



# TANZANIA Guidebook on Regulatory Aspects of Dissemination of Public Varieties

## Introduction

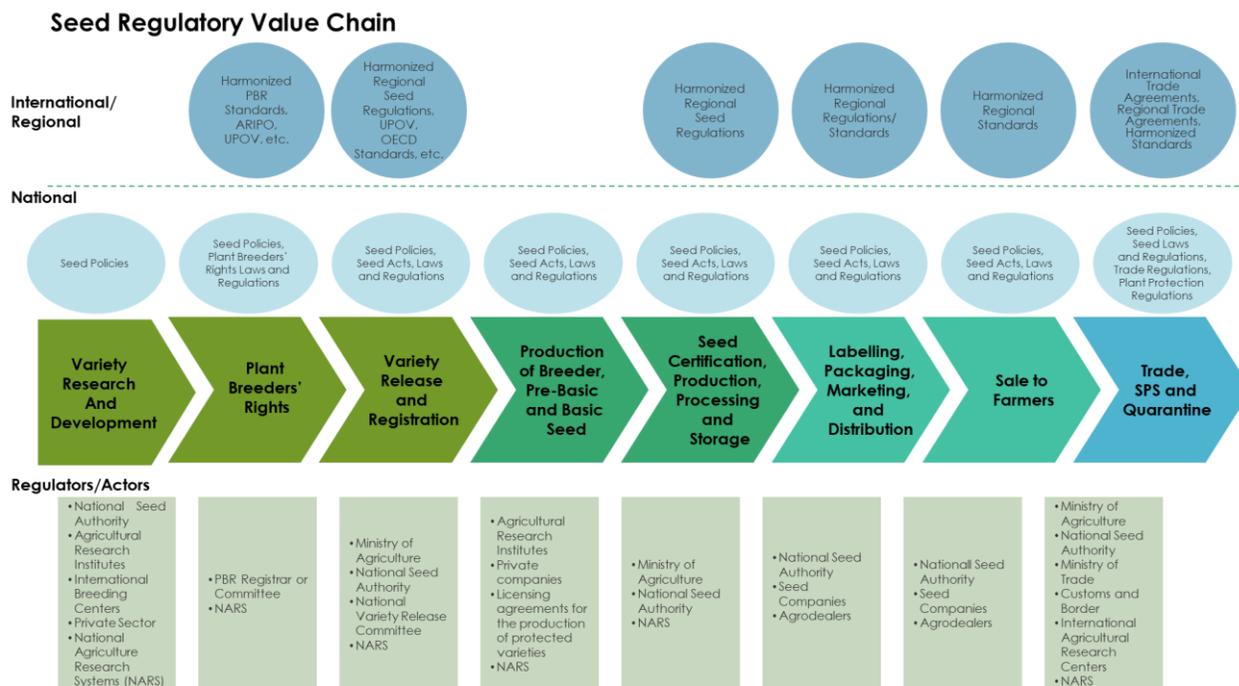
In Tanzania and throughout sub-Saharan Africa, the public sector is heavily involved in seed breeding. Yet, challenges still exist with ensuring that public seed varieties reach the market. Regulatory processes and procedures at both the national and regional levels – including rules on variety release and registration and licensing of public varieties for private commercialization – will play a direct role in the dissemination of public varieties within key markets like Tanzania and more broadly at the regional level. Ultimately, regulatory systems will impact the ability of public institutions to achieve their mandate of research and development of new seed varieties for use as a public good.

This Tanzania Guidebook on Regulatory Aspects of Dissemination of Public Varieties (Nigeria Guidebook) is designed to serve as a practical guide for National Agricultural Research Services (NARS) and their partnerships with the Centers of the Consultative Group for International Agricultural Research (CGIAR Centers) to assess common regulatory issues that affect dissemination and commercialization of public varieties. The Guidebook was developed by the New Markets Lab (NML) and Syngenta Foundation for Sustainable Agriculture (SFSA) under the Accelerated Varietal Improvement and Seed Delivery of Legumes and Cereals in Africa (AVISA) project, launched in 2018 with support from the Bill and Melinda Gates Foundation (BMGF) and

conducted in partnership with the International Crops Research Institute for the Semi-Arid Tropics (ICRISAT), the International Institute of Tropical Agriculture (IITA), and the International Center for Tropical Agriculture (CIAT). AVISA is an initiative that focuses on increasing the productivity, profitability, resilience, and marketability of grain legume and cereal crops including groundnut, common bean, cowpea, sorghum, and millet, across seven African countries.<sup>1</sup>

The Tanzania Guidebook focuses on several key aspects of the seed regulatory value chain (see Figure 1) in Tanzania. These include the process for registering seed varieties, with a particular focus on registration at the regional level, and issues related to licensing public varieties in Tanzania. Because of the increasing relevance of regional seed rules, this Tanzania Guidebook will present the different avenues available for registration of seeds in the region viewed in the context of Tanzania’s current regulatory framework, as well as explore the challenges and potential opportunities that NARS and CGIAR Centers may encounter with expanding variety registration at the regional level. It also covers legal and regulatory issues related to licensing of public varieties and should be viewed in tandem with the Guide on Licensing Agreements done under this project. Finally, it examines the process for claiming plant breeder’s rights (PBR) in Tanzania, should national public institutions wish to undertake this process.

**Figure 1: Seed Regulatory Value Chain**



© 2019 New Markets Lab, adapted from New Markets Lab, "Legal Guide to Strengthen Tanzania's Seed and Input Markets", New Markets Lab with the Southern Agricultural Growth Corridor of Tanzania (SAGCOT) Centre Ltd. for the Alliance for a Green Revolution in Africa (AGRA) and U.S. Agency for International Development (USAID) (April 2016).

<sup>1</sup> The seven focus countries under AVISA are: Burkina Faso, Ghana, Mali, Nigeria, Tanzania, Ethiopia, and Uganda.

In Tanzania, seed varieties must be registered before they can be commercialized and sold in the market. For many public varieties, a transfer will take place between the public and private sectors following variety registration and before a variety is commercialized. This is typically done through a licensing agreement, which can be a critical tool for transfer of rights to use a variety and payment of royalties to the national research institutions. Although licensing agreements can be based only on a transfer of the right to commercialize a registered variety (essentially the variety registration itself), they can also rest on plant variety protection (PVP), which ultimately strengthens protection to the breeder beyond just the commercial party. In Tanzania, variety registration is also a precondition for PVP.

This Tanzania Guidebook focuses on key regulatory areas central to the ability of the NARS to strengthen their ability to achieve their mandate of researching and developing new seed varieties for use as a public good, including:

- National and Regional Seed Variety Registration: Tanzania has a well-developed seed regulatory system and is well positioned to act as a hub for regional seed variety registration. Understanding the different regional rules and how they relate to Tanzania's regulatory system will be central to this goal, as will improving inter-operability between the different regional systems.
  - Tanzania is a member of SADC and has consequently aligned its legislation with the SADC Harmonised Seed Regulatory System (HSRS). This can be an advantage for Tanzania, since varieties seeking entry in the SADC Variety Catalogue could do so through their release and registration in Tanzania.
  - Tanzania is also a Member of the EAC. While the EAC Seed Bill is currently in draft form and in the process of being adopted, Tanzania's current system is developed enough to be generally compatible with the EAC's.<sup>2</sup> This could also be an advantage for Tanzania's market, since it could potentially increase variety registration and availability.
  - Tanzania has signed and incorporated into its legislation the Association for Strengthening Agricultural Research in Eastern and Central Africa (ASARECA) and the Eastern and Central Africa Programme for Agricultural Policy (ECAPAPA) Agreement, Monograph Series No. 4 (ASARECA/ECAPAPA Agreement), which harmonizes regional variety registration procedures and is currently applied among EAC Partner States. The streamlined procedure established by this agreement has allowed the release of numerous varieties into Tanzania's National Catalogue.

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<sup>2</sup> Katrin Kuhlmann, "Harmonizing Regional Seed Regulations in Sub-Saharan Africa: A Comparative Assessment," September 2015, 32.

- Compatibility issues could potentially arise between the SADC HSRS and the EAC Seed Bill when the EAC adopts its regional seed rules, since there are some differences between the SADC HSRS and EAC Draft Seed Bill.<sup>3</sup> In addition, the EAC Seed Act, when implemented, could allow for seed varieties registered in COMESA to be marketed within the EAC, underscoring the relevance of the COMESA rules for Tanzania, even though Tanzania is not a COMESA Member State.<sup>4</sup>
- The EAC, COMESA, and SADC are part of the Tripartite Free Trade Area (TFTA),<sup>5</sup> the objective of which is to eventually harmonize the trade regimes of SADC, COMESA, and the EAC.<sup>6</sup> Over time, this will also become part of a larger harmonization effort under the African Continental Free Trade Agreement, which went into effect in May 2019.
- COMESA and SADC have established regional seed catalogues, and the EAC Seed Bill also sets out the establishment of a regional seed catalogue, all of which are meant to facilitate intra-regional trade in seeds. Understanding the interoperability of these systems will be fundamental for NARS and CGIAR Centers, given that many countries in Africa are members of more than one REC.
- Licensing agreements have the potential to increase the presence of public varieties in the market, by crating channels and bridges between the public and private sectors in a way where both can benefit. Tanzania has a conducive legal and regulatory framework that can enable the use of licensing agreements as vehicles to increase the commercialization of public varieties and even their registration into the national and regional catalogues.
  - In 2011, the Ministry of Agriculture, Food Security, and Cooperatives (MAFC) issued the Circular on Licensing of Protected Varieties of Plants (Ministerial Circular) that allows the Tanzanian Agricultural Research Institute (TARI) to directly contract with the private sector in transferring foundation seed for commercialization. The Ministerial Circular was revised in 2016 to address issues related to its implementation and allow for more open access by the private sector and more market-appropriate application of exclusive and non-exclusive licenses.

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<sup>3</sup> NML, Regional Variety Release Test Cases: 2018 Findings, 2018; New Markets Lab, A Legal Guide to Strengthen Tanzania's Seed and Input Market, 2015; Lewis, Linzi & Masinjila, Sabrina, "Status Report on the SADC, COMESA and EAC Harmonised Seed Trade Regulations: Where Does This Leave the Regions' Smallholder Farmers?", 2018, 16; NML, Legal and Regulatory Requirements for New Variety Performance in Malawi - Draft, April 2019, 11-14; NML, Legal and Regulatory Requirements for New Variety Performance in South Africa, Draft, April 2019, 8-12; NML, Legal and Regulatory Requirements for New Variety Performance in Tanzania - Draft, April 2019, 11-14.

<sup>4</sup> Katrin Kuhlmann, "Harmonizing Regional Seed Regulations in Sub-Saharan Africa: A Comparative Assessment," September 2015, 9.

<sup>5</sup> Agreement Establishing a Tripartite Free Trade Area Among the Common Market for Eastern and Southern Africa, the East African Community and the Southern African Development Community, June 2015.

<sup>6</sup> Katrin Kuhlmann, "Harmonizing Regional Seed Regulations in Sub-Saharan Africa: A Comparative Assessment," September 2015, 9.

- The 2016 TARI Act establishes a framework for contracts performed between TARI and agricultural research services that are related to intellectual property rights (IPR), which can impact licensing agreements.<sup>7</sup>
  - Agricultural research services conduct agricultural research while TARI retains IPR of findings and discovery.
  - These contracts can include elements of licensing agreements for commercial exploitation.
- Tanzania also has a framework in place for PVP, although it has not been frequently used by public breeding institutions.

## Overview of Tanzania's Seed Regulations

Tanzania's legal and regulatory framework for seed is well developed and includes the following main instruments and measures:

- Seeds Act, No. 18 (2003, as amended) (Tanz.)
- Seeds Regulations, GN No. 37 (2007) (Tanz.)
- 2012 Plant Breeders' Rights Act
- Protection of New Plant Varieties (Plant Breeders' Rights) Regulations 2008<sup>8</sup>

For public breeding institutions, the national system is well understood, particularly with respect to variety release and registration.

At the regional level, relevant measures include: (1) the SADC Harmonised Seed Regulatory System (SADC HSRS), which was approved in 2009 and entered into force in 2013; (2) the Draft EAC Seed and Plant Varieties Bill (EAC Seed Bill), which is currently in the legislative process at the EAC level and the ASARECA/ECAPAPA Agreement followed by EAC Member States; and (3) the Common Market for Eastern and Southern Africa (COMESA) Harmonized Seed Trade Regulations (COMESA Seed Regulations), which were approved in 2014 and are being implemented on an ongoing basis (although Tanzania is not a member of COMESA, the COMESA rules have an increasing impact on Tanzania and the broader regional market).

Public institutions in Tanzania are highly involved in the seed sector, with most of the variety breeding in the country done by the public sector. Public breeding in Tanzania is done through TARI and its centers. TARI is a semi-autonomous body under the Tanzanian Ministry of Agriculture, Food Security, and Cooperatives (MAFC) with the mandate of conducting, regulating,

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<sup>7</sup> Section 16, Parliamentary Act No. 13 of 2016, The United Republic of Tanzania.

<sup>8</sup> These regulations were passed under the repealed Act, and new regulations are being created under the 2012 PBR Act.

promoting, and coordinating agricultural research activities in Tanzania.<sup>9</sup> TARI has eight research centers; TARI-Ukiriguru, TARI-Selian, TARI-Mlingano, TARI-Tumbi, TARI-Makutupora, TARI-Uyole, TARI-Ilonga, and TARI-Naliendele; and ten sub-centers across the country.<sup>10</sup> In addition to TARIs, the Sokoine University of Agriculture also engages in the development of seeds. TARIs often obtain public material through the CGIAR Centers, including the International Maize and Wheat Improvement Center (CIMMYT), the International Crops Research Institute for the Semi-Arid Tropics (ICRISAT), the International Institute of Tropical Agriculture (IITA), the International Rice Research Institute (IRRI), and the Centro Internacional de La Papa (CIP). TARIs obtain breeding materials free of charge and engage in the breeding process, producing pre-basic seeds for public varieties that are then sold to seed companies through the Agricultural Seed Agency (ASA) for the production of certified seed to be sold to farmers.<sup>11</sup> ASA was established as a semi-autonomous body under MAFC to facilitate access to seed by the private sector.<sup>12</sup> ASA's main goal is to ensure that farmers get access to high quality seeds at reasonable prices. ASA's key functions include promoting seed networks among private stakeholders, increasing private sector participation through the establishment of public-private partnerships, promoting demand of certified seeds by farmers, and strengthening research capacities.

The private sector has also increased its breeding activities, mostly in maize and seed potatoes. In 2011, MAFC released the Circular on Licensing of Protected Varieties of Plants of 2011 (Ministerial Circular) that allows TARIs to directly contract with the private sector without having to go through ASA.<sup>13</sup> The Ministerial Circular was revised in 2016 to address issues that had arisen regarding its implementation. One of the main issues was lack of information regarding tenders, since they were not well published and could, therefore, only be accessed by a few companies.<sup>14</sup> The second main issue involved tender requirements, which were found to be too difficult by companies. Exclusive licenses required companies to fulfill 80 percent of demand in the region, while non-exclusive licenses required that 50 percent of demand be filled.<sup>15</sup> The private sector proposed several changes, including removing the percentage requirement, which were addressed in the 2016 revisions. Seed companies now report that they source foundation seed from the TARIs and ASA, which suggests that the implementation issues with the Ministerial Circular were at least partially addressed. Through the Ministerial Circular, the private sector has also improved direct

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<sup>9</sup> About TARI, TARI, available at <https://www.tari.go.tz/#service>; Parliamentary Act No. 10 of 2016, The United Republic of Tanzania.

<sup>10</sup> Research Centers, TARI, available at <https://www.tari.go.tz/#team>.

<sup>11</sup> New Markets Lab with the Southern Agricultural Growth Corridor of Tanzania Centre Ltd. for the Alliance for a Green Revolution in Africa, "A Legal Guide to Strengthen Tanzania's Seed and Input Markets", April 2016.

<sup>12</sup> Agricultural Seed Agency (ASA), available at <https://www.kilimo.go.tz/index.php/en/stakeholders/view/agricultural-seed-agency-asa>.

<sup>13</sup> New Markets Lab with the Southern Agricultural Growth Corridor of Tanzania Centre Ltd. for the Alliance for a Green Revolution in Africa, "A Legal Guide to Strengthen Tanzania's Seed and Input Markets", April 2016.

<sup>14</sup> New Markets Lab with the Southern Agricultural Growth Corridor of Tanzania Centre Ltd. for the Alliance for a Green Revolution in Africa, "A Legal Guide to Strengthen Tanzania's Seed and Input Markets", April 2016.

<sup>15</sup> New Markets Lab with the Southern Agricultural Growth Corridor of Tanzania Centre Ltd. for the Alliance for a Green Revolution in Africa, "A Legal Guide to Strengthen Tanzania's Seed and Input Markets", April 2016.

access to public breeding materials, including breeding material from the CGIAR Centers, although licensing agreements and Material Transfer Agreements are required.<sup>16</sup>

There are currently more than forty breeders in Tanzania for the main four crops (maize, beans, soya bean, and pigeon pea), most of which are based at the TARIs.<sup>17</sup> There are numerous seed companies in Tanzania, but only five of them carry out breeding activities through private breeders, while the others mainly focus on sale of crops and sometimes testing and production of seeds.<sup>18</sup> Moreover, private multinational seed companies with a presence in Tanzania have their own breeders outside of Tanzania.<sup>19</sup> According to Tanzania's National Variety Catalogue, more than fifty new varieties were released between 2014 and 2016. These include forty-four maize varieties, two beans varieties, and four pigeon pea varieties. Among these varieties, forty-two were registered by four TARIs (TARI-Uyole, TARI-Ilonga, TARI-Naliendele, and TARI-Kibaha), with the remaining varieties registered by ten private seed companies.<sup>20</sup> It should be noted that the remaining TARIs, centers and subcenters included, have never registered a variety in Tanzania's National Variety Catalogue.<sup>21</sup> In addition, none of the Tanzanian TARIs have registered varieties at the regional level (e.g., SADC Variety Catalogue). Harnessing the variety release and registration processes at the regional level could facilitate registration of public varieties and strengthen Tanzania's seed system.

Despite efforts to increase access to improved varieties, most seed sector activity in Tanzania continues to occur in the informal sector, due to farmers' limited access to quality seeds.<sup>22</sup> Under 20 percent of smallholder farmers use seeds from the formal sector, while the remaining 80 percent use seeds from the informal seed system.<sup>23</sup> Access to improved seeds could greatly benefit Tanzania's seed sector and increase market opportunities at the regional level.

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<sup>16</sup> New Markets Lab with the Southern Agricultural Growth Corridor of Tanzania Centre Ltd. for the Alliance for a Green Revolution in Africa, "A Legal Guide to Strengthen Tanzania's Seed and Input Markets", April 2016.

<sup>17</sup> Tanzania Brief 2017 – The African Seed Index, 2017 (Revised 2019), available at [https://tasai.org/wp-content/themes/tasai2016/img/tasai\\_brief\\_2017\\_tanzania\\_final\\_lr.pdf](https://tasai.org/wp-content/themes/tasai2016/img/tasai_brief_2017_tanzania_final_lr.pdf).

<sup>18</sup> Tanzania Access to Seeds Profile, 2019, available at <https://www.accesstoseeds.org/index/eastern-southern-africa/country-profile/tanzania/>.

<sup>19</sup> Tanzania Access to Seeds Profile, 2019, available at <https://www.accesstoseeds.org/index/eastern-southern-africa/country-profile/tanzania/>.

<sup>20</sup> Tanzania Brief 2017 – The African Seed Index, 2017 (Revised 2019), available at [https://tasai.org/wp-content/themes/tasai2016/img/tasai\\_brief\\_2017\\_tanzania\\_final\\_lr.pdf](https://tasai.org/wp-content/themes/tasai2016/img/tasai_brief_2017_tanzania_final_lr.pdf); Tanzania Seed Variety Catalogue, Tanzania Official Seed Certification Institute, available at <https://www.tosci.go.tz/publications/22>, last visited November 6, 2019.

<sup>21</sup> Tanzania Seed Variety Catalogue, Tanzania Official Seed Certification Institute, available at <https://www.tosci.go.tz/publications/22>, last visited November 6, 2019.

<sup>22</sup> New Markets Lab with the Southern Agricultural Growth Corridor of Tanzania Centre Ltd. for the Alliance for a Green Revolution in Africa, "A Legal Guide to Strengthen Tanzania's Seed and Input Markets", April 2016.

<sup>23</sup> New Markets Lab with the Southern Agricultural Growth Corridor of Tanzania Centre Ltd. for the Alliance for a Green Revolution in Africa, "A Legal Guide to Strengthen Tanzania's Seed and Input Markets", April 2016.

Public institutions generally face significant challenges establishing sustainable sources of income to support ongoing research and registration of their varieties. The variety registration process is relevant in this context as are licensing agreements once a variety is registered.<sup>24</sup> Through licensing agreements, public institutions could move the varieties they develop into the market, while generating a source of income to support their breeding activities, including research and development of new varieties as a public good.

## Legal and Regulatory Framework for Seed Variety Release and Registration in Tanzania and Regionally

In Tanzania, the process to release a new variety is well established but can be lengthy, with some inconsistencies reported by stakeholders. The African Seed Access Index (TASAI), an index that measures key indicators for the development of the seed sector (Research & Development, Seed Policy & Regulations, Industry Competitiveness, Institutional Support and Service to Smallholder Farmers), estimates that the process for registering seed takes on average approximately thirty-six months.<sup>25</sup> TASAI has estimated that it takes thirty-three months to register maize varieties, twenty-eight months to register bean varieties, forty-two months to register soya beans varieties, and thirty-six months for pigeon pea varieties.<sup>26</sup> TASAI has also reported that most seed companies find the variety release process to be “good”.<sup>27</sup> As another measure, the World Bank Enabling the Business of Agriculture (EBA) project has estimated that registration of maize varieties takes 333 days (approximately eleven months).<sup>28</sup> The EBA Ranking 2019 measures indicators that have an impact on daily operations for farmers, including the time it takes to register a variety, the cost of registering a variety, and an assessment of good practices to promote transparency and efficiency of the process.<sup>29</sup> Tanzania ranks number 59 out of 101 countries on the EBA ranking (with one being the highest rank possible, and 101 being the lowest rank possible), with a score of 57.15 (out of a hundred). Tanzania’s ranking implies that comparatively its process is not the most cumbersome or lengthy, but it is not found to be the most accessible or fastest either. Overall, recent reports indicate that the Government of Tanzania is working to shorten the process or enable tests to run concurrently.

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<sup>24</sup> Guide on Flexible Licensing Models and Agreements, Accelerated Varietal Improvement and Seed Delivery of Legumes and Cereals in Africa (AVISA) Project, NML, November 2019.

<sup>25</sup> Edward Mabaya, Filbert Mzee, Alphonse Temu, and Mainza Mugoya, *Tanzania Brief 2017 - The African Seed Access Index*, available at [https://tasai.org/tasai2016/wp-content/themes/tasai2016/img/tasai\\_brief\\_2017\\_tanzania\\_final\\_lr.pdf](https://tasai.org/tasai2016/wp-content/themes/tasai2016/img/tasai_brief_2017_tanzania_final_lr.pdf).

<sup>26</sup> Edward Mabaya *et al*, *Tanzania Brief 2017 - The African Seed Access Index*, available at [https://tasai.org/tasai2016/wp-content/themes/tasai2016/img/tasai\\_brief\\_2017\\_tanzania\\_final\\_lr.pdf](https://tasai.org/tasai2016/wp-content/themes/tasai2016/img/tasai_brief_2017_tanzania_final_lr.pdf).

<sup>27</sup> Edward Mabaya *et al*, *Tanzania Brief 2017 - The African Seed Access Index*, available at [https://tasai.org/tasai2016/wp-content/themes/tasai2016/img/tasai\\_brief\\_2017\\_tanzania\\_final\\_lr.pdf](https://tasai.org/tasai2016/wp-content/themes/tasai2016/img/tasai_brief_2017_tanzania_final_lr.pdf).

<sup>28</sup> World Bank Enabling the Business of Agriculture (EBA) Indicator, 2019, available at <https://eba.worldbank.org/en/data/exploretopics/all-topics>.

<sup>29</sup> World Bank Enabling the Business of Agriculture (EBA) Indicator, 2019, available at <https://eba.worldbank.org/en/data/exploretopics/all-topics>.

Tanzania's public institutions are central actors in the seed sector. Under Tanzania's Seeds Act, the Tanzania Official Seed Certification Institute (TOSCI) is the National Seed Agency (NSA) and the main regulatory authority in charge of overseeing the variety release and registration process. In this role, TOSCI receives applications for varieties release and registration, oversees variety testing trials, collects data, and submits reports as appropriate to other public institutions involved in the process. For seed variety release and registration, other regulatory bodies are also involved, including the National Seeds Committee, through the National Performance Trial Technical Committee (NPT-TC) and the National Variety Release Committee (NVRC), and the Variety Release And Registration Committee. The NPT-TC is composed of members from the MAFC, a higher learning institution, a crops research institution, and the Tanzanian Seed Trade Association (TASTA). The NVRC also has members from the MAFC, in addition to an agricultural university, TASTA, the Plant Breeders' Association, and a farmers' association. The Tanzania Plant Health Services Section under the MAFC is the designated National Plant Protection Office (NPPO).

The Seeds Act and Seeds Regulations require that all new varieties undergo a minimum of two seasons of testing for Distinctness, Uniformity, and Stability (DUS) and one season of National Performance Trials (NPT) conducted by TOSCI before they can appear in Tanzania's National Variety Catalogue. TOSCI receives applications for NPT, which require at least two previous recent seasons of advanced yield trial data from not less than three recognized testing sites or from any country with which with Tanzania has a harmonized seed regulatory agreement (i.e., any SADC Member State). Applications must also be accompanied by the DUS test application fee (2,000 TShs) and the DUS testing fee for one season (500,000 TShs for two seasons).<sup>30</sup> The DUS test certificate costs 5,000 TShs. TOSCI then conducts the NPT test (2,000 TShs application fee, 600,000 TShs for one season) for at least one season on at least three scheduled sites.<sup>31</sup> The testing is conducted in TOSCI's National Laboratory, which was accredited by the International Seed Testing Association (ISTA) in 2018.<sup>32</sup>

Tanzania's seed regulations include some exceptions for DUS and NPT tests. For DUS tests, varieties may be exempt if they have undergone testing by a recognized authority or organization in any country with which Tanzania has an agreement on seed regulations or quality control. For NPT tests, vegetable varieties from countries with which Tanzania has an agreement on seed regulations or quality control may also be exempt. These types of exemptions track with the SADC HSRS and EAC Seed Bill, which, as will be discussed below, could improve Tanzania's access to the EAC market once enacted.

The process for variety release and registration in Tanzania is shown in Figure 2 (New Markets Lab Regulatory Systems Map).

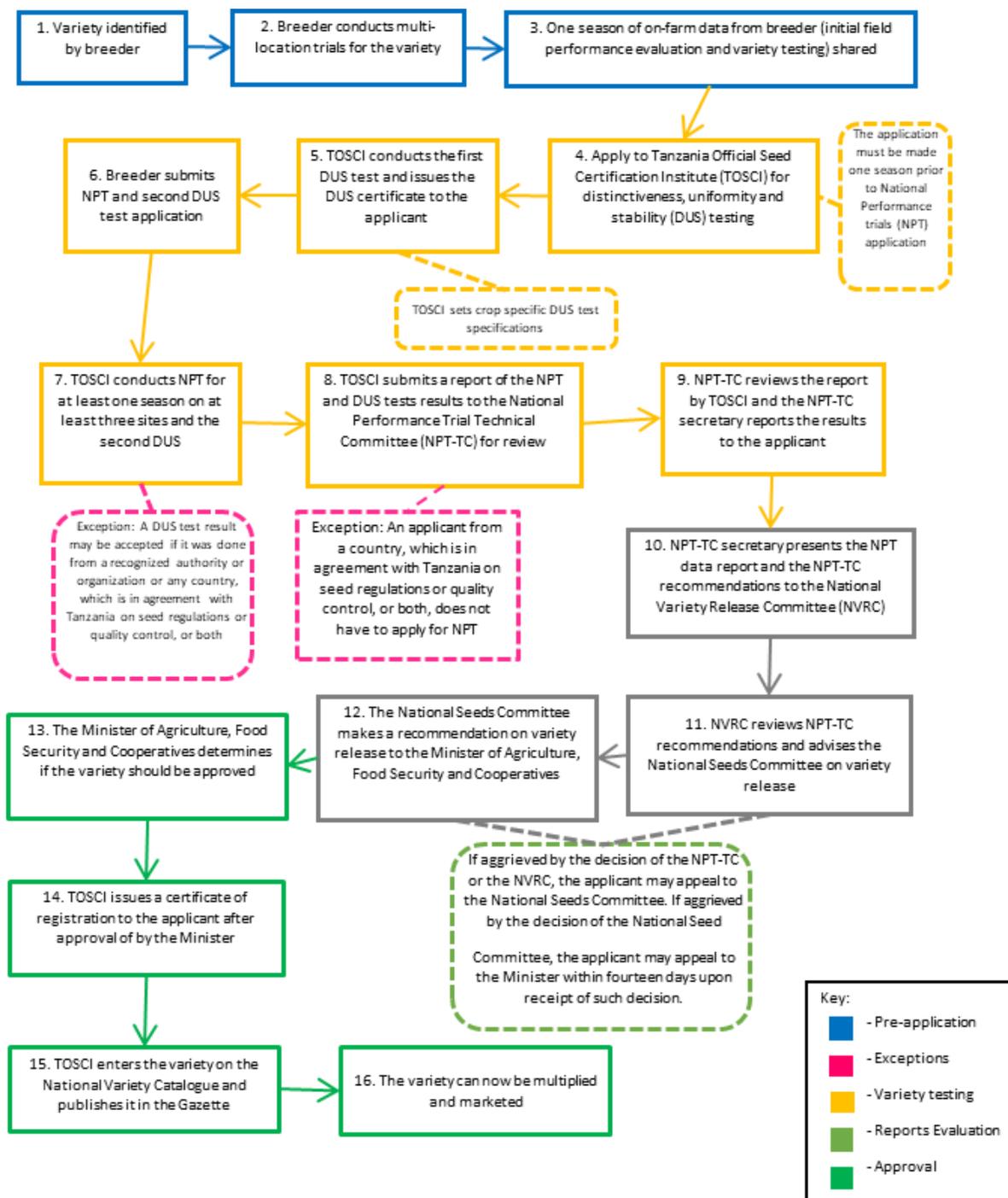
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<sup>30</sup> Sixth Schedule of the Seed Regulations, Tanzania.

<sup>31</sup> Sixth Schedule of the Seed Regulations, Tanzania.

<sup>32</sup> "Tanzania Seed Sector Get Boost with International Accreditation," Tanzania Invest, September 21, 2018, available at: <https://www.tanzaniainvest.com/agriculture/seed-sector-international-accreditation>.

**Figure 2: New Markets Lab Regulatory Systems Map for the Variety Release and Registration Process in Tanzania**



© 2019 New Markets Lab, adapted from New Markets Lab, "Legal Guide to Strengthen Tanzania's Seed and Input Markets", New Markets Lab with the Southern Agricultural Growth Corridor of Tanzania (SAGCOT) Centre Ltd. for the Alliance for a Green Revolution in Africa (AGRA) and U.S. Agency for International Development (USAID) (April 2016); and the New Markets Lab Demand-Led Breeding Report on Tanzania in partnership with Syngenta Foundation for Sustainable Agriculture, 2018.

The NPT-TC receives reports from TOSCI once the DUS and NPT tests have been conducted and makes recommendations to the NVRC, which in turn advises the National Seed Committee on the release of the variety.<sup>33</sup> Then, the National Seed Committee issues recommendation on whether to approve release of the variety to the MAFC.

The MAFC makes the final determination for a variety's entry into the National Variety Catalogue, and TOSCI issues the certificate of registration.<sup>34</sup> The fee for registering a variety is 10,000 TShs.<sup>35</sup> Applicants may appeal National Seed Committee decisions before the Ministry, which has to hear an appeal within 14 days.

As noted above, the process of registering a new variety requires the payment of various fees, including application and maintenance fees. Public institutions interested in registering new varieties must cover these costs. According to the World Bank EBA Report, registering a new variety in Tanzania costs 53.2 percent of income per capita,<sup>36</sup> which the report notes is \$905 (USD) in 2019 (Gross National Income (GNI) per capita).<sup>37</sup> This means that the cost of registering a new variety is around \$481.46 (USD).

Given the size and importance of Tanzania's market, Tanzania's system could perhaps be benchmarked against the regulatory systems in Kenya and Zambia, both of which are also considered to be regional hubs, and both of which also share membership in RECs with Tanzania (Kenya is an EAC Member, while Zambia is a SADC Member; both Kenya and Zambia are also members of COMESA). Table 1 below contains a comparison of Tanzania, Kenya, and Zambia, based on EBA indicators.

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<sup>33</sup> Section 21 of the Seed Act, Tanzania.

<sup>34</sup> Section 21(2) and (3) and Regulation 8 of the Seed Regulations, Tanzania.

<sup>35</sup> Sixth Schedule of the Seed Regulations, Tanzania.

<sup>36</sup> World Bank Enabling the Business of Agriculture (EBA) Indicator, 2019, available at <https://eba.worldbank.org/en/data/exploretopics/all-topics>.

<sup>37</sup> World Bank Enabling the Business of Agriculture (EBA) Indicator, 2019, available at <https://eba.worldbank.org/en/data/exploretopics/all-topics>.

**Table 1: Enabling Business of Agriculture Comparative Table**

Country	EBA Ranking	EBA Score	Overall Score for Supplying Seed	Total Days to Register a Variety	Cost to Register a Variety (% of GDP per capita)	Quality of Seed Regulation (%)	Is there a PVP Law?
Tanzania	59	57.15	77.47%	333	53.2%	66.7%	Yes
Kenya	50	64.80	79.47%	322	106.8%	77.8%	Yes
Zambia	52	63.73	76.76%	544	86.50%	100%	Yes

Source: New Markets Lab from Enabling the Business of Agriculture, World Bank Report, 2019.

TASAI’s indicators differ somewhat, and TASAI estimates that it takes on average thirty-six months to release a variety in Kenya and twenty four months to release a variety in Zambia.<sup>38</sup> This implies that the process in Tanzania may be shorter in Tanzania than in Kenya and longer than in Zambia. Finally, according to NML’s comparative research, it takes eleven steps to register a variety in Kenya,<sup>39</sup> and eight steps to register a variety in Zambia,<sup>40</sup> while it takes sixteen steps to register a variety in Tanzania.

Based on the EBA rankings and the number of steps involved in variety registration as measures by NML, the data may imply that the seed variety registration process is less cumbersome in Kenya and Zambia. Tanzania could still have an advantage in the region, however, and could be seen as a hub for registering varieties nationally and regionally. With respect to the latter, as discussed in greater detail below, Tanzania’s membership in more than one REC and the streamlined procedures available for regional registration could be assets for regional variety registration. Table 2 below summarizes and compares the data gathered by the different indicators.

<sup>38</sup> Michael Waithaka *et al*, *Kenya Brief 2018 - The African Seed Access Index*, available at [https://tasai.org/wp-content/themes/tasai2016/img/tasai\\_brief\\_kenya\\_2018.pdf](https://tasai.org/wp-content/themes/tasai2016/img/tasai_brief_kenya_2018.pdf); Edward Mabaya *et al*, *Zambia Brief 2017 - The African Seed Access Index*, available at [https://tasai.org/wp-content/themes/tasai2016/img/tasai\\_brief\\_2017rev2019\\_zambia\\_final\\_lr.pdf](https://tasai.org/wp-content/themes/tasai2016/img/tasai_brief_2017rev2019_zambia_final_lr.pdf).

<sup>39</sup> New Markets Lab Demand-Led Breeding Report on Kenya in Partnership with Syngenta Foundation for Sustainable Agriculture, 2018.

<sup>40</sup> Katrin Kuhlmann, Yuan Zhou and Shannon Keating, “Seed Policy Harmonization in COMESA and SADC: The Case of Zambia,” Syngenta Foundation for Sustainable Agriculture and New Markets Lab, September 2018.

**Table 2: Indicators Comparative Table**

Country	EBA Ranking	EBA Total Days to Register a Variety	TASAI Total Months to Register a Variety	NML's Total Steps to Register a Variety
Tanzania	59	333 (11 Months)	36	16
Kenya	50	322 (10 Months)	36	11
Zambia	52	544 (15 Months)	24	8

Source: New Markets Lab from Enabling the Business of Agriculture, World Bank Report, 2019; Kenya Brief 2018 TASAI, Zambia Brief 2017 TASAI; New Markets Lab Demand-Led Breeding Report on Kenya in partnership with Syngenta Foundation for Sustainable Agriculture, 2018; Katrin Kuhlmann, Yuan Zhou and Shannon Keating, “Seed Policy Harmonization in COMESA and SADC: The Case of Zambia,” Syngenta Foundation for Sustainable Agriculture and New Markets Lab, September 2018; and New Markets Lab with the Southern Agricultural Growth Corridor of Tanzania Centre Ltd. for the Alliance for a Green Revolution in Africa and USAID, “A Legal Guide to Strengthen Tanzania’s Seed and Input Markets”, April 2016.

Regional seed regulations are particularly relevant to the public sector, as they can allow public varieties to be registered and marketed in wider regional markets, reinforcing the public mandate of the TARIs and CGIAR Centers. Regionally, several legal and regulatory frameworks are relevant to Tanzania, which is a member of both SADC and the EAC. These include the SADC HSRS, ASARECA/ECAPAPA Agreement (expedited variety registration), and Draft EAC Seed Bill, which is expected to incorporate and supersede the ASARECA process. Although Tanzania is not a COMESA member, the COMESA seed regulatory framework is also relevant, given that many of Tanzania’s neighbors are members of COMESA.

In practice, public varieties face particular challenges when traded regionally. Public varieties are often developed from genetic material that comes from CGIAR Centers, which is licensed to national research institutions in different countries and it is later registered in national catalogues under commercial names. National catalogues across the region are not standardized, which means that more often than not a variety can be registered under different names in different countries. In Eastern and Southern Africa, a variety must be released and registered in at least two countries before it can be released and registered at the regional level, and this lack of standardization across national catalogues can present issues. Recently, regional initiatives are under discussions to

provide public varieties with a unique variety identification number (VIN); however, only COMESA has initiated such a process so far. Ultimately, these developments will have implications for the national variety registration process.

This following sub-section will describe how the different regional rules interact with Tanzania's national rules as described above.

### SADC HSRS Regional Variety Release and Registration

The SADC HSRS sets forth the process for variety testing and release in the region through the MoU on the Harmonization of Seed Regulations in SADC (SADC Seed MoU) and the Technical Agreements on Harmonization of Seed Regulations in the SADC Region.<sup>41</sup> Tanzania, has signed the MoU and has taken efforts to align its domestic seed regulations with SADC HSRS;<sup>42</sup> this essentially gives effect to the SADC HSRS, which is not automatically binding but does go into effect once domesticated.

The SADC process admits the registration of both new and existing seed varieties into SADC's Variety Catalogue (See Table 3). In order to enter into the SADC Variety Catalogue, new varieties are required to be released in at least two SADC Member States and have undergone one season of DUS testing in the country of application, along with two seasons of testing for value for cultivation and use (VCU), which can be simultaneous, in two SADC Member States.<sup>43</sup> SADC HSRS require the DUS to be carried out by a competent public authority, generally an NSA, or by a private organization following UPOV Guidelines.<sup>44</sup> VCU/NPT testing can be performed by the variety holder under the supervision of the NSA or delegated to private or public agricultural organizations. Existing varieties that were registered and released in two SADC Member States prior to the launch of the SADC Variety Catalogue may enter the catalogue automatically, provided that DUS and VCU data are submitted along with the application.<sup>45</sup>

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<sup>41</sup> Memorandum of Understanding on the Harmonization of Seed Regulations in the Southern African Development Community (MoU), 2008., Annex II, Art. 1-15.

<sup>42</sup> NML, Regional Variety Release Test Cases: 2018 Findings, 2018; New Markets Lab, A Legal Guide to Strengthen Tanzania's Seed and Input Market, 2015; Lewis, Linzi & Masinjila, Sabrina, "Status Report on the SADC, COMESA and EAC Harmonised Seed Trade Regulations: Where Does this Leave the Regions' Smallholder Farmers?", 2018, 16; NML, Legal and Regulatory Requirements for New Variety Performance in Malawi - Draft, April 2019, 11-14; NML, Legal and Regulatory Requirements for New Variety Performance in South Africa, Draft, April 2019, 8-12; NML, Legal and Regulatory Requirements for New Variety Performance in Tanzania - Draft, April 2019, 11-14.

<sup>43</sup> Memorandum of Understanding on the Harmonization of Seed Regulations in the Southern African Development Community (MoU), 2008, Annex II, Arts. 11 and 13.

<sup>44</sup> Memorandum of Understanding on the Harmonization of Seed Regulations in the Southern African Development Community (MoU), 2008, Annex II, Arts. 11.

<sup>45</sup> Memorandum of Understanding on the Harmonization of Seed Regulations in the Southern African Development Community (MoU), 2008, Annex II, Art. 15.

**Table 3: SADC Variety Release & Registration Process Requirements**

New Varieties	Varieties Released in 2+ SADC Countries before SADC Variety Catalogue
<ul style="list-style-type: none"><li>• Application for entry in the SADC Variety Catalogue</li><li>• Proof of release in two SADC Member States</li><li>• One growing season of DUS testing in country of application</li><li>• Two growing seasons of VCU testing in two SADC Member States</li><li>• Variety holder has a registered business in the country of application</li><li>• Suggested Variety Name</li><li>• Reference sample provided to the NSA</li><li>• Initial Registration Fee (amount TBD)</li><li>• Annual Registration Fee (amount TBD)</li></ul>	<ul style="list-style-type: none"><li>• Application for entry in the SADC Variety Catalogue</li><li>• Submission of necessary DUS &amp; VCU test data</li><li>• Proof of registration and release in two SADC Member States</li><li>• Initial Registration Fee (amount TBD)</li><li>• Annual Registration Fee (amount TBD)</li></ul>

Source: New Markets Lab (2019), based on the SADC HSRS MoU, (2008).

In order to register a variety within SADC, an application must be presented to the relevant NSA (See Figure 3), and an applicant must have legal presence in the country of application.<sup>46</sup> In Tanzania, entry into the SADC Variety Catalogue would have to be initiated through TOSCI. However, varieties from Tanzania would also have to be released in another SADC Member States, which would require VCU/NPT trialing in a second country under national laws or releasing a CG variety regionally that has already been registered in two countries within a REC under different commercial names.

Tanzania could become a hub for varieties seeking entry in the SADC Variety Catalogue, provided that its market is viewed as desirable and its national variety registration system is seen as relatively easy to navigate in relation to other countries, as discussed above. Additionally, some stakeholders have reported differences in implementation among SADC Member States. Some practices, such as the step taken by Zimbabwe to link the national catalogue to the SADC Variety Catalogue, have helped facilitate trade of registered varieties while implementing the SADC system.

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<sup>46</sup> Applicants are required to submit the application form available on the SADC Seed Centre’s website and include the suggested variety name and a sample to be stored by the NSA. Memorandum of Understanding on the Harmonization of Seed Regulations in the Southern African Development Community (MoU), 2008, Annex II, Art. 1; Technical Agreements on Harmonization of Seed Regulations in the SADC Region, the SADC Secretariat, 2008, 2.3.2.

Applicants are also required to pay an initial registration fee and an annual fee,<sup>47</sup> which would have implications for the TARIs; however, fees have not yet been assessed in practice. Once a variety enters the SADC Variety Catalogue, it remains registered for 20 years, and applicants may submit a renewal application before its expiration.<sup>48</sup> Upon receipt of the application for registration, the NSA has thirty days to verify it and notify the SADC Seed Centre. If all the requirements are met, the SADC Seed Centre will include the variety in the SADC Variety Catalogue, meaning that the variety can be traded freely anywhere in the SADC Region.<sup>49</sup> If a variety is not approved, the SADC Seed Centre will notify the NSA and the applicant of the reasons for rejection,<sup>50</sup> and the decision can be appealed by the applicants within thirty days of notification.<sup>51</sup>

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<sup>47</sup> Technical Agreements on Harmonization of Seed Regulations in the SADC Region, the SADC Secretariat, 2008, 2.2.13.

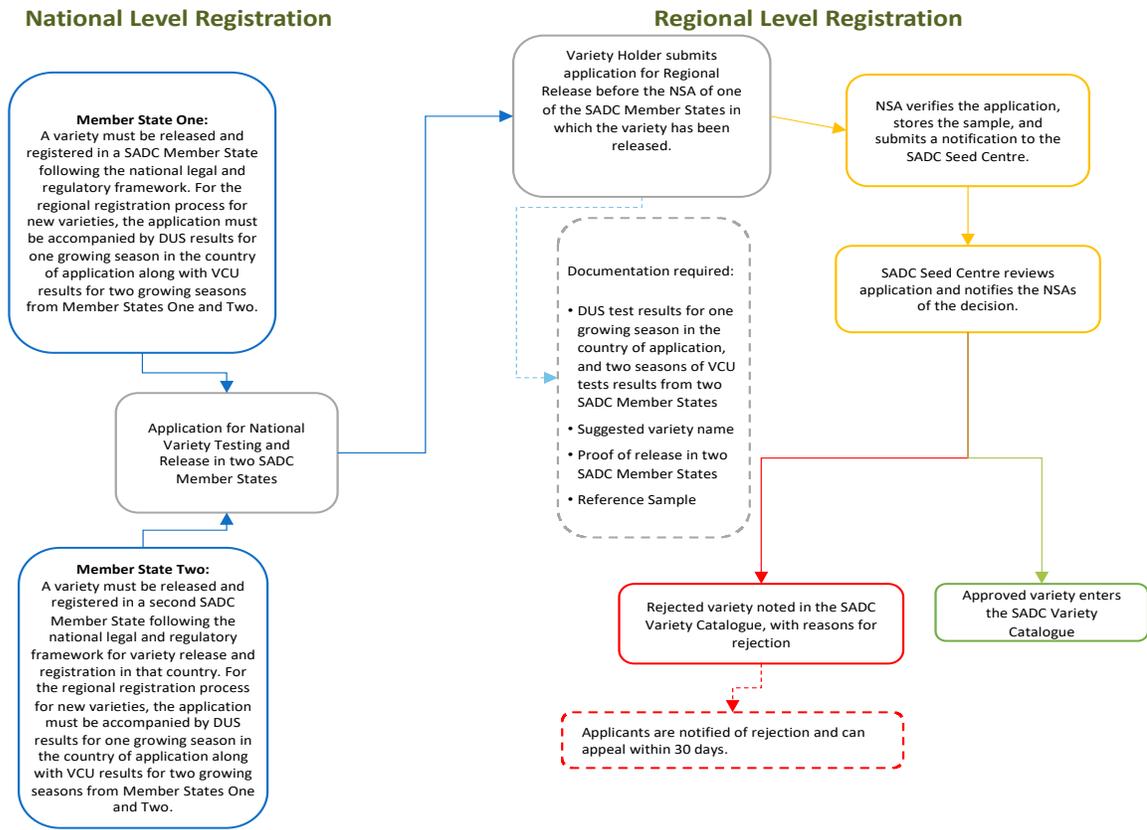
<sup>48</sup> Memorandum of Understanding on the Harmonization of Seed Regulations in the Southern African Development Community (MoU), 2008, Annex II, Arts. 6.6.

<sup>49</sup> Memorandum of Understanding on the Harmonization of Seed Regulations in the Southern African Development Community (MoU), 2008, Annex II, Art. 3.4.

<sup>50</sup> Memorandum of Understanding on the Harmonization of Seed Regulations in the Southern African Development Community (MoU), 2008, Annex II, Art. 3.

<sup>51</sup> Memorandum of Understanding on the Harmonization of Seed Regulations in the Southern African Development Community (MoU), 2008, Annex II, Art. 3.

**Figure 3: New Markets Lab Regulatory Systems Map for the Variety Release and Registration Process in SADC**



©2019 New Markets Lab from the Manual on Regional Seed Regulations in the Southern African Development Community (SADC) publication forthcoming, based on Memorandum of Understanding on the Harmonization of Seed Regulations in the Southern African Development Community.

In addition to new and existing varieties, SADC is the only REC that currently allows for the registration of landrace varieties in the SADC Variety Catalogue.<sup>52</sup> Landrace varieties are local varieties produced by farmers, which typically do not perform as consistently when subject to testing for DUS.<sup>53</sup> SADC also formally recognizes Quality Declared Seed (QDS) as a seed class, as aligned with the Organization for Economic Co-Operation and Development (OECD) Seed Schemes (Tanzania also recognizes QDS).<sup>54</sup> According to the SADC HSRs, landraces could be registered based on a standard similar to QDS,<sup>55</sup> which would allow farmers to regionally trade their varieties. While it is not yet clear how the procedures will be designed and implemented, the SADC MoU does recognize that that landraces and any other local variety for which sufficient documentation is available would be exempted from field tests.<sup>56</sup>

Currently, SADC’s Variety Catalogue does not show any entries by public research institutions. However, the COMESA Variety Catalogue does include one NARS variety and two CGIAR varieties, implying that it would be possible for both the TARIs and CGIAR Centers to register varieties in the SADC Variety Catalogue. As Table 3 shows, as of June 2019, the Ugandan National Crop Resources Research Institute (NaCRRI) had registered two maize varieties, the Kadoma Research Centre in Zimbabwe had registered a common bean variety, and ICRISAT had registered two groundnut varieties, all in the COMESA Variety Catalogue.

**Table 4: Public Varieties Registered in COMESA Variety Catalogue (as of June 2019)**

<i>Variety name</i>	<i>Variety synonym</i>	<i>Release year</i>	<i>Species common name</i>	<i>Breeder</i>	<i>Origin of the variety</i>	<i>Type of the variety</i>	<i>Duration to maturity</i>	<i>Average yield</i>
<i>Longe10H</i>	Longe10H	2019	Maize	NaCRRI, National Crop Resources Research Institute	Conventional Breeding from Uganda	Simple hybrid	Medium	7.50 MT/ha
<i>UH5354</i>	Bazooka	2019	Maize	NaCRRI, National Crop Resources Research Institute	Conventional Breeding from Uganda	Simple hybrid	Medium	10.00 MT/ha

<sup>52</sup> Technical Agreements on Harmonization of Seed Regulations in the SADC Region, the SADC Secretariat, 2008, 25.

<sup>53</sup> Technical Agreements on Harmonization of Seed Regulations in the SADC Region, the SADC Secretariat, 2008, 25.

<sup>54</sup> COMESA Manual, 2019, 2; Katrin Kuhlmann, Yuan Zhou, and Shannon Keating, “Seed Policy Harmonization in COMESA and SADC: The Case of Zambia,” Syngenta Foundation for Sustainable Agriculture and New Markets Lab, September 2018, 7-8.

<sup>55</sup> Lewis, Linzi & Masinjila, Sabrina, “Status Report on the SADC, COMESA and EAC Harmonized Seed Trade Regulations: Where Does This Leave the Regions’ Smallholder Farmers?”, 2018, 18.

<sup>56</sup> Lewis, Linzi & Masinjila, Sabrina, “Status report on the SADC, COMESA and EAC Harmonized seed trade Regulations: Where Does This Leave the Regions’ Smallholder Farmers?”, 2018, 7.

<i>SC Bounty</i>	2017	Common bean	Seed Co Ltd	Kadoma Research Centre in Zimbabwe	Simple hybrid	Medium	2.00 MT/ha
<i>SC Mwenje</i>	2017	Groundnut	Seed Co Ltd	ICRISAT, Malawi	Other hybrid	Early	1.25 MT/ha
<i>SC Nyanda</i>	2017	Groundnut	Seed Co Ltd	ICRISAT Asia Centre	Simple hybrid	Early	1.20 MT/ha

Source: COMESA Variety Catalogue, Website.

Tanzania's national seed rules and regulations and SADC's processes for variety release and registration share similarities that could facilitate regional access:

- Tanzania's Regulations require two seasons of DUS tests and one season of NPT, while SADC requires one season of DUS and NPT trials in each of the two SADC Member States, including the country of application, which can be conducted simultaneously. This means that public institutions interested in registering varieties at the regional level would only be required to undergo one additional step, the NPT test in a second SADC Member State.
- SADC requires that applications for entry in the regional catalogue be submitted to an NSA, which shall also oversee relevant testing. In Tanzania, applications would be submitted to TOSCI, with which the TARIs already work closely. Public institutions would be required to submit the SADC Application Form, along with the payment of the release fee and the annual fee. TOSCI would then be in charge of notifying SADC Seed Centre of the application.
- Tanzania admits a streamlined process for varieties accompanied by test results from other countries with which Tanzania has an existing agreement. This means that varieties already released in another country (SADC Member State) that apply for registration in Tanzania could benefit from this streamlined process when seeking entry into the SADC Variety Catalogue.
- Regional variety registration and release in SADC also requires legal presence (including business registration for a commercial entity).
- Tanzania could also be an important location for testing how the SADC procedures on landraces will be implemented. Because, as noted above, landraces tend to be grown and marketed locally and generally do not meet DUS and VCU standards, it would be insightful to determine what their regional release and registration would entail and whether landraces released in a country could be registered and traded in another SADC Member States.

## Rules Governing Seed Trade in the EAC: ASARECA and the EAC Seed Bill

The EAC is currently in the process of adopting a regional policy and bill for seed, and the process is expected to conclude soon. To date, the EAC has followed the variety release and registration process established by the ASARECA/ECAPAPA Agreement.<sup>57</sup> The ASARECA/ECAPAPA Agreement is a non-binding agreement to harmonize regional variety registration procedures, which has become binding through its incorporation into the national regulations of participating countries.

The ASARECA/ECAPAPA Agreement allows varieties registered in an EAC Member Country to be released in a second EAC Member Country following an expedited process of one season of VCU testing, provided there is sufficient test data available from previous field trials in similar agro-ecological conditions.<sup>58</sup> This streamlined procedure can significantly reduce the time necessary for subsequent release in additional EAC Members, allowing release in a second (or third) country after only one season of VCU/NPT testing.<sup>59</sup> Tanzania has signed and incorporated the ASARECA/ECAPAPA Agreement into its legislation, and the process has been applied in practice.<sup>60</sup> According to Test Cases done by NML and SFSA, the streamlined procedure established by the ASARECA/ECAPAPA Agreement has been used by companies and CGIAR Centers to register varieties. In particular, in 2017 CIAT registered nine bean varieties in Tanzania's National Catalogue through this process.<sup>61</sup>

The EAC Seed Bill lays out similar procedures for release and registration of varieties in the EAC, along with rules related to other stages in the regulatory value chain. The most current version of the EAC Seed Bill includes a Community Plant Variety Catalogue, with the process managed through the NSAs in the EAC Partner States similar to the SADC rules. As is true with other RECs (SADC HSRS, COMESA Seed Trade Regulations), EAC Partner States are expected to designate a National Plant Variety Release Committee in charge of the evaluation and registration of new and existing plant varieties, an aspect with which Tanzania already complies.<sup>62</sup>

Under the EAC Seed Bill, a variety must undergo two seasons of DUS testing and two seasons of VCU or NPT testing performed in a Partner State in order to be registered in the Community Plant Variety Catalogue. In addition, the EAC Seed Bill establishes a streamlined procedure for release and registration in a second Partner State, which requires only one season of DUS and VCU/NPT

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<sup>57</sup> New Markets Lab, derived from research and adapted from Katrin Kuhlmann, "Harmonizing Regional Seed Regulations in Sub-Saharan Africa: A Comparative Assessment," SFSA, September 2015.

<sup>58</sup> New Markets Lab, derived from research and adapted from Katrin Kuhlmann, "Harmonizing Regional Seed Regulations in Sub-Saharan Africa: A Comparative Assessment," SFSA, September 2015.

<sup>59</sup> New Markets Lab, derived from research and adapted from Katrin Kuhlmann, "Harmonizing Regional Seed Regulations in Sub-Saharan Africa: A Comparative Assessment," SFSA, September 2015.

<sup>60</sup> New Markets Lab, derived from research and adapted from Katrin Kuhlmann, "Harmonizing Regional Seed Regulations in Sub-Saharan Africa: A Comparative Assessment," SFSA, September 2015.

<sup>61</sup> New Markets Lab and SFSA, Regional Variety Release Test Cases: 2018 Findings, December 2018.

<sup>62</sup> Draft East African Community Seed and Plant Varieties Bill, 7, September 2018.

testing. Once varieties comply with these requirements, they may be entered in the EAC Community Plant Variety Catalogue.<sup>63</sup> Moreover, EAC admits the automatic release of a variety in a third Partner State under similar agro-ecological conditions after its release in two other Partner States, provided that the data used for the release is made available for verification of the third Partner State.

It should be noted that the EAC Seed Bill establishes the creation of a Community Plant Variety Catalogue and the requirements for variety release and registration, but it does not require such registration as a mandatory step for varieties to be traded within the region.<sup>64</sup> Unlike SADC and COMESA, varieties released in EAC Partner States may be traded within the region without having been registered in the Community Plant Variety Catalogue. Since the EAC Seed Bill is still in the process of being passed and will then require implementing regulations, other details such as procedural steps and associated fees have not yet been established.

The ASARECA/ECAPAPA system currently in place within the EAC and the Draft EAC Seed Bill allow for some conclusions and comparisons as to how this regional system would align with Tanzania's national seed regulation system and the SADC HSRS, even though the EAC Seed Bill is still subject to change:

- Tanzania's Regulations require two seasons of DUS testing and one season of NPT testing, while the EAC Seed Bill requires two seasons of DUS testing and two seasons of VCU or NPT testing for the first country of release and registration. In this context, an additional season of VCU/NPT testing would be required in the second country through the streamlined process.
- Tanzania's laws and regulations recognize a streamlined process for varieties that have been registered in another country within a REC of which Tanzania is a member (and accompanied by relevant test results), which mirrors the ASARECA/ECAPAPA process and shares similarities with EAC Seed Bill. This streamlined process, sometimes referred to as a "confirmation trial", admits the release of a variety after one additional season of VCU/NPT and/or an additional DUS test). Streamlined procedures would greatly benefit public institutions, since they would be able to register varieties regionally once released in Tanzania without having to undergo significant additional testing.
- A potential challenge rests with data sharing among NSAs. This has been an ongoing challenge with regional variety release and registration, and the EAC Seed Bill requires that information be shared among NSAs before varieties can be released through streamlined procedures, perhaps giving rise to the need for a more formal process for

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<sup>63</sup> Draft East African Community Seed and Plant Varieties Bill, 8, September 2018.

<sup>64</sup> Draft East African Community Seed and Plant Varieties Bill, 8, September 2018.

test data sharing. This would help facilitate variety release and registration in other regional markets as well.

- Another challenge will likely arise with respect to the differences between regional rules in SADC and the EAC. Since Tanzania is a member of both RECs, public institutions will have to be aware of the main differences in these regional systems, not only with regard to the registration of varieties, but more broadly as well.
  - SADC requires DUS test results for one season and VCU/NPT test results for two seasons, yet the EAC requires two seasons of test results for each. This means that public institutions might need to verify different test results for the same variety seeking entry into two different regional catalogues.
  - Moreover, while varieties are required to be registered in SADC in order to be traded in the region, according to the most recent version of the EAC Seed Bill, varieties may be traded without being registered. Public institutions should be aware of this difference when considering regional variety release and registration.

### COMESA's Harmonized Seed Regulatory System

As mentioned above, Tanzania is not a Member of COMESA. Nevertheless, COMESA Seed Trade Regulations are worth considering due to their relevance within the region. For example, four of the EAC Partner States, namely Kenya, Uganda, Rwanda and Burundi, are also COMESA Members States. Several of the most significant seed markets in Eastern and Southern Africa, such as Kenya, Zambia, and Zimbabwe, are also members of COMESA. Tanzania could be potentially impacted by the seeds that could enter its market through the EAC, which, in turn, might enter the market through COMESA.

The COMESA Seed Trade Regulations establish the procedure for the registration of both new and existing varieties. In addition, the COMESA Seed Trade Regulations set out a streamlined procedure for the registration of varieties released in one or two COMESA countries.<sup>65</sup> In all cases, the procedure requires varieties to undergo DUS testing, in accordance with UPOV guidelines, and VCU or NPT testing.<sup>66</sup> New varieties are required to undergo two seasons of DUS and VCU testing in two COMESA Member States,<sup>67</sup> while varieties released in one country require only one season of additional testing. Varieties released in two countries are automatically registered in the COMESA Variety Catalogue upon submission of DUS and VUC testing.<sup>68</sup> Table 5 summarizes these requirements.

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<sup>65</sup> COMESA Seed Trade Harmonization Regulations, 27-28, 2014.

<sup>66</sup> COMESA Seed Trade Harmonization Regulations, 20, 2014.

<sup>67</sup> COMESA Seed Trade Harmonization Regulations 27.

<sup>68</sup> COMESA Seed Trade Harmonization Regulations, 27-28, 2014.

**Table 5: COMESA Variety Release & Registration Process Requirements**

COMESA Variety Release & Registration Process – Requirements		
Varieties Released in 2+ COMESA Countries	Varieties Released in 1 COMESA Country	New Varieties
<ul style="list-style-type: none"> <li>• Application for Regional Catalogue entry</li> <li>• Submission of necessary DUS &amp; VCU Data</li> <li>• Initial Registration Fee</li> <li>• Annual Registration Fee</li> </ul>	<ul style="list-style-type: none"> <li>• Application for Regional Catalogue entry</li> <li>• Submission of necessary DUS &amp; VCU data from 1<sup>st</sup> Member State</li> <li>• Proof of release in 2<sup>nd</sup> Member State (only one season of DUS and VCU required)</li> <li>• Initial Registration Fee</li> <li>• Annual Registration Fee</li> </ul>	<ul style="list-style-type: none"> <li>• Application for Regional Catalogue entry</li> <li>• Two seasons of DUS and VCU Testing</li> <li>• Proof of release in two Member States</li> <li>• Initial Registration Fee</li> <li>• Annual Registration Fee</li> <li>• Suggested Variety Name</li> <li>• Reference sample provided to National Seed Authority</li> </ul>

Source: New Markets Lab, Manual on Regional Seed Regulations in the Common Market for Eastern and Southern Africa (COMESA), Syngenta Foundation for Sustainable Agriculture under the Seeds2B Initiative and Partnerships for Seed Technology Transfer in Africa (PASTTA), February 2019, (based on the COMESA Seed Trade Harmonization Regulations, (2014)).

In contrast to SADC and the proposed rules in the EAC, applications for entry in the COMESA Variety Catalogue must be submitted to the COMESA Seed Office (See Figure 4, along with test results and samples to be stored).<sup>69</sup> Applicants must be located in one of COMESA Member States or be represented by an agent located in one of the Member States and need to create an online account.<sup>70</sup> In addition, applicants must submit a letter to the COMESA Seed Office Secretariat signed by a legal representative attesting that the applicant is authorized to apply for a COMESA registration.<sup>71</sup> In COMESA, the fees have been established and are applied, with applicants required to pay a registration fee of \$350 and an annual fee of \$200,<sup>72</sup> along with any national fees established by NSAs.

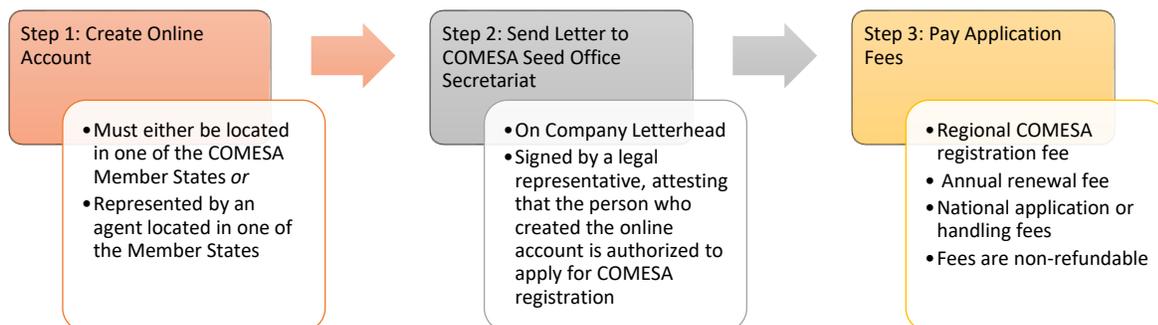
<sup>69</sup> COMESA Seed Trade Harmonization Regulations, 27.

<sup>70</sup> “Filing an Application,” *COMESA Variety Catalogue*, December 2017, <https://varietycatalogue.comesa.int/fillinghelp>.

<sup>71</sup> *Ibid.*

<sup>72</sup> *Ibid*; Regulation 24.

**Figure 4: COMESA Variety Release & Registration Process**



Source: New Markets Lab, Manual on Regional Seed Regulations in the Common Market for Eastern and Southern Africa (COMESA), Syngenta Foundation for Sustainable Agriculture under the Seeds2B Initiative and Partnerships for Seed Technology Transfer in Africa (PASTTA), February 2019.

### Comparison Across Regions

As explained above, the variety release and registration processes across RECs share some similarities with each other and with Tanzania’s national rules. These include the adoption of a streamlined procedure for the registration in a second or a third country, and the payment of annual and registration fees. Nevertheless, these procedures do differ, mainly in relation to the number of seasons required for DUS/VCU testing. Table 6 below highlights the similarities and differences across rules in Tanzania, the SADC HSRS, the EAC Seed Bill and the COMESA Seed Trade Regulations.

**Table 6: Comparison of Regional Variety Release and Registration Procedures in Eastern and Southern Africa**

Tanzania	SADC HSRS	EAC Seed Bill	COMESA Seed Trade Regulations
<b>New Variety</b>	<b>New Variety</b>	<b>New Variety</b>	<b>New Variety</b>
<ul style="list-style-type: none"> <li>DUS Two Seasons</li> <li>VCU One Season</li> </ul>	<ul style="list-style-type: none"> <li>Released in two countries</li> <li>DUS One Season</li> <li>VCU in each of two SADC Member States</li> </ul>	<ul style="list-style-type: none"> <li>DUS Two Seasons</li> <li>NPT Two Seasons</li> </ul>	<ul style="list-style-type: none"> <li>DUS Two Seasons</li> <li>VCU/NPT Two Seasons</li> </ul>

<p><b>Regionally Registered Varieties</b></p> <ul style="list-style-type: none"> <li>• Entry in National Catalogue through streamlined procedure of one additional season of testing, codified under national law</li> </ul>	<p><b>Variety Released in one Member State to be released in a Second Member State</b></p> <ul style="list-style-type: none"> <li>• DUS One Season</li> <li>• VCU Two Seasons</li> <li>• Procedure not streamlined as in other RECs</li> </ul>	<p><b>Variety Already Released in one Partner State and Seeking Release in a Second Partner State</b></p> <ul style="list-style-type: none"> <li>• DUS One Season</li> <li>• VCU One Season</li> </ul>	<p><b>Variety Already Released in one Member State and Seeking Release in a Second Member State</b></p> <ul style="list-style-type: none"> <li>• VCU/NPT One Season</li> </ul>
<p><b>EAC Registered Varieties</b></p> <ul style="list-style-type: none"> <li>• Not implemented yet</li> </ul>	<p><b>Variety Released in two Member States prior to SADC Variety Catalogue</b></p> <ul style="list-style-type: none"> <li>• Entrance in the SADC Catalogue upon submission of DUS/VCU</li> </ul>	<p><b>Variety Released in two Partner States</b></p> <ul style="list-style-type: none"> <li>• Automatic release in third Partner State</li> </ul>	<p><b>Variety released in two Member States prior to COMESA Variety Catalogue</b></p> <ul style="list-style-type: none"> <li>• Entrance in the COMESA Variety Catalogue upon submission of DUS/VCU</li> </ul>
<p><b>Fees</b></p> <ul style="list-style-type: none"> <li>• Registration Fee \$4.33</li> <li>• Total (DUS, NPT, Application Fees) \$481.46</li> </ul>	<p><b>Fees<sup>73</sup></b></p> <ul style="list-style-type: none"> <li>• Registration Fee (TBD)</li> <li>• Annual Fee (TBD)</li> </ul>	<p><b>Fees</b></p> <ul style="list-style-type: none"> <li>• Not established yet</li> </ul>	<p><b>Fees</b></p> <ul style="list-style-type: none"> <li>• Registration Fee \$350</li> <li>• Annual Fee \$200</li> </ul>

Source: New Markets Lab, November 2019.

## Licensing Agreements

Licensing agreements are contracts between two parties where one party authorizes the other to use and commercialize a plant variety in exchange for a royalty payment. They have been used in

<sup>73</sup> Initial Registration and Annual Registration Fees are in the process of being established by the SADC Seed Centre, and no fees are being charge for registration and maintenance in the SADC Variety Catalogue as of December 2019.

Africa for several decades, with positive outcomes.<sup>74</sup> TARI already uses licensing agreements in some cases and may increase use of them to facilitate exchange between the public institutions and the private sector.

Tanzania's legal and regulatory framework, including the PBR Act of 2012, is conducive for these agreements. NARS and CGIAR Centers would benefit from being aware of the different dimensions of licensing agreements, which can be concluded independent of or based on PVP and PBR rules. More information on the different models and options for entering into licensing agreements can be found in the *Annotated Guide on Flexible Licensing Models and Agreements*,<sup>75</sup> and a Tanzania- or TARI-specific model agreement could be developed.

Overall, licensing agreements can be used as vehicles to get more public varieties into the market, either by transferring the right to commercialize a variety that has already been registered or by licensing the right to register a variety in national or regional catalogues. There is often a misconception that licensing agreements can only be entered into if a variety has been protected under PBR. However, in many countries in Africa, public institutions have entered into licensing agreements with private companies for varieties that are not protected under PVP frameworks. The trade-offs of entering into one type of licensing agreement over another are explored in more depth in the *Annotated Guide on Flexible Licensing Models and Agreements*.

When used as a channel for commercializing new varieties, public research institutions can give private companies, or other public institutions, access to germplasm and authorize registry in the national (or regional catalogue) or public institutions can grant the right to commercialize an already registered variety in the national or regional market. The former model is more common between CGIAR Centers and NARS or private companies (although the CGIAR Centers rely upon a Standard Material Transfer Agreement and not licensing agreements), and the latter is more common between NARS and private companies. In exchange for use rights, a private company would agree to pay a royalty fee to the public breeder. In this sense, licensing agreements not only formalize relationships between the public and private sectors, but they also create alternative sources of income for public research institutions that can be reinvested into future varietal development programs.

In addition to licensing agreements, under the Parliamentary Act No. 13 of 2016 of Tanzania (TARI Act), there is another type of contract that is related to IPR and can have implications for licensing agreements. The Act foresees the implementation of performance contracts or arrangements between TARI and agricultural research services.<sup>76</sup> Through the performance

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<sup>74</sup> New Markets Lab, "Case Study on KALRO Model Plant Varieties Licensing Agreement," Syngenta Foundation for Sustainable Agriculture and New Markets Lab, 2019, publication forthcoming.

<sup>75</sup> New Markets Lab, "Annotated Guide on Flexible Licensing Models and Agreements," New Markets Lab and SFSA, publication forthcoming.

<sup>76</sup> Section 16, Parliamentary Act No. 13 of 2016, The United Republic of Tanzania.

contracts, agricultural research services are expected to conduct agricultural research either with public funds or on behalf of TARI, while TARI retains the IPR of the findings and discovery. The MFAC passed the Act to encourage TARI Centers to engage in the necessary agreements to generate additional revenue and operate at their maximum capacity.<sup>77</sup> These contracts could include elements from licensing agreements, since TARI is allowed, for the purposes of commercial exploitation, to arrange with any person to buy, sell, take or grant IPR related to the discovery.<sup>78</sup> These agreements could be a useful tool for TARI Centers, since they could expand their research while commercially exploiting IPR, which, as mentioned above, could increase revenue for the TARI Centers. Examples of these agreements include, among others, TARI's partnership in the Next Generation Cassava breeding project, a Cornell-based project funded by BMGF and the Department for International Development of the United Kingdom<sup>79</sup> and TARI's agreement with local farmers to produce more resilient potatoes varieties.<sup>80</sup>

## **Plant Variety Protection and Plant Breeders' Rights in Tanzania**

Tanzania regulates PVP and PBRs through the 2012 Plant Breeders' Rights Act (PBR Act, 2012) and the Protection of New Plant Varieties (Plant Breeders' Rights) Regulations 2008 (PBR Regulations). The regulatory framework for PBR has been in place for some time, but it has not been frequently used by public breeding institutions. Tanzania's PBR Registry is not easily accessible online; however, as of January 2009,<sup>81</sup> 25 applications for PBRs had reportedly been submitted by public institutions. This number is lower than the number of public varieties registered in the national catalogue, but it shows that public institutions are users of the PVP system. Continuing to track how public institutions use PBR protection through the PBR Registry could be an issue for future focus.

At the international and regional levels, there are three main instruments for PVP, the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (WTO TRIPS Agreement), the Union for the Protection of New Plant Varieties Internationally Convention (UPOV Convention), and the Arusha Protocol of the African Regional Intellectual Property Organization (ARIPO). Tanzania is a member of the WTO and joined UPOV on November 22, 2015.<sup>82</sup> Tanzania is also a Member of ARIPO and a signatory to the Arusha Protocol. Tanzania's

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<sup>77</sup> Tanzania Urges Agro-Research Institutes To Find Alternative Sources Of Funds, The Citizen, June 2018, available at <https://www.thecitizen.co.tz/news/1840340-4612422-5gadskz/index.html>.

<sup>78</sup> Section 18(1)(2), Parliamentary Act No. 13 of 2016, The United Republic of Tanzania.

<sup>79</sup> Tanzania Partners With Cornell-Affiliated Nextgen Cassava, Cornell Chronicle, December 2016, available at <http://news.cornell.edu/stories/2016/12/tanzania-partners-cornell-affiliated-nextgen-cassava>.

<sup>80</sup> Tanzania Agricultural Research Institute Wants To Produce More Resilient Potatoes, Fresh Plaza, September 2019, available at <https://www.freshplaza.com/article/9141294/tanzania-agricultural-research-institute-wants-to-produce-more-resilient-potatoes/>.

<sup>81</sup> Patrick Ngwediagi, "Establishment of Plant Breeders' Rights Act in Tanzania: Achievements and Challenges" Institutionalisation of Intellectual Property Management: Case Studies from Four Agricultural Institutions in Developing Countries. Italy: CAS-IP.

<sup>82</sup> <https://www.upov.int/export/sites/upov/news/en/pressroom/pdf/pr102.pdf>

PBR Act is aligned with the WTO TRIPS Agreement and the UPOV Convention and protects the intellectual property rights (IPR) of breeders.<sup>83</sup> In addition, Tanzania has also been a Member of the International Treaty of Plant Genetic Resources for Food and Agriculture (ITPGRFA) since 2004, which also contains provisions related to the protection of farmers' rights.

Tanzania has designated a PBRs Office as the key regulatory body under the PBR Act. The PBRs Office is mandated to grant PBRs, maintain the PBRs register, facilitate the transfer and licensing of PBRs, and coordinate with domestic, regional and international bodies on all issues relating to PBRs. Breeders can apply for PBRs to the Registrar of the PBRs Offices, who can request that TOSCI perform a DUS test on a sample. The results are then submitted to the PBRs Advisory Committee for review, and, upon its recommendation, the PBRs Registrar may grant either provisional or final PBR protection, issue a PBR certificate, enter the variety in the PBR register in accordance with the regulations, and publish a notice of the grant of PBR and the approved denomination in the Gazette. The PBR holder is free to license the rights of use of the protected variety, subject to limitations under the PBR Act.

At the regional level, SADC does not regulate PBRs; however, the EAC Seed Bill, in its current form, does regulate PBR. The implications of this is that PBRs registered in a country that is a SADC Member State would not be protected within the broader SADC region but would be protected within the EAC once the EAC Seed Law goes into effect. The EAC Seed Bill seeks to harmonize PVP and PBR in the region, to preserve rights on protected varieties, expand knowledge on PBR and PVP, and render protection more enforceable. In addition, the EAC Seed Bill contains a provision recognizing PVP protections that have been granted under other international or national schemes. This means that any variety already protected under Tanzania's PVP law would be protected within the entire EAC region once the EAC Seed Bill is implemented.

As Tanzania's PVP law highlights, countries may (but do not always) include provisions on licensing and royalties in national PVP laws. Tanzania's Plant Breeders' Act 2012 requires the authorization (possibly through a license) from the plant breeders' right holder for the production or reproduction, conditioning for the purpose of propagation, offering for sale, selling or marketing, exporting, importing, and stocking for any purposes covered in the previous list.<sup>84</sup> Tanzania's Plant Breeders' Act 2012 does not require the payment of royalties as part of the licensing agreement (although this would not preclude payment of royalties), but it does require that the plant breeders' right holder be compensated when a compulsory license is granted for public interest reasons.<sup>85</sup>

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<sup>83</sup> New Markets Lab with the Southern Agricultural Growth Corridor of Tanzania Centre Ltd. for the Alliance for a Green Revolution in Africa, "A Legal Guide to Strengthen Tanzania's Seed and Input Markets", April 2016.

<sup>84</sup> Plant Breeders' Right Act 2012, Section 30(1).

<sup>85</sup> Plant Breeders' Right Act 2012, Section 41(2).

In terms of enforcement of PBRs, Section 34 of Tanzania's Plant Breeders' Act 2012 states that:

1. Breeders' rights are protected by both civil and criminal measures stipulated in written law.
2. A suit by the holder of breeder's right against any person who infringes the breeder's right may be brought in any court of competent jurisdiction.
3. The court may in addition to the cost of the action, grant an injunction or damages or both, as it may appear to be reasonable in the circumstances of the case.

## **Main Findings and Questions for Discussion**

Overall, Tanzania has a robust and well developed seed regulatory system. In addition, Tanzania's system is generally aligned with the RECs of which it is a member, namely SADC and the EAC. This regulatory context, along with the market potential in Tanzania (where most breeding is currently carried out by TARIs), can be particularly beneficial for NARS and CGIAR Centers to bring their developed varieties to broader markets. Nevertheless, as mentioned above, expanding to regional markets does come with costs that could pose challenges for public institutions.

Tanzania's main regulatory institution for seed, TOSCI, is not only mandated with the national variety release and registration process, but, as the designated NSA, TOSCI is also mandated with implementing regional seed harmonization. As noted above, while the SADC and draft EAC process do align somewhat, there are still notable differences with regard to the requirements of each system, including the number of seasons of required DUS and VCU/NPT testing, documentation, and registration requirements and annual fees.

Several aspects are worth highlighting for NARS and CGIAR Centers. First, the EAC's proposed process would require more testing for variety registration than Tanzania's national system and the SADC HSRs currently do, as the Draft EAC Seed Bill currently mandates two seasons of DSU testing and two seasons of VCU/NPT testing, which would entail additional steps in the regional variety registration process, although application of a streamlined process, as currently applied under the ASARECA system and as envisioned in the EAC rules, could simplify the process. Second, a pool of varieties could enter Tanzania's market through other processes, since the EAC does not require that varieties be registered in the EAC in order to be traded within region, potentially linking Tanzania's much more closely to COMESA.

Moreover, NARS and CGIAR Centers should bear in mind the possibility to enter into Licensing Agreements as a tool to access wider regional markets while raising their revenues to continue their breeding activities. Licensing agreements will be increasingly essential for increasing the commercialization of public varieties, including at the regional level, and a model could be developed specific to Tanzania. These agreements need not be based on PBR. It is notable though

that as the EAC Seed Bill moves forward, protection for PBR granted under Tanzanian law will have broader application.

#### Questions for Discussion:

- 1) *As mentioned above, only three public institutions have registered new varieties in Tanzania's National Variety Catalogue. What are the main challenges that public institutions face regarding variety registration, and what could help facilitate a greater number of varieties registered across crops?*
- 2) *What is the current common experience in completing the variety release and registration process? Are there still inconsistencies and delays? Are the national breeding institutions increasingly active?*
- 3) *Why have public institutions not registered varieties in regional catalogues? Some stakeholders have reported lack of knowledge of the process, while others stress that registration and annual fees are a burden. Are there any other challenges for public institutions, and how could they be overcome?*
- 4) *Some stakeholders have reported lack of knowledge related to licensing agreements and existing policies in Tanzania. Are there any public institutions that regularly use these agreements? Do they find them to be a useful tool? What are the main challenges for increasing use of licensing agreements?*
- 5) *As mentioned above, Tanzania has implemented a PBR Registry. Have any public institutions claimed PBR in Tanzania? If so, did they encounter any challenges? And if they have not claimed PBR yet, why?*