps and areas of ambiguity highlighted in this Report could be incorporated into the Draft Seed Proclamation, which is close to being finalized:
  - Include CoC on Variety Development and Research to enable the private sector to more fully engage in EGS and align with the 2020 Seed Policy, simultaneously addressing key gaps in the dimensions on varietal development and the CoC (Note: While the Draft Seed Proclamation adds a CoC for pre-basic seed production, it does not address this issue, and the provisions in the 2020 Seed Policy on a CoC on Variety Development and Research are dependent upon further action through a binding legal instrument.)
  - Streamline the import permitting process for parent material to enable private sector involvement in varietal development and research.
  - Clarify important issues related to DUS testing, namely: (a) development of DUS protocols to support the requirement for DUS testing, and (b) clarification that DUS testing is distinct from QDS standards (this is particularly important for the inclusion of small farmers and bridges the varietal release and PBR dimensions; over the long-term, changes would have to be made to the PBR Directive, as noted below).
  - Address inclusion issues by legally mandating the involvement of women and the private sector in the NVRC (this could also be done through revision of the Variety Release Policy and Mechanism Manual of 2001). Although the Seed Policy calls for this, it is not currently operational in practice.
  - Fully align with regional seed rules like the COMESA Seed Trade Harmonization Regulations by defining “prioritized development goals” to include varieties that have been released in at least two countries of a REC in which Ethiopia is a member.

- Include flexible requirements for smallholder farmers to obtain a CoC to ensure their inclusion in the formal sector (this is also an important inclusion issue, which has implications across all dimensions; it could also be addressed through the Ministerial Directive on Criteria and Implementation Procedures for Issuing CoC).
  - Clarify provisions on several aspects of anti-counterfeiting, such as the process for filing a complaint, the process of informing seed dealers whether seed is conforming or non-conforming, and the appeal process, all of which are unclear in the legal framework.
2. As noted, the 2020 Seed Policy includes important provisions on alignment of the seed legal framework with regional seed laws and international best practices, but this is contingent upon approval of the Agriculture and Rural Development Policy (the policy is already in draft form and awaiting approval from the Council of Ministers), which would give full effect to the 2020 Seed Policy.
  3. Improved access and availability of EGS will be dependent upon licensing of public varieties by PRIs and approval of the Ministerial Directive on Licensing of Public Varieties and corresponding guidelines (the directive is already in draft form and awaiting ministerial signature).
  4. Programs to build capacity and raise awareness should be undertaken in the short-run and expanded upon in the medium- and long-terms. This will be especially important as the rules surrounding the seed system change and should be targeted at farmers, small enterprises, and larger enterprise alike.

## B. Medium-Term Steps (Modify Other Legal/Regulatory Instruments):

1. Simplification of the process for variety release and registration should be a priority, which is dependent upon several steps:
  - Revision of the Variety Release Policy and Mechanism Manual of 2001 to legally mandate the inclusion of women and private sector in the NVRC (this process involves the Ministry of Agriculture revising the Manual and forwarding it to the Minister for signature).
  - Approval of DUS protocols for wheat and barley by the MoA, and development of DUS Protocols for other crops.
  - Revision of the Service Fee Regulation to include fees involved in the variety registration process, including DUS and VCU testing, that is reflective of the current economic status.

2. The legal and regulatory framework for PBR has undergone important changes, and its implementation will depend upon approval of the draft PBR Regulations and clarification of several key provisions in the PBR Directive:
  - Alignment of the DUS criteria for granting farmers' rights with international standards and best practices and de-linking of DUS from QDS standards under the PBR Directive, as the two are qualitatively different.
  - Definition of the length for provisional PBR under the PBR Proclamation and PBR Directive.

### C. Long-Term Steps (Align with Regional Developments Underway):

Over the longer-term, the certification process will need to be aligned with internationally recognized seed classes and coloring requirements, which is also a requirement under the COMESA rules. This will depend upon revision of 2016 Seed Regulations to make specific recognition of seed labels issued by Regional Economic Communities of which Ethiopia is a member.

### D. Summary of Legal Instruments that Require Revision and Approval

1. The Draft Seed Proclamation
2. The 2016 Seed Regulations
3. The Draft PBR Regulations
4. The PBR Directive
5. The Variety Release Policy and Mechanism Manual of 2001
6. The Ministerial Directive on Criteria and Implementation Procedures for Issuing CoC
7. The Ministerial Directive on Licensing of Public Varieties

### E. Impact and Measurement

Liberalizing the seed sector requires accountability and ownership. In addition to assessing whether the sector at large is moving in the desired direction, stakeholders could use key metrics for communication purposes and to foster greater transparency between different regulatory value chain actors in the seed systems. Table 3 below provides illustrative indicators to capture the dynamic components of the regulatory arena.

Table 3: Proposed Indicators to Track Systemic Progress

<b><i>Dimensions</i></b>	<b>Issues</b>	<b>Proposed indicators</b>
<b><i>Varietal research, development, and transfer</i></b>	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
<b><i>Seed dealer registration</i></b>	Seed producers contracting land holders	# of contractual arrangements made (per year – age and gender disaggregated)
<b><i>Variety registration and release</i></b>	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, and private sector entities # of times the NVRC convenes per year
<b><i>PBR</i></b>	Share PBR directive widely	# of stakeholders participated in the sensitization of the directive (age and sex disaggregated)
<b><i>Seed quality assurance</i></b>	Seed certification is delayed	Amount of time (in # of days) taken for seed certification (disaggregated by types of applicants)
<b><i>Anti-counterfeiting</i></b>	Some regional authorities have less capacity than others.	# of court cases filed; Guidelines established and shared in the public domain

## F. Conclusion

Ethiopia's seed system is in the process of ushering in significant reforms. Alongside these reforms, however, several factors should be considered to ensure that changes in the legal and regulatory system deliver the desired impact.

First, financial and operational planning and accountability will be needed to execute many of the changes proposed in the new seed rules. For example, a new institutional structure has been put forward for the seed sector (reportedly called the 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, as discussed above.

As emphasized throughout this Report, 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 Ethiopia's system 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.

Finally, given the different initiatives focused on Ethiopia's seed systems, sectoral coordination and co-location will be critical to raising awareness, engaging stakeholders, and building capacity as rules, institutions, and system overall evolve.

## Annex I: List of Stakeholders Consulted

### Public Sector Stakeholders

No.	Institution	Respondent	Position	Contact: email/Tel.
1.	Ethiopian Institute of Agricultural Research	Abebe Atilaw Dr.	Lead, EGS Production	
2.	EIAR	Karta Kalsa Dr	Director, Technology Multiplication and Seed Research	
3.	EIAR	Taye Tadesse Dr.	Director Crop Production	
4.	Amhara Regional Agricultural Research Institution (RARI)	Semagn Asredie Kolech Dr.	Director Seed Technology	
5.		Alemayem Assefa Dr.	Crop Director	
6.	Oromia RARI	Assefa Taae Dr.	DDG	
7.	Ministry of Agriculture, Plant Variety Release, Protection and Seed Quality Control Directorate	Medemedemiyaw Nekenkie Debaleke	Senior Agronomist and specialist on variety release and registration	
8.		Fisseha Teshone Abebe	Variety Release/registration case team leader	
9.	Haramaya University	Firew Mekbib Dr.	Chairperson, National Variety Release Committee	
10.	Ministry of Agriculture	Mesfin Melaku Abebe	Variety Release/Registration Senior Expert	
11.	Ministry of Agriculture MoA	Girma Bekele	Director General, Plant Variety Release, Protection and Seed Quality Control Directorate	
		Medememedemiyaw Nekenkie Debaleke	Plant Variety Release, Protection, and Seed Quality Control Directorate	
12.		Belete Siefu	Director Legal Services Advisor	
13.		Anteneh Girma Dr.	Policy Advisor to the Minister	
14.		Tefera Zeray	Advisor	
15.		Mandefro Negussie Dr.	CEO (In person briefing about the Study)	
16.	Amhara Regional Bureau of Agriculture (RBoA)	Gurmesa	Quality Control/Inspection	
17.				
18.	Oromia RBoA	Messeretu Lemma	Regulatory Directorate Head	
19.	Ministry of Agriculture	Girma Bekele	Director, Plant Variety Release, Protection and Seed Quality Control Directorate	
20.	ATA	Anteneh Girma	PBR Project Lead	

21.	ATA	Dr. Yitbarek Semane	Advisor to CEO/Seeds	
22.	GIZ	Dawit Tsegaye	GIZ Seed Systems project	

### **Private and Public Seed Companies**

No.	Institution	Respondent	Position	Contact: email/Tel.	Location	Consultation Date
<b>Public Seed Enterprises (National and Regional)</b>						
1.	Ethiopian Seed Enterprise	Zenebe W Selassie	Executive officer		Addis Ababa	24/09
2.	Oromia Seed Enterprise	Ashinie Gonfa	GM		Addis Ababa	24/09
3.	Amhara Seed Enterprise	Emishaw Worknes	DGM			29/09
4.	Southern Seed Enterprise	Belay Hirso	GM			29/09
<b>Private Seed Companies</b>						
5	Anno Agro-Industry	Tesfaye Kumsa Dr.	General Manager		Bako	15/09
6	Yimam Tesema PLC	Yimam Tesema	General Manager		BhirDar	16/09
7	Wama Seed Private	Asefa Senbeta	General Manager		Nekemte	13/09
8	Amuwari Seed Business	Amha Abrham	General Manager		Bishoftu	18/09
9	Ethiopian Seed Association	Melaku Admasse	Chairperson		Addis Ababa	17/09
10	Mohammed Awel Oumer Farm	Jafer Mohammed	General Manager		SNNP	13/09
11	Afri Seeds	Mulugeta Semneh	General Manager		Debre Markos	14/09

## Annex II: Seed Dealer Registration/CoC Process

**Application Process:** Applications for CoC shall be directed to the RBoA in the region in which an enterprise is operating and to the MoA if operating in different regions.<sup>80</sup> The application process is set out in **Step 1 of Figure 6**,<sup>81</sup> and the application process for operating in multiple regions is shown in the dotted left-hand box attached to **Step 1 of Figure 6**.<sup>82</sup> As per the 2016 Seed Regulation, an application should contain an applicant's full name and address, along with detailed information on compliance with criteria for the type of seed dealer, set out under the 2016 Seed Regulations. The Ministerial Directive for CoC to engage in the Seed Business includes additional requirements.

**Evaluation:** To obtain a CoC, a seed processor shall also have suitable warehouse facilities for seed storage, requisite machinery and manpower to perform processing activities, and a professional with basic knowledge and experience in seed processing (this is depicted in the right-hand dotted box attached to **Step 2 of Figure 6**). A seed distributor shall own or rent suitable warehouse facilities for seed storage and be a professional with basic knowledge and experience in seed handling (this depicted in the right-hand dotted box attached to **Step 2 of Figure 6**).

**Regulatory Determination and Post Determination:** After issuance of a CoC, a seed dealer cannot transfer or assign a CoC to a third party.<sup>83</sup> A CoC can be suspended if a seed dealer fails to maintain the conditions under which CoC was issued or contravenes any provision in seed law or regulation.<sup>84</sup> A CoC can also be revoked if it was obtained based on false evidence or if the seed dealer fails to rectify any irregularities or commits an offence under seed law.<sup>85</sup> The suspension and revocation process is depicted in **Step 6 of Figure 6**. At the federal level, the MoA has the obligation to maintain a registry of seed producers and distributors,<sup>86</sup> as well as a seed production database in an electronic format.<sup>87</sup> This is depicted in the second right-hand pink dotted box as well as in the blue shaded box attached to **Step 5 of Figure 6**. With respect to the registry, the MoA is obligated to routinely update it with relevant information, such as the name and address of the producer/distributor, kind of species, variety name and class of seed produced, hectare of land used, status of the CoC, and year of production of seed.<sup>88</sup> The MoA is also obligated to work with regional authorities and public and private stakeholders to set out an annual production plan,<sup>89</sup> which shall be attached to the registry of seed producers and distributors.<sup>90</sup>

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<sup>80</sup> Ministry of Foreign Affairs Ethiopia, *IMC&NA Ethiopia Public Seed Sector Services*, 12 (2020), <https://www.rvo.nl/sites/default/files/2020/03/IMNA-Ethiopia-Public-Seed-Sector-Services.pdf> (See also 2013 Seed Proclamation, A 19).

<sup>81</sup> Rates of Fees for Seed Competency and Related Services Fees Regulation, No. 361/2015 (Services Fees Regulation).

<sup>82</sup> 2013 Seed Proclamation, A 19.

<sup>83</sup> 2016 Seed Regulation, 2016, r 44.

<sup>84</sup> Ministerial Directive on Criteria and Implementation Procedures for Issuing CoC. See also 2013 Seed Proclamation, A 21.

<sup>85</sup> 2013 Seed Proclamation, A 21.

<sup>86</sup> 2013 Seed Proclamation, A 9.

<sup>87</sup> 2013 Seed Proclamation, A 7.

<sup>88</sup> 2016 Seed Regulation, r 15.

<sup>89</sup> 2016 Seed Regulation, r 15.

<sup>90</sup> 2016 Seed Regulation, r 16.

## Annex III: Variety Registration and Release Process

**Variety Testing:**<sup>91</sup> The details for an application for variety registration and release are provided for in the 2016 Seed Regulations and Variety Release Policy and Mechanism Manual of 2001 (this is depicted in **Step 1** of **Figure 8**).<sup>92</sup> New varieties are subject to NPT tests conducted on three sites for two seasons or six sites for one season, as well as to DUS tests for two seasons in three locations (see dotted box to the left of **Step 2** of **Figure 8**).<sup>93</sup> The application fee for DUS and NPT comes with a fee of 100 Birr each (see right dotted box to the right of **Step 1** of **Figure 8**), although the actual costs reportedly differ in practice. Under the Ministerial Directive on Import and Multiplication of Unregistered Varieties Exclusive for Re-Export, certain imported varieties maybe exempt from registration obligations in the exceptional case that the variety is imported to be produced/multiplied for re-export purposes only (see dotted box to the left of **Step 1** of **Figure 8**).

**Evaluation:** The NPTC evaluates a variety based on two criteria: (i) DUS and (ii) Value for Cultivation and Use characteristic (VCU) or NPT (see Step 3 of the RSM for the Current Variety Registration and Release Process in Ethiopia).<sup>94</sup> For DUS, the variety has to be clearly distinguishable from other varieties in one or more characteristics, uniform in characteristics, and stable in multiple cycles.<sup>95</sup> For VCU/NPT, the variety has to be superior to other varieties in characteristics such as yield, resistance to disease, maturity, and other similar characteristics, and it has to be highly desirable to users.<sup>96</sup> Based on the NPTC report, the NVRC will recommend to the MoA to either (i) fully release the variety; (ii) provisionally release the variety; (iii) further test the variety; or (iv) reject the variety (see **Step 6** of **Figure 8**).<sup>97</sup> The evaluation process also involves the assignment of a permanent designation (or a variety name) to the new variety by the breeder. The regulations set out certain conditions for assigning the permanent designation, which shall be (i) short and precise; (ii) allow the variety to be identified but not consist of only numeric figures, (iii) not be misleading or confusing with regard to the identity of the variety with other varieties, (iv) not have similarity with the name of other varieties registered in the National Variety Registry, and (v) not affect rights previously granted in Ethiopia or any other country.<sup>98</sup> The permanent designation can be rejected by the MoA if it does not conform to these criteria.<sup>99</sup> An applicant may also change the permanent designation in future.<sup>100</sup>

**Regulatory Determination:** MoA has the following functions (i) organize and keep the Register; (ii) regularly register new varieties in the Register, (iii) remove obsolete varieties from the register, and (iv) annually publish the Register and make it accessible to stakeholders.<sup>101</sup> The National Variety Register

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<sup>91</sup> Rates of Fees for Seed Competency and Related Services Regulation, No. 361/2015 (2015 Regulation on Fees)/

<sup>92</sup> Seed Regulation No.365/2016 (2016 Seed Regulation), r 4.2.

<sup>93</sup> Variety Release Policy and Mechanism manual of 2001. See also, *IME&NA Ethiopia Public Seed Sector Services*, MINISTRY OF FOREIGN AFFAIRS ETHIOPIA, 12 (2020) <https://www.rvo.nl/sites/default/files/2020/03/IMNA-Ethiopia-Public-Seed-Sector-Services.pdf>.

<sup>94</sup> 2016 Seed Regulation, r 6.

<sup>95</sup> 2016 Seed Regulation, r 3.

<sup>96</sup> 2016 Seed Regulation, r 3.

<sup>97</sup> 2016 Seed Regulation, r 7.2.

<sup>98</sup> 2016 Seed Regulation, r 8.

<sup>99</sup> 2016 Seed Regulation, r 8.

<sup>100</sup> 2016 Seed Regulation, r 8.

<sup>101</sup> 2016 Seed Regulation, r 10.

shall contain the following information: (i) crop name, variety name, registration number, registration date, year of release, DUS trait and pedigree of variety crop name; (ii) conditions of release; (iii) additional data such as yield potential, adaptation, quality, disease and pest reaction; and (iv) name of person registering the variety or maintainer of variety.<sup>102</sup> The MoA may also cancel the registration of the variety if the variety: (i) loses, changes, or degrades characteristics; (ii) poses risk to human or animal health or the environment; (iii) is indistinguishable from a variety registered under a different name; or (iv) is released or registered based on false or misleading information, as depicted in **Step 8** of **Figure 8**.<sup>103</sup>

**Appeal or Cancellation of a Variety:** If the MoA decides to reject the variety, there is an option to appeal under general grievance procedures set out under the 2013 Seed Proclamation, whereby a person who is either aggrieved or unsatisfied by any decision taken under the Proclamation can apply to the MoA by formal letter within 30 days of knowledge of the decision (see red box off of **Step 7a** of **Figure 8**).<sup>104</sup>

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<sup>102</sup> 2016 Seed Regulation, r 9.

<sup>103</sup> 2016 Seed Regulation, r 11.

<sup>104</sup> 2013 Seed Proclamation, A 25.

## Annex IV: Plant Breeder Right's Process

**Application by an Individual/Private Institution:** To apply for PBR, a breeder applies by formal letter to the MoA, presenting a filled-out application template (provided by the MoA) accompanied by an affidavit swearing to the origin of the genetic material, its lawful acquisition, and, where relevant, compliance with National Bio-safety Proclamation No. 655/2009<sup>105</sup> on proper handling of genetically modified organisms in order to protect the environment.<sup>106</sup> This is depicted in **Step 1** of **Figure 10**. The application must include a proper denomination, which shall be short, not consist of only numeric figures, not be confused with other variety name, not be the same as a name registered earlier in Ethiopia or another country, and retain the same name under which it was protected earlier in another country. The application should also have the right holder's name and address; the agent's name and address if the application is submitted by an agent; the variety's family, crop species, and common name; the breeder's candidate variety reference code; the candidate variety breeder's name; a brief description of the breeding process; name of the country if the variety is protected outside Ethiopia; any documentation related to any special privilege to the applicant due to international or continental agreements that Ethiopia has ratified; duration of the variety on the market; and prior consent on breeding maintenance of the variety.<sup>107</sup> The application may be submitted to the MoA by post, electronically, by fax, or physically.<sup>108</sup> This process is set out in the right-hand box attached to **Step 1** in **Figure 10**.

**Evaluation:** Within 14 days of receipt of the application, the Minister makes a preliminary determination of whether the application merits a full examination by evaluating whether the application has been submitted in the right manner (see **Step 2** of the right-hand process in **Figure 10**). In doing so, the Minister will check to see whether the application is accompanied by all the relevant documentation, that the DUS characteristics described are different from those of any other protected varieties, and that the variety has a denomination that meets the legal requirements (see dotted box attached to **Step 2** of the right-hand process in **Figure 10**). In examining the DUS characteristics, the MoA may order an additional DUS test to be conducted or accept a DUS report submitted by the applicant if it is done by an institution recognized by the MoA.<sup>109</sup> Following this preliminary evaluation, if the MoA finds the application to be in order, provisional PBR is granted, as seen in **Step 2** of the far-right process in **Figure 10**. The length of the process will be determined by regulations; however, these are not yet in place. If not in order, the application will be rejected and the applicant notified.

At the applicant's cost, the Minister publishes a call for opposition to the application of the grant of PBR as depicted in **Step 4** of the far-right process in **Figure 10**.<sup>110</sup> The notice is made through mass media with wide circulation detailing information about the applicant and the variety. Further, as set out in **Step 5** of the far-right process in **Figure 10**, any person who finds that the grant of PBR will be contrary to public interest or that the applicant is not entitled to PBR can oppose the application

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<sup>105</sup> PBR Proclamation, A 15.

<sup>106</sup> Plant Breeders' Rights Directive No. 765 of 2021 (PBR Directive) A. 3(1)m).

<sup>107</sup> PBR Directive, A 3(1).

<sup>108</sup> PBR Directive A 3(2).

<sup>109</sup> PBR Directive A 3(3)e).

<sup>110</sup> PBR Proclamation, A 17.

within the time prescribed in the call for opposition.<sup>111</sup> The objection must be in writing and submitted to the MoA physically, electronically, or by fax.<sup>112</sup> MoA is meant to inform the applicant of an objection within five working days from its receipt, and the applicant has ten working days from receipt of the MoA's notice to respond (see **Step 6** of the far-right process in **Figure 10**). If the objection relates to damage to the public, the MoA will investigate the issue in collaboration with the relevant institutions. If the objection relates to the unfulfillment of the criteria for PBR grant, the MoA shall conduct research to assess whether the variety meets the novelty and DUS requirements. After considering the objection, the MoA may: (i) reject the opposition and approve the applicant's PBR, (ii) cancel or deny the grant of PBR, or (iii) cancel or deny the grant of PBR and transfer the PBR to the appropriate body as highlighted in **Step 7** of **Figure 10**.

When PBR is granted, the MoA gives public notice through mass media having with wide circulation. Once granted, PBR is valid for twenty years in the case of annual crops and twenty-five years in the case of trees, vines and other perennial plants.<sup>113</sup> If rejected, the applicant may lodge an appeal against the MoA's decision in a regular court of law within sixty days from the date of receipt of the decision (see red-shaded box linked to **Step 7** of **Figure 10**).

**Application by a Farmers' Community or Farmer as an Individual:** The first level of application for PBR by a farmer or community of farmers is the Kebele agricultural office (KAO) (see **Step 1** of the far-left process in **Figure 10**).<sup>114</sup> The application should be in written form, describing the variety and how it is distinguished from other varieties, with any supporting documentation attached as specified in the format annexed with the PBR Directive (see the dotted box attached to the far-left aspect of **Step 1** in **Figure 10**).<sup>115</sup> Notably though, such this format is missing from the PBR Directive. For farmers' varieties, the KAO conducts a survey regarding the candidate variety and ensures that there is no objection to the grant of PVP in respect of such variety.<sup>116</sup> Once that is ascertained, the KAO grants a supporting letter to the applicant's application.<sup>117</sup> The next stage for the applicant is to submit the letter from the KAO to the Woreda agricultural office (WAO). The WAO conducts an intra-Woreda survey to ensure that there is no objection and then writes a letter to the zonal or regional agricultural office.<sup>118</sup> The zonal or regional agricultural office, through the seed regulatory body or crop development department, conducts intra-zonal or intra-regional surveys to ensure that the variety does not exist in any other zones, and submits such evidence to the MoA.<sup>119</sup> This process is depicted in **Steps 1 to 9** of the far-left process in **Figure 10**. Based on the application and other supporting evidence received, the MoA requests the national biodiversity institution to consent to the local candidate variety (see **Step 9** of the far-left process in **Figure 10**).<sup>120</sup> If consent is granted, the MoA issues a public notice through mass media, inviting anyone to file an objection to the granting of PBR

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<sup>111</sup> PBR Proclamation, A 17(2).

<sup>112</sup> PBR Directive A 12.

<sup>113</sup> PBR Proclamation, A 10.

<sup>114</sup> PBR Directive A 6 (1).

<sup>115</sup> PBR Directive A 6 (2).

<sup>116</sup> PBR Directive A 6 (5).

<sup>117</sup> *Ibid.*

<sup>118</sup> *Ibid.*

<sup>119</sup> *Ibid.*

<sup>120</sup> PBR Directive A 6 (6) (a).

within the time indicated in the notice.<sup>121</sup> If no objection is made, the MoA performs a DUS test on the farmer's or community's variety either on its own or through delegated research centers near to applicant's address as depicted in **Step 11** of **Figure 10**. According to the language of the Directive, farmers' and communities' varieties are evaluated based on minimum QDS standards; however, QDS standards are not relevant to the PBR process, and this should mention DUS instead, highlighting a gap in how DUS is approached.<sup>122</sup> If the variety passes the DUS test, the MoA will grant the applicant PBR.<sup>123</sup>

**Applications by Public Research Institutions:** The PRI should make an application to the MoA in writing requesting granting of PBR (see the middle **Step 1** process related to public research institutions in **Figure 10**). The application should include the name of the research center, the list of participating breeders, and evidence that the variety was developed using public funds. If the MoA finds the application to be in order regarding the requirements, it can grant the public research institution a certificate showing that the variety is a public good (see **Step 2** of the relevant process in **Figure 10**).

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<sup>121</sup> PBR Directive A 6 (6) (b).

<sup>122</sup> PBR Directive A 6 (6) (c).

<sup>123</sup> *Ibid.*

## Annex V: Seed Quality Control

**General Application:** The application for a certificate of seed quality is made by completing a form prepared by the responsible authority, accompanying it with a receipt of payment of inspection fees, and including seed from one official tag taken from each of the planted seeds.<sup>124</sup> The application includes plot history, source of basic seed, and area and location, which helps the regulatory services plan the field inspections.

**Application for QDS at the Regional Level:** The application has to be accompanied by an application form, receipt of payment of inspection fees, and seed from one official tag taken from each lot of planted seed. In relation to the international quality control system to be maintained by the producer, information related to the source of the seed must be maintained; conformity with the prescribed standards on seed processing, packaging, seed sampling must be verified; quality of the seed needs to be analyzed; and applicable tags and seals must be affixed to the packaging, all as depicted in dotted area off of **Step 2** on the right-hand side of **Figure 12**.<sup>125</sup> A certificate of seed quality is valid for one year.<sup>126</sup>

### Seed Quality Assessment

#### i. Field Inspection

The application for field inspection is made to the relevant federal or regional authority a month before sowing.<sup>127</sup> MoA inspectors undertake field inspections of seed meant for export to assess quality, while RBoA inspectors inspect seed fields in the respective regions (see Step 3 of the RSM on the Current System for Seed Quality Assurance). Field inspections are done according to standards that assess crop purity, rotation, isolation distance, maximum percentage of other varieties or off-types, maximum percentage of seed-borne diseases, and maximum percentage of objectionable weed plants (with a minimum number of inspections required).<sup>128</sup> Inspections are conducted at least three times for hybrids and at least twice for other crops, as highlighted in the dotted box attached to **Step 3** of **Figure 12**.<sup>129</sup> The cost of field inspection is Birr 30 per hectare for hybrids and Birr 20 per hectare for other crops.<sup>130</sup> For QDS, only 10% of the field is inspected.<sup>131</sup>

An inspector will release the field analysis results after inspection (see **Step 4** of **Figure 12**). This can take anywhere from a few minutes to five working days depending upon the RBoA and its capacity. If the producer disagrees with the results of the inspection, he or she may lodge an appeal to the RBoA within five working days for inspection, as set out in the red box attached to Step 4(a) of the RSM on

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<sup>124</sup> 2016 Seed Regulation, r 20.

<sup>125</sup> 2016 Seed Regulation, r 21.

<sup>126</sup> Ministerial Directive on QDS.

<sup>127</sup> *IMENA Ethiopia Public Seed Sector Services*, MINISTRY OF FOREIGN AFFAIRS ETHIOPIA, 15 (2020) <https://www.rvo.nl/sites/default/files/2020/03/IMNA-Ethiopia-Public-Seed-Sector-Services.pdf>.

<sup>128</sup> 2016 Seed Regulation, r 23.

<sup>129</sup> 2016 Seed Regulation, r 45.

<sup>130</sup> Rates of Fees for Seed Competency and Related Services Regulation, No. 361/2015.

<sup>131</sup> Ministerial Directive on QDS.

the Current System for Seed Quality Assurance.<sup>132</sup> The producer must pay for re-inspection. If the standard of the field is approved after re-inspection, the fee paid for re-inspection is refunded to the producer (see orange dotted box attached to **Step 4 (b)** of **Figure 12**).<sup>133</sup>

## ii. Seed Processing, Sampling, and Testing

After field testing, a registered seed processor with a CoC should process the seed before it can be sent to the laboratory (see **Step 5** of **Figure 12**). The processor collects seed lots from harvested seed in accordance with maximum size requirements under ISTA, as set out under **Step 6** of **Figure 12**. Each seed lot is then assigned a unique identifying lot number following an internationally recognized code scheme, identifying the federal or regional authority and year of production.

Seed processing is followed by drawing of samples by samplers or inspectors authorized by the MoA or the RBoA, in accordance with ISTA rules (see blue shaded box for **Step 7** of **Figure 12**).<sup>134</sup> The sample should not exceed the maximum weight limits prescribed under ISTA and should be packaged and labeled in accordance with the Ministerial Directive to Administer Seed Marketing. Collection of the sample has a cost of Birr 100, as highlighted in the pink dotted box attached to **Step 7** of **Figure 12**. A sample, once properly collected, is taken to the laboratory for testing in accordance with ISTA rules,<sup>135</sup> subject to payment of a fee prescribed under the 2015 Fees Regulation (see blue shaded box for **Step 7** of **Figure 12**). Seed is tested for purity (Birr 20/sample), germination (Birr 40/sample), moisture (Birr 25/sample), health (Birr 182/sample), tetrazolium (Birr 47/sample), and other relevant tests. Laboratory testing results are provided to the applicant anywhere from seven to twenty-one days after testing, as highlighted in the right-hand pink dotted box attached to **Step 7** of **Figure 12**.<sup>136</sup> For QDS, after samples are collected, tests are conducted from 10 percent of the produced seed.<sup>137</sup> QDS seed must be packaged and labelled, with the label containing 14 parameters ranging from the producer's name to information regarding applicable health hazards. Article 4.1 of the QDS Directive stipulates that the variety to be used should be a variety registered through the QDS systems.

**Issuance of Certificate of Quality, Rejection, and Appeal:** Once seed is found to meet the laboratory testing standards, the relevant authority issues a certificate of seed quality, as depicted in **Step 8** of **Figure 12**. Appeals against any decisions of the RBoA must be made in writing to the MoA in within 30 days, while appeals against any decisions made by the MoA must be made to the concerned judicial organ within 30 days, as set out in **Step 9** of **Figure 12**.<sup>138</sup>

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<sup>132</sup> 2016 Seed Regulation, r 23.

<sup>133</sup> 2016 Seed Regulation, r 23.

<sup>134</sup> 2016 Seed Regulation, r 26.

<sup>135</sup> 2016 Seed Regulation, r 28.

<sup>136</sup> *Ibid.*

<sup>137</sup> Ministerial Directive on QDS.

<sup>138</sup> 2013 Seed Proclamation, A 25.

## Annex VI: Anti-Counterfeit Procedures

**Enforcement by MoA and RBoA:** The 2013 Seed Proclamation prohibits trade in substandard seed in Ethiopia: (a) the supply of unregistered or substandard seed is an offence and, if found guilty, the perpetrator and any accomplices would be sentenced to imprisonment of five to ten years, with a fine of Birr 50,000 to 10,000;<sup>139</sup> (b) provision of a wrong sample for testing, sample tampering, provision of false information under any application under the 2013 Seed Proclamation, failure to label in accordance with the relevant laws, and removal of any official record are offences punishable by imprisonment from three to five years and a fine of Birr 30,000 to 50,000; (c) obstruction of an inspector is an offence punishable with imprisonment of up to one year and a fine from Birr 5,000 to 10,000; and (d) any abuse of power by a federal or regional official is an offence punishable with imprisonment from ten to fifteen years and a fine of Birr 20,000 to 50,000.

**Enforcement by Ministry of Trade:** The Industry Consumers Protection Authority also conducts investigations where there is sufficient ground to suspect, based on its own information or information given to it by any person, that seed is substandard, wrongfully labeled, or sold on the market without a standards mark.<sup>140</sup> An investigating officer from the Ministry of Trade and Industry with a search or seizure order from the adjudicative bench of the Authority may, upon showing the authorization to conduct an investigation to the owner or representative of the business establishment, storage, or vehicle subjected to the investigation: (i) enter the business premises of the suspect or any other place where goods are stored or stop a vehicle loaded with goods and conduct a search; (ii) take samples of goods necessary for the investigation; (iii) examine and take copies of records and documents kept in any form; and (iv) seize goods illegally stored or being transported or seal their storage or container. Based on the findings of the investigation detailed in the investigation report, the Prosecutor of the Authority institutes an action before the adjudicative bench of the Authority or the regional consumers' protection judicial organs against the alleged perpetrators, as highlighted in **Step 6** of **Figure 14**.<sup>141</sup> During the hearing, the adjudicative bench of the Authority or the regional consumers' protection judicial organ could order any person to furnish information and summon any witness to appear and testify.<sup>142</sup>

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<sup>139</sup> 2013 Seed Proclamation, A 26.

<sup>140</sup> Consumer Protection Proclamation, A 36(1).

<sup>141</sup> Consumer Protection Proclamation, A 37.

<sup>142</sup> Consumer Protection Proclamation, A 38.

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