WORKING PAPER

Seed Policy Harmonization in the EAC and COMESA: The Case of Kenya

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Syngenta Foundation for Sustainable Agriculture

September 2015

The paper is part of a series of research on regional seed policy harmonization in Africa, to assess the process for implementing a seed regulatory system that can better deliver improved seed varieties to farmers. It is part of Syngenta Foundation's Seeds2B initiative.

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Executive Summary

There is wide consensus that seed, especially seed of improved varieties, is one of the most important elements for increasing agricultural productivity and improving rural livelihoods. It is also well recognized that the legal and regulatory framework, both within countries and regionally, is a significant factor in both access and availability of improved seed. However, there is no established roadmap for how to make legal and regulatory systems work in practice. In spite of improvements in national level seed law and regulation and strengthened regional seed protocols, implementation of these legal and regulatory frameworks remains a challenge throughout markets in sub-Saharan Africa.

This case study on Kenya is part of a series developed by the Syngenta Foundation for Sustainable Agriculture (SFSA) and its partner the New Markets Lab to assess the process for implementing a seed regulatory system that can better deliver improved seed varieties to farmers. These case studies are part of a larger project on regional seed harmonization launched by the partners in 2014, and it complements an assessment on regional harmonization efforts in seeds done by the New Markets Lab for SFSA in 2015 by focusing on how these measures are being implemented within a particular country. Other case studies in the series will cover Zimbabwe (a member of the Common Market for Eastern and Southern Africa (COMESA) and the Southern African Development Community (SADC)) and a country in the Economic Community of West African States (ECOWAS). This case study, and the others in this series, will assess the current national level legal and regulatory environment and progress on implementing regional seed protocols and identify key decision points that could drive the process forward towards development of an inclusive and well-functioning seed regulatory system. While each case study is meant to stand alone, the body of case studies will allow for a comparison of regulatory practices that could help build a stronger understanding of the mechanics of implementation of a well-functioning seed regulatory system. As a next step, in 2016 the partners will conduct test cases to work through the regulatory process in several of Africa's regions.

While Africa's regional economic communities (RECs) are currently taking steps to harmonize seed regulation, the task is complicated and will require significant action by national governments and regulators to come into full effect. This case study assesses the significant legal and regulatory elements of the seed system in Kenya, which is a member of both the East African Community (EAC) and COMESA. Substantive areas of law and regulation include variety release and registration,

certification, and trade), viewing these in the context of regional harmonization efforts. Company interviews are included below and provide a method for examining Kenya's legal and regulatory system in practice. This case study attempts to qualitatively assess the pace at which regional harmonized seed policy is being implemented in Kenya and recommends intervention points for moving the system forward.

Based on the authors' findings, Kenya is developing notable regulatory best practices in some areas (for example efforts underway to allow private inspection) that could perhaps be applied more broadly in order to increase availability and access of high-quality seed. By all accounts, it can still take several years to register new seed varieties in Kenya. This is often true even when the varieties are already available in neighboring countries or when fellow Member States belong to a common trading area such as the EAC or COMESA that has a framework in place for facilitating regional seed trade. This lengthy registration process contributes to smallholders' limited access to improved seeds, and therefore further restricts their ability to increase yields and benefit economically from their crops. Well- implemented national and regional seed policies would have major benefits, and mutual recognition of varietal registration and easier movement of seeds between countries would significantly reduce costs and delay.

Overview of the Kenyan Seed System

Kenya has a relatively well-developed seed market within sub-Saharan Africa, yet only one-third of seed currently comes from seed companies, while two-third of seed derives from the informal sector. Less than 10 percent of the total area is sown using certified seeds. Farmers do not use improved seeds, because they are not available or accessible to them.

Kenya's regulatory system, including implementation of regional seed protocols, must be assessed in the context of the country's seed market. As noted, Kenya's seed market is relatively well developed, although much of the sector remains informal, and access and availability of quality seed remain challenges. As is true throughout the region, seed is also an issue. The brief overview of Kenya's seed market below is followed by details on the regulatory process for registering, certifying, and trading seeds.

Plant Breeding and Varietal Improvement

Plant breeding and varietal improvement in Kenya are carried out within public institutions and private companies. The main public institutions involved in cultivar development are the Kenya Agricultural and Livestock Research Organizations (KALRO, previously KARI), public universities, and international centers such as CIMMYT's regional offices. Private seed companies also undertake breeding activities according to their capacity. The regulatory structure does present some challenges with respect to breeding and varietal improvement, which are discussed in greater detail below.

Variety Maintenance and Early Generation Seed Multiplication

The production of quality seed and especially the preservation of the characteristics of varieties throughout generations require that the breeder maintain a quantity of very high-quality seed, often called nucleus seed. The multiplication of subsequent early generations of seed, pre-basic seed, and basic seed (also known as breeder and foundation seed), which requires high technical expertise and specific equipment and infrastructure, is generally carried out under control of the breeder. In Kenya, maize and other staple crops are largely undertaken by the public sector (e.g. KALRO or universities). Issues relating to delays in timely availability of adequate quantities and quality of early generation seed can cause major bottlenecks for the production of improved seed.

Formal and Informal Seed Delivery Systems

The formal seed system is thoroughly regulated and focuses on breeding, producing, and selling certified seeds by registered seed companies. As the main regulatory body, or the National Designated Authority (NDA), KEPHIS manages these activities as well as the importation of seed. The formal seed sector started with the establishment of the Kenya Seed Company (KSC) in 1956 to produce pasture seeds for the colonial settlers (Sikinyi, 2010). The company later diversified into other crops and continued to play a predominant role in the seed sector until the sector was liberalized in mid 1990s. After liberalization of the sector, many private companies entered the formal sector, and as of May 2015 there were 112 registered seed companies (KEPHIS, 2015), many of which are members of the Seed Trade Association of Kenya (STAK).

Table 1: Role of Key Players in the Kenyan Formal Seed Sector

ROLE	KEY PLAYERS
Research and breeding	KALRO; universities; MNCs; local seed companies
Variety release & regulation	KEPHIS
Breeder and foundation seed production	KARI; Universities; MNCs; local seed companies
Seed production	KALRO, local seed companies; MNCs; community organizations
Processing and packaging	KALRO Seed Unit, local seed companies; MNCs
Education, training, extension	Seed companies, extension agents, NGOs, rural agro-dealers
Distribution and sales	Private sector seed merchants; Kenya Seed Company, KALRO Seed Unit and other parastatals, rural agro-dealers; NGOs

Source: TASAI, 2015.

Most Kenyan seed companies produce cereal seed (especially maize, wheat, and barley) and legumes (especially beans), which are under mandatory certification (Schedule II crops; see discussion below), and distribute imported vegetable seeds. Schedule II crops include cereals (maize, wheat, barley, sorghum, millet, oats, triticale); pulses (beans, peas, cowpeas, pigeon peas); oil seeds (sunflower, oil-seed rape, linseed, soya, sesame); grasses (setaria, Rhodes grass, Sudan grass, Congo signal, panicum); pasture legumes (Centro, Stylo, Desmodium, Clover, Lucerne, Siratro, lupins); and root crops (Irish potato).

Except for maize, there is very little certified seed of pigeon pea, cowpea, sorghum, millet or green gram produced by private companies. The demand for such crops, often open-pollinated varieties, is considered unreliable and insufficient to make a viable business for many seed companies. An issue often raised is that farmers will buy seeds once and use farm-saved seeds in subsequent seasons. It is a typical 'catch 22' situation. Farmers save seeds because they are not assured of regular and timely availability of seed locally, and the supply of quality seeds on the market is impacted by the practice of saving seeds.

The informal seed sector refers to the seed supply by unregistered seed producers. The informal seed sector is substantial and accounts for 60 to 80 percent of the total seed market. Seed produced is variable in quality and is not produced under a certification scheme. Production and marketing are often localized and based on low-input technology. Key players in this system include farmers, farmer groups, NGOs, researchers, and community-based organizations (CBOs). In Kenya, most seed of open-pollinated varieties of cereals, grain legumes and also of vegetatively propagated crops such as sweet potato and cassava are produced informally. This part of the sector accounts for over 90 percent of the seed of non-maize crops planted each season (Kimani et al., 2014). Except for Schedule II crops, no certification

is required, although the situation is shifting in favor of certification of more crops. Unlike other countries in the region, Kenya does not allow for alternatives to centralized seed certification. These include Quality Declared Seed (QDS), a process often cited to be less cumbersome, which has been used to certify vegetatively propagated seed in some regions.

Seed traded and used in Kenya is made up of locally produced and imported seed. As part of the trade business, Kenya also exports seed, particularly to its neighbors in the region. The movement of seed within and between countries can be restricted by regulations governing registrations and permits, variety testing and release procedures, seed certification and standards, phytosanitary measures, plant variety protection, and import and export requirements (See Sikinyi, 2010). Recognition of another country's regulatory practices is a significant issue across these areas, and this is perhaps one of the greatest challenges to implementation of a seed regulatory system that spans borders. These areas of regulation and their implications for regional trade are discussed in greater detail below.

Legal and Regulatory Framework

Kenya is one of the few African countries recognized for having well developed seed laws and regulatory institutions for a number of years, despite the challenges associated with the content and application of the laws, the degree of regulations, and the capacities of associated implementing institutions (Dwijen, 2006). Currently, Kenya regulates the seed sector through a number of legal instruments, including the Seed and Plant Varieties Act (Seed Act; Cap 326, Commencement 1975; last amended 2012; gazetted January 4, 2013); the Crops Act 2013 (gazetted January 25, 2013); the Plant Protection Act (Cap 324); the Agriculture, Fisheries, and Food Authority Act 2013 (gazetted January 25, 2013), the Pest Control Products Act (Cap 346), and related regulations such as the Seeds and Plant Varieties Regulations (Seeds Regulations), the Seeds and Plant Varieties Regulations (National Performance Trials Regulations), and the Plant Breeder's Rights Regulations, all of which are currently subject to amendment. In general, the laws provide a broader framework for governance of the seed sector, while regulations contain more specific guidelines for regulatory processes and day-to-day operations. Even with a comprehensive legal and regulatory system, laws and regulations on paper will not address every possibility that could arise in practice, and issues surrounding clear and consistent implementation of laws and regulations are common. As the regional seed protocols enter into force, the potential for developing Kenya's seed system will increase, as will the possibility of challenges with implementation of the legal and regulatory system.

In general, a country's seed laws govern the processes of variety release, registration, testing, marketing, packaging, and certification (quality control), among other things (Kuhlmann, 2013). A clear and properly designed legal framework on seeds is one of the most important requirements for the development of the agricultural sector, as it facilitates the development of the seed sub-sector and create a suitable environment for seed stockholders (FAO, 2011).

Under Kenya's seed laws and regulations, different institutions have been established to implement seed laws and regulations. The Ministry of Agriculture, Livestock and Fisheries is mandated to formulate, implement, and monitor agricultural acts, regulations, and policies that support agricultural research, promote technology, ensure quality of seeds and other inputs, and control pests. MOA also has the final approval on all varieties released to market. As noted above, KEPHIS is the primary regulatory authority for seeds and has a regulatory mandate to protect seeds and plant varieties, provide seed certification and laboratory services, and administer sanitary and phytosanitary (SPS) matters.

The Seeds and Plant Varieties Act (Cap 326) is central to the seed industry; however, with the dynamic changes following the liberalization of the seed sector, there are a number of areas that are not fully addressed. These include the authorization of seed certification and testing services; regional harmonization of seed laws, policies, and regulations; and a thorough review of the legal framework (Ministry of Agriculture, 2010). Other contemplated or necessary changes in law and regulation are noted below. Laws and regulations will be a significant factor in determining how different elements of the seed system can be taken to scale. For instance, regional harmonization of seed rules and regulations can both serve to streamline market regulation and, in some cases, add another layer of complexity on top of national level laws and regulations.

Variety Release and Registration

The Seed and Plant Varieties Act, Cap 326 of the Laws of Kenya, guides the regulatory process of seed release, certification, and production. Variety release procedures are designed to evaluate and regulate the varieties of seed that can be produced and traded. The purpose of this system is to ensure that varieties made available to farmers are superior in their performance and more diverse in their characteristics than existing varieties on the market.

Variety release procedures usually consist of performance testing through multi-location trials and administrative registration procedures. In order to be officially released and registered in Kenya, a new variety listed under the second schedule of the Seeds and Plant Varieties Act (CAP 326) must:

- Undergo National Performance Trials (NPTs) for at least two seasons be found to be superior in terms of yield or other special attributes. *Where a plant variety has already been officially released in any country within the regional economic blocks to which Kenya is a member and has harmonized performance trial regulations* (emphasis added), the variety shall undergo performance trials for at least one season in similar agro-ecological zones, provided that an applicant shall provide the data leading to release of the plant variety in that other country;
- Be proven to be distinct, uniform, and stable (DUS) in the essential characteristics;
- Have a valid descriptor for seed certification; and
- Have been approved and released by the National Variety Release Committee (NVRC) (Sikinyi, 2010).

Once a variety has been officially released, it is gazetted and entered into the National Variety List. Commercialization can either be done by the applicant or by another who is permitted to multiply varieties under license.

NPT (VCU) and DUS testing are officially conducted by KEPHIS, which also organizes meetings for the NPT Technical Committee and the National Variety Release Committee (NVRC) on behalf of the Ministry of Agriculture. KEPHIS maintains a register of released varieties and post-control plots, inspects seed crops, issues labels for certified seed, and regulates seed exports and imports in accordance with the Seeds Act.

The DUS and VCU tests are usually carried out for a minimum of two seasons according to UPOV protocols (Kenya has been a UPOV member since 1999). While these tests are sometimes done concurrently, both market and crop considerations may require that tests are conducted sequentially, and the length of the process will vary according to the crop. In addition to VCU and DUS data, on-farm data must also be submitted by the breeder, which includes initial field performance evaluations and data. After completion of the DUS and VCU tests by KEPHIS, the data are submitted to the National Performance Trials Committee (NPTC) for assessment. KEPHIS chairs the NPTC meetings that include various stakeholders from the seed sector, including

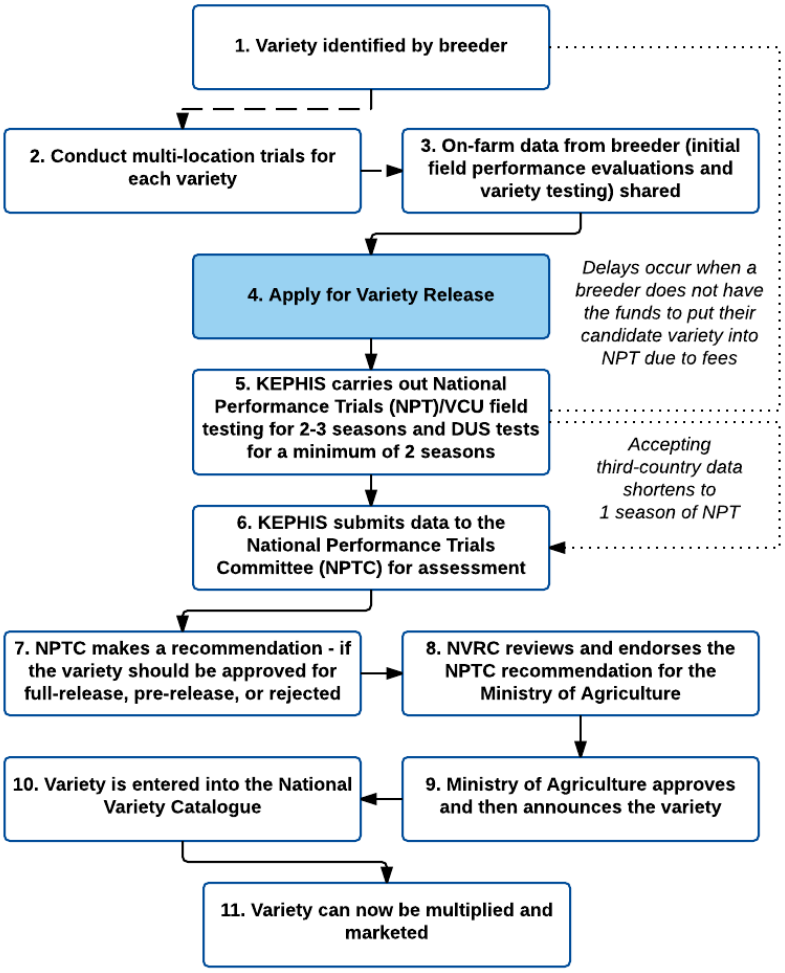
STAK. At the end of the meeting, the NPTC makes its recommendation on whether or not the variety should be approved for full release, pre-release, or rejected.

The recommendations are forwarded to the NVRC for endorsement and final recommendation and approval by the Ministry of Agriculture (MOA). The released varieties are then announced by the MOA before being entered into the national variety catalogue.

Figure 1 illustrates the variety release process in Kenya.

Maize is the crop with the largest number of varieties registered in Kenya. Besides the national breeding program, a number of seed companies also evaluate and conduct variety trials in various ecologies. When superior varieties with good agronomic traits have been identified from multi-environmental trials, they are included in the NPTs for further evaluation by KEPHIS. KEPHIS will then carry out its own independent VCU and DUS tests of the candidate variety. The NPT trials are largely conducted in rain-fed conditions, which means that drought can delay the process considerably.

Figure 1: Variety Release Process in Kenya



Source: Cap 326, Seed Regulations, and National Performance Trials Regulations, 2009. See also Setimela, 2009. For the National Variety List, see KEPHIS.

Under regional harmonization, the whole process could be shortened by accepting third-country data if the same varieties have been registered in other countries in the same regional blocs. The precise frameworks and processes surrounding regional variety release will vary, however. For example, within the EAC, Kenya, Tanzania, and Uganda agreed to allow for more open trade of varieties approved in another country through an agreement developed by the Association for Strengthening Agricultural Research in Eastern and Central Africa (ASARECA), which provides that only one season of additional NPT testing in the destination market will be required if DUS and VCU data is submitted from the first registration and similar agro-ecological conditions exist. As stated in the National Performance Trials Regulations 10(2): "Where a plant variety has already been officially released in any one of the East African Community Countries, the variety shall undergo both performance trial and

distinctness, uniformity and stability tests *for at least one season* in similar agro ecological zones, provided that an applicant shall provide the date leading to release the plant variety in that other country to the authorized officer (emphasis added). While this reference is a helpful step towards integrating regional protocols into Kenyan laws and regulations, the phrase "at least" adds uncertainty as to how this provision will be implemented in practice.

Similarly, under COMESA, a variety registered in one member state could also be subjected to a streamlined NPT process. According to the COMESA Seed Trade Harmonization Regulations of 2014, a variety registered in one COMESA member country can be entered into the COMESA Variety Catalogue following one season of NPT/VCU testing in the second member state's market and submission of relevant DUS and VCU data from the first member state (Chapter 4, Section 28). A variety registered in two COMESA member states can be entered into the COMESA Variety Catalogue with an application containing the appropriate DUS and VCU data. Thus far, only the East African system has been put in practice to some degree (See Annex 1). If these regional frameworks are applied consistently and transparently, considerable time and cost savings could result.

As Figure 1 illustrates, there are time lags between variety identification and release. Once the variety has been identified by the breeder, "all varieties submitted for the performance trials shall undergo testing for at least 2 seasons" (National Performance Trials Regulations, 10 (1), 2009), unless a regional shortcut is available as discussed above. Two seasons of DUS testing are also required, which can sometimes be done concurrently with NPT trials but often add additional time in the release system. The whole process can easily take three to four years, depending upon the type of crop. For maize seed, for example, the registration process is very difficult to complete within three years (according to some of the companies interviewed, attempting to complete the process within two years could pose a significant risk), and four years for the process is more likely.

The NPTC meeting, during which recommendations for release are made, is scheduled to take place around March every year, and variety release applicants must plan accordingly. The NVRC meeting that reviews these submissions will generally be held sometime between July and December, followed by approval by MOA and a ceremony and press conference where results are officially announced. The timing of this process can be unpredictable, as some of the seed companies interviewed flagged, which can add additional time, uncertainty, and cost to the process.

A variety has to be formally released before seed multiplication and marketing can begin. When the length of the breeding process is added to the length of the variety release process, the time it takes to get an improved seed variety to market can be considerable. For example, the development of a new potato variety takes twelve to fifteen years and currently costs KHz 50 million ($530,000 USD) to bulk the required 20 tons of pre-release material (Ministry of Agriculture, 2010).

Another issue often raised is that the criteria that the NPTC uses to make decisions for release does not always reflect market and farmer demand. The yield improvement requirement tends to overshadow other important variety characteristics such as earliness, storability, usability for fodder, disease resistance, etc. The unwritten rule of 10 percent yield increase against commercial checks is a high order. As the private sector has noted, "many highly evolved private companies elsewhere have grown based on a steady stream of new varieties that outperform existing varieties" by five percent or less (Private Sector Roundtable, 2014). Over time and with innovation, these percentages can add up to significant yield increases (Private Sector Roundtable, 2014). On the other hand, many of the approved varieties, often registered by public research institutions, have never been taken up by farmers.

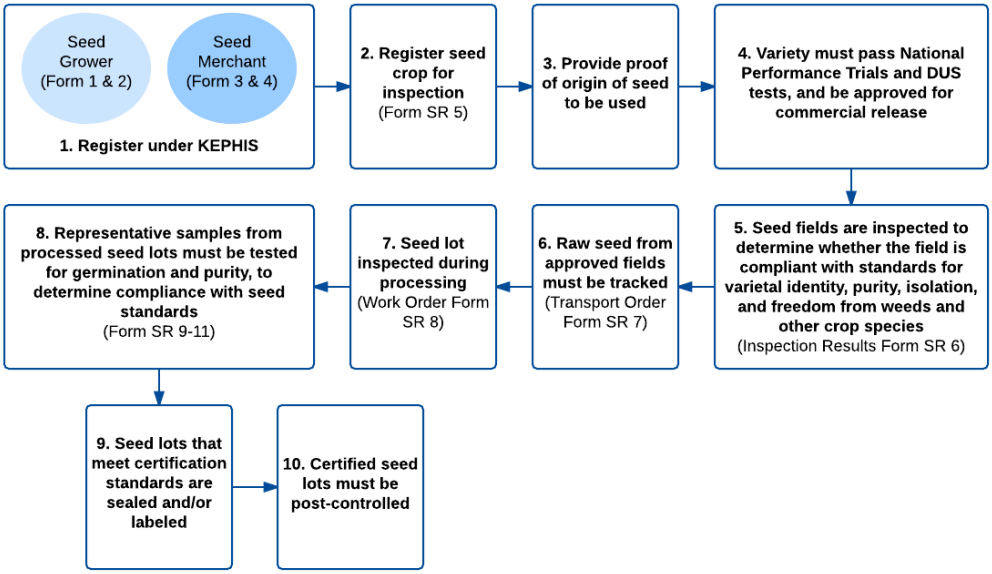
Seed Certification

Kenya maintains a centralized seed certification system, and KEPHIS is largely responsible for seed certification according to the standards stipulated in the Seeds Regulations under Cap 326. Seed Quality Assurance Services operate within the guidelines and procedures stipulated in the Seeds Act (Cap 326). Inspections (both in the field and at the seed processing stage) are undertaken as per these standards, which follow the OECD standards.

The 2012 Amendment to the Seed Act allows the private sector to participate in conducting inspections (particularly preliminary inspections, pre-harvest inspections, seed sampling, and dispatch), although this is yet to be fully operationalized and will require regulatory change as well as an operational process. The Amendment Act states that, "For the purposes of enforcing the provisions of this Act, the Service— (a) shall appoint seed inspectors, seed analysts and plant examiners; and (b) may authorize competent private or public persons to perform specified functions under this Act on its behalf: Provided that an authorization may be withdrawn in cases of misconduct" (Seed and Plant Varieties (Amendment) Act, 5(3B), 2012). Laboratory seed tests and analysis are carried out according to ISTA standards and rules (Kenya is also one of the few countries in the region to adhere to ISTA standards). See Figure 2 below for the complete seed certification process.

One issue raised by Kenyan industry is that the list of seeds subject to mandatory certification is too extensive and that the government lacks the capacity to administer such a broad-ranging seed certification program. Some degree of self-certification could be a viable alternative.

Figure 2: Seed Certification Process in Kenya for Schedule II Crops



Source: Cap 326, Seed Regulations and KEPHIS "Seed Certification Services". See also Sikinyi, 2010.

Another frequently raised issue is that the certification standards set by the Seed Regulations are too stringent and do not reflect the reality of the country. For example, the standard for Irish potato requires zero tolerance to bacterial wilt, which is a common disease in Kenya. On that ground, KEPHIS inspectors could easily reject the whole lot of seed produced, although in reality a level of 0.5 percent tolerance is far better than what farmers are growing today. Another issue is that regulators have imposed zero tolerance standards to maize lethal necrosis (MLN), which is not listed in the regulations. The bar is sometimes set too high for seed companies to reach. As a result, many seed companies have stopped bulking up seeds in Kenya and have opted for producing seeds in other countries and then importing them into Kenya.

Kenyan regulation currently provides for eight classes of certified seed: breeder, pre-basic, basic, certified first generation, certified second generation, certified third generation, and standard seed. The first three seed classes cover foundation seed,

and the latter five commercialized seed. Proposed amendments to the Seed Regulations would remove several existing seed classes and reduce the number to five (certified third generation, certified fourth generation, and standard seed classes would all be eliminated). This will bring Kenyan regulation more closely into conformity with COMESA's seed classes COMESA Seed Trade Harmonization Regulations of 2014 (pre-basic, basic, first generation certified and second generation certified seed); COMESA does not recognize breeder seed as a certified seed class.

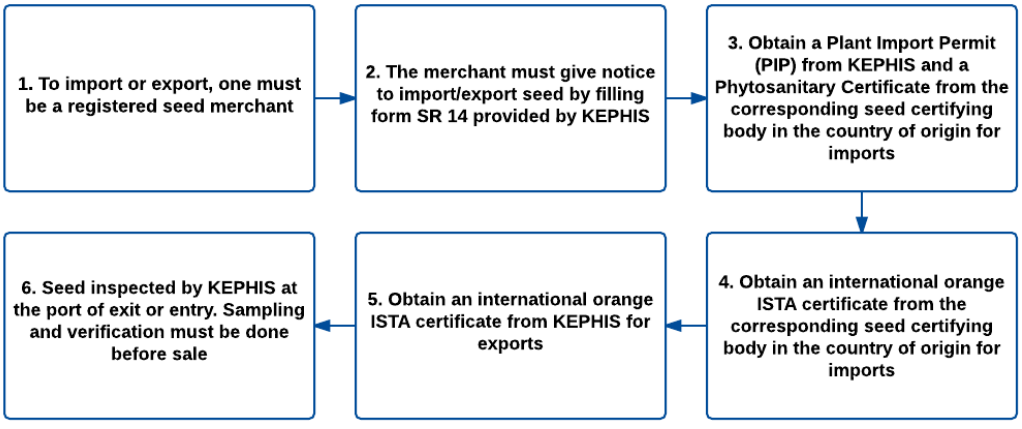
Counterfeit seed remains a challenge. One regulatory change under discussion is increasing the penalties for counterfeit seed, which at present are too low to act as a deterrent. Clearer penalties, coupled with a better process for enforcing them and more streamlined process to bring legitimate, high-quality seed to market, could help create a more trustworthy environment for seed trade.

Cross-Border Trade

Within Eastern and Southern Africa, Kenya regularly trades seed with Uganda, Tanzania, Rwanda, Zambia, Zimbabwe, South Africa, Sudan, and Somalia. International trade in seeds also occurs, particularly in vegetable and other horticultural crops (Sikinyi, 2009).

KEPHIS has the power to issue import and export permits and phytosanitary certificates for qualified plant produce. Registration as a seed merchant is required before seed can be imported or exported, and KEPHIS controls the registration process as well as import and export permits.

Figure 3: Kenya Seed Import and Export Procedures



Source: Cap 326, Seed Regulations 20(1) – 20(8) and KEPHIS "Import Requirements". See also Sikinyi, 2010.

As the private sector has pointed out, registration as a seed merchant currently sets a rather high bar, with the requirement that 75 percent of the company's business be focused in the seed sector.

Imports fall into three categories: (1) low risk permitted imports that are allowed with the appropriate application; (2) Higher risk imports subject to quarantine and risk assessment; and (3) Very high risk imports that are not permitted without the express permission of the Kenyan Standing Technical Committee on Import and Export (Sikinyi, 2010). Kenya does have a quarantine pest list, as do other countries, but these lists are often out of date, which can present a challenge to cross-border trade. Increased capacity to maintain appropriate pest lists as well as regulatory collaboration (the Plant Health Laboratory at KEPHIS has been identified as a Center of Excellence within COMESA) could facilitate regional trade (Sikinyi, 2010).

At different entry and exit points, the agency has designated plant health clinics, plant quarantine stations, graders, and inspectors to perform a diagnosis of pests and diseases (KEPHIS, 2015). Under the Seed Act, MOA ensures that imported plants, packages, covers, and other materials will not adversely affect the safety of plants in Kenya.

All seed imported into the country must fulfill ISTA requirements in addition to satisfying the relevant phytosanitary measures, including laboratory quality tests upon arrival. Kenya's adherence to OECD and ISTA standards should both create a more transparent process for seed entering and exiting Kenya and enable Kenyan certified seed to more easily enter foreign markets. However, a majority of Kenya's trading partners in Africa are not members of either OECD or ISTA as noted above. This can make cross-border seed trade difficult, as neighboring countries do not adhere to these international seed certification standards and regional harmonization in certification remains at an early stage (and also follows OECD and ISTA standards). Kenya's choice to sign onto OECD and ISTA has been questioned at this stage in the development of Kenya's seed industry, due to the capacity required to fulfill these standards, but interviews held during the course of this case study and in other EAC countries indicate that adopting an international standard (rather than a new regional standard) may be a more acceptable way of achieving regional harmonization. With a new standard, one country's system might dominate, but by adopting an international standard, all countries are held to the same objective standard.

Regardless, a number of other countries are now pushing forward to adopt OECD and ISTA standards, including neighboring Tanzania.

With respect to cross-border trade, a number of actors in the seed market are subject to varying degrees of regulation. Seed growers, merchants, and sellers have more explicit regulations regarding their role in the Kenyan seed system. For instance, the Seed Regulations require that every seed merchant contract with registered growers, and the seed grower must complete Form SR 1 and pay an application fee of 200 KS. A merchant must fill out Form SR3 and pay an application fee of 57,500 KS, while agents pay an application fee of 120,000 KS, sub-agents pay 5,000 KS, and stockists pay 150 KS. Realizing the costs attached to the market entry of different roles in the seed system is important to understanding the channel through which movements of seed can be traced.

In general, legal and regulatory issues surrounding trade in seeds were not noted to be as complex as issues with variety release and registration or certification. As in other areas, regulation of imports and exports is important, but any inconsistencies in the process for importing and exporting seed can add an additional layer of regulatory uncertainty as Kenya's seed system develops.

Regional Harmonization

The openness of regional markets can have a significant impact on whether farmers can take advantage of opportunities along agricultural value chains (Brenton et al., 2013). For companies that understand and can navigate regulations across regions, access to broader markets presents the possibility of better prices and possible business expansion. For many, however, the complex system of national, regional, and international laws and regulations can present a hurdle to market access and future potential (Kuhlmann and Sourang, forthcoming).

While regional seed harmonization efforts are now well underway, much remains to be done, and further study of the differences in process and substance surrounding regional requirements is warranted. COMESA, for example, is institutionally structured such that national level implementation is required even if regional rules are binding. Although EAC laws and regulations are automatically binding upon member states, this does not apply to regional harmonization efforts developed through other institutions (e.g., ASARECA). Implementation of regional trade agreements and measures at the border can have far-reaching impact, and these are

significant factors that impact market size and weigh heavily in the ability to obtain agricultural financing (Kuhlmann and Sourang, forthcoming). Differences in seed policies and standards across countries (and between different regions), as well as differing levels of technical capacity can create challenges that ultimately impact the availability and access of seeds. In every case, a country's rules on variety release and registration, seed certification, SPS measures, and PVP laws need to be assessed within the context of regional harmonization in order to understand future market potential and how implementation of rules will work in practice.

As noted above, Kenya's membership in regional associations has also played an important role in framing harmonized seed rules. For example, the EAC's work on streamlined variety release within the region has largely taken place through ASARECA, with full EAC harmonization still under discussion. Kenya, Tanzania, and Uganda are currently implementing the ASARECA approach, but no other multi-country list of approved varieties is yet in operation (Keyser, 2013). These three countries have the benefit of being united through the EAC and ASARECA agreement and have been able to streamline variety release procedures to a degree based on a mutual recognition of test results, but even these procedures are still being tested and implemented. Expanding the reach of this approach to other countries within the EAC and other regions would help expedite variety release and increase market potential. A comparison of COMESA and EAC efforts on variety release, certification, and cross border trade follow (see also Annex 1), all of which are discussed in greater detail in Kuhlmann SFSA (2015).

The EAC Protocol on Standardization, Quality Assurance, Metrology and Testing and the Standardization, Quality Assurance, Metrology and Testing Act, set regional standards for seed varieties of certain crops, including seed potato. COMESA is working to establish harmonized labeling based on ISTA standards, but much remains to be done before seed certification regulations are fully implemented in the region. Since Kenya has ISTA-accredited laboratories and follows OECD seed certification schemes, mutual recognition across member countries in both regions will be needed to trade certified seed across borders.

Both the EAC and COMESA recognize ISTA, OECD, and UPOV guidelines, and Kenya is working to implement these standards through ISTA-accredited laboratories and OECD seed certification schemes. Since both the EAC and COMESA recognize these international standards, movement towards regional harmonization is promising; however, capacity challenges within member countries currently make it difficult to meet regional requirements, leading to difficulties in cross-border trade.

The EAC and COMESA protocols on SPS measures are similar in structure, yet different in practice. The EAC's SPS Protocol, which is based on Article 108 of the EAC treaty, requires Kenya to adopt the EAC harmonized rules on SPS measures to protect plant health. The Government of Kenya implemented this protocol by designating KEPHIS as the National Plant Protection Organization (NPPO) responsible for maintaining SPS measures based on science and ensuring that these measures are transparent to all parties from member states involved in the seed trade according to the International Plant Protection Convention (IPPC). In July 2015, the EAC Protocol on Sanitary and Phytosanitary (SPS) Measures, which covers seed and other goods, was passed and is now binding on all members. In addition, the EAC Legislative Assembly passed the Elimination of Non-Tariff Barriers Act in 2015, which will be binding on all members after it is approved by the EAC Summit. This Act would provide a process for companies to report non-tariff barriers directly to the EAC Secretariat and establish a process by which companies could seek financial compensation (Nderitu, 2015). The 2014 COMESA Seed Regulations, on the other hand, are only a framework that has to be enforced through regional and national institutions, and changes in national law and regulation will be required. Since countries have to domesticate agreements through their national instruments and mechanisms, implementation among COMESA member states will vary. In September 2015, COMESA launched its seed committee in Lusaka, Zambia, which, among other responsibilities, will help provide members with technical expertise for implementation of the COMESA seed system. In Kenya, development of a pest list by the NPPO (KEPHIS) and review of Kenya's quarantine and phytosanitary regulations are noted as priorities under the COMESA Seed Harmonization Implementation Plan (Mukuka, 2014). Implementation of standards and SPS measures at the border can be a challenge, and many countries do not consistently recognize the inspection processes and SPS regimes of neighboring countries, despite regional trade agreements requiring this type of treatment (Kuhlmann and Sourang, forthcoming).

Kenya is also a signatory to other international treaties, including the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights and has been a member to UPOV since May 1999. Conforming to UPOV requirements, Kenya adopted the Seeds and Plant Varieties (Plant Breeder's Rights) Regulation, subsidiary regulation to the Seeds Act (Cap 326) to grant and protect plant breeders' rights. KEPHIS is the recognized institutional authority for enforcing plant breeder's rights under the Seeds Act. Although implementation of UPOV guidelines might allow Kenya to be more competitive internationally, within the EAC, Kenya is the only country that is currently party to the UPOV Convention at the time of writing (Tanzania will soon become a full UPOV member, however), and other EAC member

countries are either in the process of adopting laws that are compatible with international standards for plant variety protection or have none. Across regions, different levels of harmonization under UPOV can cause cross-border trade challenges with respect to quality standards and breeders' rights. A similar challenge is present in COMESA, where Kenya is the only UPOV member at present. For Kenya, domestication of PVP is a strategic objective under the COMESA Seed Harmonization Implementation Plan (Mukuka, 2014).

Differences in institutional capacity within different countries in the RECs present a significant challenge. Within the EAC, the legal and regulatory systems of Rwanda and Burundi are relatively less developed than those of Kenya, Tanzania, and Uganda. Within COMESA, which has nineteen members, institutional capacities vary. As part of the implementation strategy for COMESA, countries have been grouped into three categories that signify readiness to implement the COMESA Seed Trade Harmonization Regulations: (1) Countries with existing legal structures: Egypt, Ethiopia, Kenya, Madagascar, Malawi, Sudan, Swaziland, Uganda, Zambia, and Zimbabwe; (2) Countries with legal structures in draft form: Burundi, the Democratic Republic of Congo, Mauritius, Rwanda, and Seychelles; and (3) Countries with no legal structures: Comoros, Djibouti, Eritrea, Libya, and South Sudan (Mukuka, 2014). While collaboration within the first group of countries may be possible, regulatory cooperation (and implementation of the regional regulations) will become significantly more difficult between countries with more developed systems and those with less developed systems. This effectively means that there will be tiered implementation of COMESA and other regional frameworks, and this will be a critical area to watch as regional protocols move forward.

Industry Experience

In development of this case study, the authors conducted interviews with a variety of seed companies in Kenya to understand their perspectives with respect to variety registration, seed certification, and trade. Their experiences are summarized as below.

Company A started selling registered seed varieties in Kenya over ten years ago. It does R&D, local production, and sales. Maize is the major crop in the company's portfolio, and seeds are imported or produced locally in Kenya. For registration, Company A has gone through two seasons of NPT as required, but in practice a third season is often added to double check the results. Once the trials are complete, the process for review can also be lengthy and unpredictable, as discussed above.

Because of the maize lethal necrosis (MLN) disease, regulators are required to draw a sample of the imported seeds at port and test for the virus. The procedure usually takes two weeks. Seed companies have to queue at the same time to get tested, which both reflects a lack of capacity of the regulators and is often a cause for delays.

For seed certification of locally produced seeds, KEPHIS typically does three inspections: two field inspections and a warehouse inspection. In the latter, seed samples are taken and tested in the lab. Often there is queuing in the lab, thereby delaying the entire certification process.

The cost of field inspection is about 7000 KSH per lot, which is usually about 40 tons of seeds. For the warehouse inspection, sampling costs are 30 KSH per ton. For 40 tons of seeds, the total costs of inspections amount to 8200 KSH.

The company thinks that self-regulation is the best way forward. There are countries in Africa that allow companies to have their own licensed inspectors who follow seed through the certification process. The system has proven to be more effective and less costly than centralized certification.

Company B started NPT trials for several maize varieties in various agro-ecological zones in Kenya in 2014. According to KEPHIS, two seasons of NPT and two seasons of DUS are required. For highland varieties it was possible to do only one season a year, while for lowland varieties two seasons could be completed within a year. In December, the company could usually get trialing results from the first season of NPTs. The results from the second season of NPTs, in the case of the lowland varieties, are due in May the following year. The company had a good sense about certain lowland varieties and hence started with the DUS testing in 2015, before fully receiving the trial results of the two seasons' NPTs. If the two seasons of DUS can be completed successfully in 2015, the company plans to get those varieties registered in April or May 2016 and start the process of commercialization.

In terms of the costs of registration, NPTs currently cost USD 1200 per variety per season and DUS trials cost USD 600 per variety per season. For a variety to go through the full cycle, the total cost amount to USD 3600. If the varieties are rejected, there seems no clear process for appeal. Companies are inclined not to appeal in order to maintain a good relationship with the regulators.

While Company B felt that regional harmonization would help develop the seed market, the company would like to see clearly spelled out procedures on what is needed to fast track the registration process, for example clarity on what kind of data

from field trials in another country can be accepted and specific regulatory guidance on the application process.

Company C is a recently established company that started selling bean seeds in 2014. The bean variety came from the KALRO seed unit. Company C has obtained a non-exclusive license to multiply the seeds. The royalties were about 80 KSH per kg in 2014 and are set to be about 2.5 percent of the sales in 2015.

In Kenya there were nearly 1000 tons of bean seeds sold in 2013, of which a high majority came from the Kenya Seed Company. Most bean varieties are quite old. For a small private company to compete in this space, the varieties need to be superior to what is currently on the market, and there must be a clear market demand for good quality bean seeds.

As a Schedule II crop, bean seed needs to be certified. It costs 26,000 KSH for inspections of 76 tons of bean seeds. The labeling costs 15.15 KSH per label, regardless of the size. Small packages suitable for smallholder farmers (e.g. less than one kg) require payment of the same amount as labeling for large packages, which raised a number of questions. In addition, the delivery of labels can be delayed, thereby reducing the windows during which the company can reach farmers and sell the seeds.

Company D's crop varieties are mostly from KALRO, and maize is from AATF/CIMMYT. The company is well known for its small packages, ranging from one kg to 2.5 kg. The company has registered two maize varieties. NPT trials took two years and DUS trials took one to two years. From the third year onward, the company started to develop the lines. The lines can take three to four years until reaching the established 'proof of origin.' Every step of the entire process must be controlled by KEPHIS.

The company has experienced a lengthy certification process:

- Preliminary inspection was about land and plot;
- First and second inspections during the growing season;
- Cob inspection before harvest;
- Transport order;
- Work order;
- MLN sampling and germination test.

The MLN sampling and germination test took nearly two months after the harvest time. Ideally the company would propose that the process be shortened into three

steps: 1) first inspection, 2) cob inspection, and 3) germination test. Efficiency improvements in lab testing and delivery of the certification certificate and labeling materials could really help the company deliver seeds to farmers in a timely manner.

The variety registration costs about USD 2800 per year plus mileage expenses. Sampling of 30 tons alone costs about 900 KSH. The certification costs on average about three KSH per kg.

In sum, the seed companies raised a few concerns relating to seed registration, certification, and trade. First, there is a general feeling about an uneven playing field between private companies and public sector suppliers such as the Kenya Seed Company. KSC is a natural monopoly of many crops, and the government supports it through procuring seeds for governmental programs. In addition, KSC may have an advantage in accessing public sector varieties and an edge in getting its varieties approved. Second, Kenya's approach to variety release, particularly regarding NPTs is questioned, as some other countries without mandatory registration (e.g. the US and India) are much more industry friendly. The variety release decisions are not always transparent and sensible. Third, seed testing requirements are viewed as more costly and burdensome than necessary. Each and every step of seed production must be inspected. When inspectors cannot get to the field in time, critical harvesting and processing time is lost, often resulting in significant costs and burdens on seed companies (Private Sector Roundtable Meeting, 2014). Another issue is that there are too many steps and inspections in the seed certification process, some of which are considered unnecessary and may interrupt operations. The process needs to be revisited and optimized. In this context, higher self-regulation and the use of truthful labeling are regarded as alternatives or remedies, which could be considered going forward.

Another concern is related to packaging, labeling, and sealing. The regulatory and labeling requirement is overly burdensome for many companies. Regulations require that seeds shall be labeled or sealed using KEPHIS assigned labels after the official seed tester has released test results. Seed testing is often not done on time, causing significant delays. In addition, the cost of labeling is unnecessarily high due to the bureaucracy involved, especially for small packs, which are preferred by small-scale farmers. Alternatively, as most seed companies have the capacity to label and seal their seeds according to official requirements, for example on inclusion of lot serial number and design of their labels, they could be given more freedom to produce their own labels (Private Sector Roundtable Meeting, 2014). This way, the companies remain more in control of the timing and delivery of seeds to farmers and can expedite the process.

In addition, several companies raised the issue that imported seeds with ISTA certificates must be re-tested at entry by KEPHIS. On paper it takes seven days for maize and nine days for beans, but in reality it often takes two weeks or more. Since ISTA standards are internationally recognized and a cornerstone of regional seed harmonization efforts, this need for re-testing seems duplicative.

Cross-border Data Sharing

One significant benefit of regional harmonization that is already beginning to gain traction is that countries will begin to recognize each other's data and regulatory processes. Thus far, progress has primarily been made on variety registration within the EAC due to the ASARECA agreement among Kenya, Tanzania, and Uganda. Any variety registered in one country's variety catalogue could be registered in another following one year of domestic testing if sufficient and appropriate test data is available and provided (previous trials in similar agro-ecological zones). While there are several specific cases of application of this agreement in practice, it is extremely difficult to get an accurate picture of how many varieties have benefited from these regional provisions, since many instances are anecdotal. Table 2 summarized the cases of which we are aware.

Table 2: Third Country Data Use in Variety Release in East Africa

Country Accepting Variety Data	Crop/Variety	Country of Origin	Year Variety Release
Tanzania	Seed Potato (4 varieties from International Potato Center)	Kenya	2012
Rwanda	Maize (Pannar 618)	Kenya, Tanzania	2011
Uganda	Sunflower	Kenya	TBD
Kenya	Sweet Potato (4 varieties)	Uganda	TBD
Kenya	Rice	Tanzania	TBD

Source: Authors' research and interviews.

Although it is difficult to obtain reliable information on the full extent to which third country data has been used in regional variety release, it is an extremely important aspect of regional harmonization and one that deserves special mention and study. All of the cases noted above are examples of regional harmonization in practice, and one recommendation of the authors is that information on these cases be more

widely collected and shared. For example, the four seed potato varieties registered in Tanzania using the ASARECA agreement resulted in the commercialization of the potato sector in Tanzania, which has a large number of smallholder farmers but struggled for years in the absence of access to high-yielding seed potato varieties. The four new seed potato varieties that were successfully introduced in Tanzania have transformed the potato sector and given rise to both new commercial opportunity and greater collaboration among regulators. Many lessons can be drawn from this case, including the importance of sustained effort (the process needed to be followed through step by step) and partnership. This case was a particularly compelling example of partnership between the private sector (Mtanga Foods, Ltd., the company that imported the seed potatoes for trial and multiplication), the public sector (agricultural ministries and regulators in Tanzania and Kenya), and instrumental facilitating actors such as the Southern Agricultural Growth Corridor of Tanzania (SAGCOT) Centre (the farm is located along the SAGCOT corridor) and a consortium of donors, practitioners, and experts (including the Syngenta Foundation for Sustainable Agriculture and New Markets Lab through TransFarm Africa).

Recommendations for Implementing Regional Seed Harmonization

Over the past several years, the frameworks for regional harmonization of seed systems have significantly advanced. This is an important step forward, but the true test will be how these frameworks are implemented in practice. In contrast to development of the frameworks themselves, much of the process of implementation will take place at the market level (such as the example of third country data use in variety registration above) and involve companies, market-focused platforms, and the regulators who are making day-by-day decisions on how rules and regulations are applied. Successful implementation will often involve a series of smaller steps rather than higher-level gestures.

While a number of decision points are involved in implementing regional seed protocols, several critical steps at both the national and regional levels are outlined below. All of these, if applied well and consistently, could act as wedges to bring dynamic change to the seed sector.

National Level

- **Accreditation Process for Inspections and Testing**: This aspect of self-regulation was flagged as a significant milestone in further developing Kenya's seed sector. While the newest version of the Seed Law does provide for this authority, new Seed Regulations will also be needed, as will a process for making private seed testing operational in practice. A number of the stakeholders interviewed in the development of this case study highlighted the importance of moving towards some degree of self-regulation. While the Seed Law provides a basis for private seed inspection, the Seeds Regulations also need to be amended, and KEPHIS will have to build both the capacity to allow for private inspection and develop a clear process for authorizing private sector inspections. Improvements in this area could have a significant impact in Kenya's seed market, and this aspect of implementation is particularly promising.

- **Streamlining Processes for Variety Release and Certification**: These regulatory processes have important roles in Kenya's seed sector, but both are lengthy and involve a number of sometimes overlapping steps and considerable uncertainty in timeline. As a next step, we would suggest identifying specific elements of the process that could be streamlined or removed. For example, Company D had clear recommendations for streamlining the certification process for maize seed. Further documenting how these processes could be improved in practice and moving forward with test cases would be a significant step toward regional harmonization and development of Kenya's seed market.

- **Strengthening Enforcement of Counterfeit Seed:** Although Kenya has a relatively well-developed regulatory system, counterfeit seed remains a problem and hampers effective cross-border seed trade. Two specific steps have been identified to address this challenge: increasing penalties for counterfeit seed and more effectively enforcing violations. The first can be done through a change in regulation; the second requires a better system for implementing laws and regulations. To move forward with the latter, the authors recommend identifying successful models that other countries have used to reduce the incidence of counterfeit seed.

- **Further Linking National Regulations to Regional Frameworks:** Work is already underway in this area, but additional focus will be needed as the

relatively recent (2014) COMESA Seed Regulations are implemented. Changes will be needed throughout Kenya's regulations, including an update to the regional variety registration reference included in the Kenyan regulations discussed below and assessment of how Kenya's regulations conform to regional regulations in areas such as SPS and PVP (See Mukuka, 2014).

- **Clear Reference to Regional Protocols**: One critical and concrete step in implementing regional frameworks at the national level is to include clear references in country regulations to regional protocols. Kenya's regulations do include a specific reference to the EAC variety release agreement that shortens the number of VCU/NPT trials required from two to one, although the regulations still allow for possible discretion (and uncertainty) but including the words "at least" before the reference to the streamlined NPT trial provision. The authors would recommend making this language as clear as possible as it is amended to include reference to the COMESA Seed Regulations, which is currently being considered.

Regional Level

- **Increasing Awareness of Regional Frameworks:** Getting the right frameworks at the regional level is certainly an important step forward, but many market participants are not aware of the content of these high-level frameworks, or, more importantly, how they will impact individual market stakeholders. Information on the new regional rules could be shared in several ways: through simple and clear legal guides that outline the regional regulations and how to take advantage of them in practice, in-country platforms or innovation platforms focused on a particular crop. Building regulatory awareness of regional frameworks will be a key step in implementation and is explicitly recognized in the COMESA implementation guidelines as a strategic objective.

- **Joint Regulatory Guidance for Regional Standards**: As countries amend laws and regulations to incorporate regional frameworks, it may still be unclear how these regulatory changes will work in practice. We recommend issuing guidance on how new regulations will be applied regionally. This should be done at both the national level and regionally through joint guidance with other regulators.

- **Regulatory Collaboration**: One of the most significant hurdles to effective regional harmonization appears to be the degree to which regulators within a particular region are willing to work together and recognize each other's procedures and results. The Tanzania seed potato case described above resulted in regulatory training between KEPHIS and TOSCI. Much more could be done and shared in this area, and regulatory collaboration appears to be the most significant sticking point in effectively implementing regional harmonization.

- **Third Country Data Sharing**: As Table 2 above shows, there are some documented cases of third country data sharing and regional variety release. However, the rate of implementation of these regional rules is far behind actual need and demand. In addition, while the ACTESA/EAC variety registration provisions have been tested in practice, the COMESA regional variety release rules have not. We recommend identifying demand for improved varieties that could be addressed by regional variety registration within COMESA and conducting several test cases to try, document, and share the COMESA process in practice.

Conclusion

As this Kenya Case Study shows, regional harmonization efforts are gaining ground, but much more work will be needed to implement these frameworks. This phase of work will be quite different than developing the regional protocols and will require creating, sharing, and refining regulatory practices to put the regional rules into effect in practice and address the questions that will inevitably arise in the process. Under the Syngenta Foundation for Sustainable Agriculture's Seeds2B project, the authors will move forward with some of the recommendations noted above, including in partnership with the RECs, companies, and other stakeholders and institutions working to implement these important frameworks.

Going forward, additional analysis of how regional harmonization is being carried out at the country level should be done and updated on an ongoing basis, and tools for measuring and sharing information and progress in some of the areas noted above will be critical. All of the decision points outlined above could evolve into concrete initiatives, best practices, and regulatory guidance, and all will require a greater degree of private sector input (approaches should be tied to market demand and will

vary to some degree with the particular crops and circumstances involved) to become operational. Innovative models for advancing implementation of laws, regulations, and regional protocols can be taken from work in other countries and regions, such as corridors approaches, innovation platforms focused on a particular sector or crop, and inclusive legal models. As the other Case Studies in this series are completed, we hope that a greater degree of comparative assessment will be possible as well, with best practices, successes, and challenges shared within and across regions.

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ANNEX 1: Comparison of COMESA and EAC Harmonization on Variety Release, Certification, and SPS

Comparison of COMESA and EAC Harmonization on Variety Release		
COMESA	**Regional Status**	**National Implementation**
COMESA member states are bound by its regulations, but countries must domesticate the agreements through their national instruments and mechanisms before they can take full effect.	• Covered in COMESA Seed Trade Harmonization Regulations 2014 (Chapter 4). • Shortens variety release to two seasons of DUS and VCU/NPT tests, and members are required to follow UPOV guidelines. • Regional seed catalogue is under development that would allow entry of a new variety when it has been registered in two member countries upon application with necessary DUS and VCU data. • Process streamlined if variety registered in one other COMESA country; can register variety following one season of NPT if DUS and VCU data from first country submitted. • However, members can ban a variety for technical reasons, including unsuitability for cultivation or risk to other seed varieties, human or animal health, and the environment. • GM varieties may only be released at the national level and in compliance with national bio-safety regulations.	• Given the recent passage of the COMESA Seed Trade Harmonization Regulations, Member States have not yet harmonized their national seed laws with the new seed regulation. • ACTESA highlights that institutional capacities will have to be developed to implement the regional regulations, such as accreditation of seed laboratories to ISTA standards, and licensing and registration of seed inspectors, seed sampler, and seed analysts. • Kenya is the only COMESA members of UPOV (out of 19 members).
EAC	**Regional Status**	**National Implementation**

EAC laws and regulations are automatically binding on its members at the national level. EAC Acts supersede national legislation.	• No EAC Protocol on variety release; harmonization on variety release has occurred within a subset of EAC countries (Kenya, Tanzania, and Uganda) based on work within ASARECA. • ASARECA agreement stipulates that any variety registered in one country's variety catalogue could be registered in another following one season of NPT if sufficient and appropriate test data is available (previous DUS and VCU trials in similar agro-ecological zones).	• Kenya, Uganda, and Tanzania begun implementing ASARECA agreement, but it has not been consistently applied. • Kenya has made variety registration automatic for vegetable seed; Kenya also has automatic registration for pasture seed.
Comparison of COMESA and EAC Harmonization on Certification		
COMESA	**Regional Status**	**National Implementation**
COMESA member states are bound by regulations, but countries must domesticate the agreements through their national instruments and mechanisms.	• Covered in COMESA Seed Trade Harmonization Regulations 2014 (Chapter 3), which require members to adopt common Seed Certification Rules • Harmonized labeling to be established based on ISTA standards. • COMESA Seed Classes (four total): (1) pre-basic seed (violet band on white); (2) basic seed (labeled white); (3) first generation certified seed (labeled blue); and (4) second generation certified seed (labeled red).	• Regulation very new, so much remains to be done before it is fully implemented • Kenya and Zimbabwe participate in OECD seed certification schemes. • Egypt, Kenya, Malawi, Uganda, Zambia, and Zimbabwe have ISTA-accredited laboratories. • Kenya reducing number of seed classes from eight to five, brining its regulations more closely in conformity with COMESA.
EAC	**Regional Status**	**National Implementation**
EAC laws and regulations are automatically	• The Protocol on Standardization, Quality Assurance, Metrology and Testing and the Standardization,	• Burundi, Tanzania, and Uganda have developed shared seed certification

binding on its members at the national level. EAC Acts supersede national legislation, but national laws must still be brought into conformity.	Quality Assurance, Metrology and Testing Act, set regional standards for seed varieties of certain crops, including seed potato. • Through the efforts of ASARECA and EASCOM, the EAC has agreed to harmonize certification standards covering at least 42 staple foods, including grains, pulses, edible oil, and tubers. Of these standards, 29 are already in place while 13 new standards were in the final draft stage and awaiting comment. • EAC recognizes ISTA rules, OECD guidelines, and UPOV. • Seed classes vary among different crops but mainly consist of three classes: (1) pre-basic seed; (2) basic seed; and (3) certified seed with varying generations.	standards for ten crops but none has recognized other countries' seed certification tests. • The Centre for Biosciences International (CABI) formulated and implemented three farmer-led seed enterprise (FLSE) models from 2009-2012, including QDS. This work is being scaled up throughout East Africa. • Kenya and Uganda participate in OECD seed certification schemes. Tanzania is in the process of joining OECD seed certification schemes as well. • Kenya and Uganda have ISTA-accredited laboratories, but Uganda in particular still has capacity challenges meeting national and regional demand. Tanzania is in the process of becoming ISTA certified.
Comparison of COMESA and EAC Harmonization on SPS		
COMESA	**Regional Status**	**National Implementation**
COMESA member states are bound by regulations, but countries must domesticate the agreements in their national	• Covered in COMESA Seed Trade Harmonization Regulations 2014 (Chapter 5). • Universal pest list being developed for each seed crop.	• COMESA has prepared one set of draft lists for all types of seed trade. • NPPO is involved in development of a pest list in Kenya.

instruments and mechanisms		
EAC EAC laws and regulations are automatically binding on its members at the national level. EAC Acts supersede national legislation.	**Regional Status** • An SPS Protocol for some goods, including seeds (but excluding food safety measures) was approved by the EAC Summit in 2015, and, therefore, is binding upon members. • The East African Standards (EAS) provides unified SPS standards for a number of staple foods, including seed potato and other tubers, grains and pulses. For example, phytosanitary provisions for seed potato must follow the International Plant Protection Convention (IPPC). • Countries are encouraged to review pest lists, but no universal pest quarantine list.	**National Implementation** • Quarantine pest list for Kenya, Tanzania, and Uganda. • Full implementation of EAC SPS Protocol still under development. • KEPHIS is the NPPO in Kenya, which is member IPPC, and works on SPS standards and is also developing a pest list.

Source: Kuhlmann, SFSA 2015.