

Legal and Regulatory Frameworks for Seed in COMESA, SADC, and EAC

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About the New Markets Lab

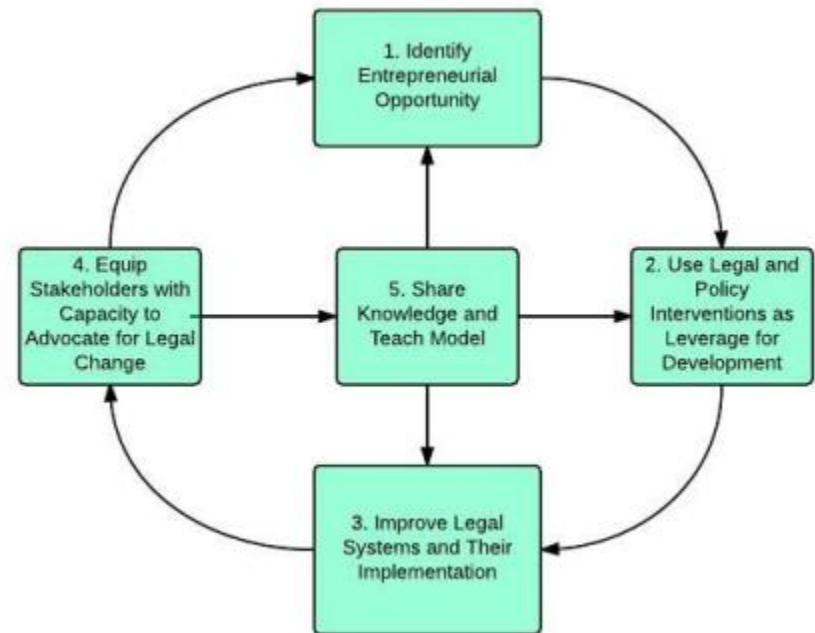
- NML is a legal and regulatory innovation lab created to use systems for economic law and regulation as driver for inclusive market development and entrepreneurship
- Created NML to address gaps in legal, regulatory, and policy structures and their implementation -- without knowledge of legal systems or a channel through which to shape them, inclusive development will not occur
- NML has developed a unique methodology and set of tools with diverse partnerships and international team of lawyers



New Markets Lab: Role of Law and Regulation in Building Sustainable and Inclusive Markets

- NML Focuses on Law and Regulation
 - Change agent in economic development and market growth
 - Tool for bringing innovation closer to enterprises
 - Potential vehicle for innovation itself

- NML Develops New Models/Approaches
 - Respond to changing nature of markets
 - Promote sustainability and inclusive application of law
 - Improve implementation of law and regulation
 - Enhance links between high-level policy frameworks and day-to-day reality
 - Train new generation of lawyers



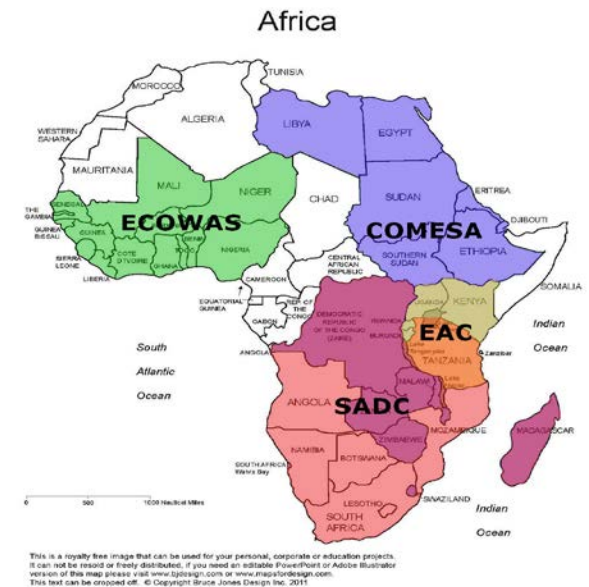
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Partnership with SFSA/Seeds2B

- The New Markets Lab is partnering with SFSA and its Seeds2B initiative to use legal and regulatory reform to scale seed systems, including at the regional level
- 2013: ***Legal and Regulatory Best Practices Assessment*** (“Enabling Environment for Scaling Seed Systems”) as one chapter in an eight-chapter Brief on Planning for Scale produced in collaboration between SFSA and USAID
- 2014: ***Comparative Analysis of Regional Seed Regulatory Systems***
- 2015: ***Country Case Studies*** designed to assess implementation of regional seed initiatives at the national level in Kenya, Zimbabwe, and Ghana
- 2016: ***Regional Test Cases*** to test regional variety release systems in the EAC, COMESA, SADC, and ECOWAS

Comparative Assessment

- Looked at four RECs
 - SADC, ECOWAS, COMESA, EAC
- Covered four key areas:
 - Legal Structure
 - Variety Release
 - Seed Certification
 - Cross-border Trade
- Overall finding: Regional seed harmonization efforts are gaining momentum, albeit at different paces, but deeper analysis is needed to assess and measure the pace of implementation



Comparison of Legal Effect of Regional Instruments

	COMESA	SADC	East Africa	West Africa
Legal Effect of Regional Instruments	<p>Regulations are binding on all member states (enter into force on the date of their publication in Gazette or date specified in Regulation); Directives and Decisions also binding</p> <p>Recommendations and opinions not binding</p> <p>Countries must domesticate measures through national laws</p>	<p>Protocols are legally binding but other instruments are not</p> <p>Measures can become binding through domestication</p>	<p>All legal instruments (Treaty, Protocols, Acts, Regulations, Directives, and Decisions) approved by the Summit/Council of Ministers are automatically binding on all EAC partner states once published in the EAC Gazette</p> <p>All EAC legal instruments take precedence over similar national laws, but domestication still common</p>	<p>Law, Regulations, Directives, Decisions, and Recommendations passed by Council of Ministers binding upon Member States and immediately supersede national law once gazetted</p> <p>Common Law countries (such as Ghana and Nigeria) take additional steps to domesticate</p> <p>ECOWAS reports that 14 out of 17 countries have seed regulatory regimes in line with ECOWAS</p>

Comparison of Regional Seed Frameworks

	COMESA	SADC	East Africa	West Africa
Overview of Regional Seed Framework	<p>COMESA Seed Regulations (2015) establish regional rules for variety release, seed certification, and SPS</p> <p>Institutional Structure: COMESA Seed Coordination Unit (Seed Office); COMESA Seed Committee; National Seed Authority (NSA) in each member state</p>	<p>SADC Harmonized Seed Regulatory System (HSRS)</p> <p>2008 Technical Agreements on Harmonization of Seed Regulations in the SADC Region (Technical Agreements) cover SADC Variety Release System, SADC Seed Certification and Quality Assurance System, and SADC Quarantine and Phytosanitary Measures for Seeds</p> <p>Institutional Structure: SADC Seed Center; SADC Seed Committee (2016); NSAs in each member state</p>	<p>ASARECA/ECAPAPA Agreement, Monograph Series No. 4: Offers fast-track system (no regional catalogue)</p> <ul style="list-style-type: none"> Kenya, Uganda, and Tanzania have achieved highest degree of harmonization Rwanda and Burundi incorporating elements of ASARECA Agreement into national legislation <p>EAC developing harmonized legislative and regulatory framework (Intended to align with COMESA)</p>	<p>West Africa: ECOWAS-UEMOA-CILSS Regional Seed Regulation (2008)</p> <p>Membership overlaps and includes all ECOWAS members plus Mauritania and Chad (part of CILSS)</p> <p>Regional Seed Regulation on Harmonization of Rules Governing Quality Control, Certification and Marketing of Plant Seeds & Seedlings (ECOWAS C/REG.4/05/2008)</p> <p>Institutional Structure: CORAF (technical arm in ECOWAS for CAADP implementation, including Regional Seed Regulation); West African Seed Committee Secretariat; National Seed Committees in 17 partner states</p>

Comparison of Regional Variety Release Requirements

	COMESA	SADC	East Africa	West Africa
Overview of Harmonized Variety Release Process	<p>Seed Regulations harmonize variety release (2 seasons of DUS and 2 seasons VCU/NPT)</p> <p>Regional Seed Catalogue</p> <p>Fast track option if variety registered in one COMESA country – can register in a second COMESA country following one season of VCU/NPT if DUS and VCU data from first country submitted</p> <p>Members must follow UPOV guidelines</p>	<p>Overarching requirement of one season of DUS and two of VCU; varies by country in practice (South Africa does not require VCU)</p> <p>Once a variety is released and registered in 2 member states, it qualifies, (upon application) for entry into the regional seed catalogue and can be accessed in the rest of the SADC market without further testing</p>	<p>Any variety registered in one country could be registered in another following one season of VCU/NPT if sufficient and appropriate test data is available (previous DUS and VCU trials in similar agro-ecological zones)</p>	<p>ECOWAS Protocols and Procedures for release and registration of new varieties and DUS/VCU guidelines for maize, rice, and sorghum</p> <p>ECOWAS Members must have a procedural manual for variety release</p>
Variety Release Exceptions	<p>Member States can ban a variety for technical reasons, including unsuitability for cultivation or risk to other seed varieties, human or animal health, or the environment</p>	<p>Country may reject the approved variety if the agro-ecological conditions are deemed unsuitable</p>		

Regional Variety Catalogues

	COMESA	SADC	EAC/East Africa	ECOWAS/West Africa
Regional Variety Catalogue	COMESA Variety Catalogue	SADC Seed Variety Catalogue	No regional catalogue, only an option to fast-track the national variety release and registration process in one member country if a variety has already been released in another member country	ECOWAS-UEMOA-CILSS Regional Common Catalogue of Plant Species and Varieties (2016)
Conditions to Qualify for Listing in the Regional Catalogue	<p>Variety holder can apply for registration of a variety in the COMESA Variety Catalogue if the variety has already been released in two COMESA Member States</p> <p>Once a variety is registered in the COMESA Variety Catalogue, it can be marketed in any country in the region</p>	<p>A variety holder may apply for regional listing of a variety in the SADC Variety Catalogue once it has already been released in two SADC Member States</p> <p>Once regionally listed, a variety is supposed to be freely marketable throughout the region</p>	<p>A variety that is already registered in one member country's catalogue can be released in another member country following at least one season of VCU testing, provided there is sufficient test data available from previous field trials in similar agro-ecological zones</p>	<p>The regional catalogue is the sum of national catalogues of Member States</p> <p>Varieties that are released and registered nationally in accordance with regional protocols are automatically included in the regional catalogue and marketable in the region</p>

Comparison of Regional Seed Certification

	COMESA	SADC	East Africa	West Africa
Regional Standards and Certification Processes	Members must adopt common Seed Certification Rules	<p>SADC Seed Certification and Quality Assurance System ensures quality of seeds listed in the SADC Variety Catalogue</p> <p>SADC Seed Committee provides technical aid for implementation & development</p> <p>National Authorities authorize samplers and field inspectors (which must undergo course and field training) and labs</p> <p>QDS okay if variety registered under regional DUS/VCU requirements</p>	<p>Protocol on Standardization, Quality Assurance, Metrology and Testing and the Standardization, Quality Assurance, Metrology and Testing Act set regional standards for varieties of certain crops, including seed potato</p> <p>EAC harmonizing certification standards covering at least 42 staple foods, including grains, pulses, edible oil, and tubers</p>	<p>Seed certified in one member country can be freely accessed in the market of another member, eliminating the need for a second certification</p> <p>Countries are required to develop procedural manuals for seed quality control & certification</p> <p>Enabling Technical Regulations under development</p>
Seed Classes	4 Seed Classes: pre-basic (violet band on white); basic (labeled white); 1 st generation certified (labeled blue); and 2 nd generation certified (red label)	5 Seed Classes: Pre-basic Seed (labeled violet band on white), Basic Seed (labeled white), 1 st Generation Certified Seed (labeled blue), 2 nd Generation Certified Seed (labeled red), and Quality Declared Seed (labeled green)	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	4 ECOWAS Seed Classes: Parent Material, Pre-basic Seed (three generations), Basic Seed, and Certified Seed (three generations and hybrid)
Testing, Labelling, & Packaging Requirements	Harmonized labeling to be established based on ISTA standards.	Testing procedures are based on ISTA rules	EAC recognizes ISTA rules, OECD guidelines, and UPOV	Labeling rules to be established based on ISTA – Members must base regulations on international standards, and recommendations

Implementation of Regional Seed Certification

	COMESA	SADC	East Africa	West Africa
Regional Seed Certification: Level of National Implementation	<p>Regulation new, implementation (domestication) steps remain</p> <p>Countries grouped into three categories highlighting readiness to implement the COMESA Seed Trade Harmonization Regulations: (1) Countries with existing legal structures; (2) Countries with legal structures in draft form; and (3) Countries with no legal structures in place (Mukuka, 2014)</p>	<p>Domestication steps remain</p>	<p>Burundi, Tanzania, and Uganda have developed shared seed certification standards for ten crops, but none has recognized other countries' seed certification tests</p>	<p>CORAF coordinating implementation support until 2018</p> <p>Most countries have regulations related to seed production, quality control, and certification</p> <p>Few countries have developed procedural manuals for seed quality control & certification to comply with ECOWAS standards</p> <p>Executive regulation on the modalities for quality control and seed certification in the ECOWAS area</p>
Testing, Labelling and Packaging Requirements: Level of Implementation at National Level	<p>Egypt, Kenya, Malawi, Uganda, Zambia, and Zimbabwe have ISTA-accredited laboratories</p> <p>Kenya and Zimbabwe participate in OECD seed certification schemes</p>	<p>South Africa, Malawi, Zambia, and Zimbabwe have ISTA-accredited laboratories</p> <p>South Africa formally participates in OECD seed certification</p>	<p>Kenya and Uganda have ISTA-accredited laboratories, but Uganda in particular still has capacity challenges; Tanzania is in the process of becoming ISTA certified</p> <p>Kenya and Uganda participate in OECD seed certification schemes; Tanzania is in the process of joining OECD seed certification schemes as well</p>	<p>Certification following ISTA procedures, but no country within ECOWAS has an ISTA-accredited lab (although Ghana is a member of ISTA)</p>

Comparison of Regional SPS Requirements

	COMESA	SADC	East Africa	West Africa
SPS	<p>Members must adopt the common quarantine pest list, which includes exceptions; if a pest is listed on COMESA exception list, then importing member's national pest list is considered</p> <p>COMESA has prepared one set of draft lists for all types of seed trade</p> <p>Common Plant Import Permit and Phytosanitary Certificate must accompany seed shipments</p>	<p>SADC harmonized Quarantine and Phytosanitary Measures for seed</p> <p>2 pest lists established, which only include pests that "are of economic significance, are not common in the SADC region, and are seed borne" (SADC Seed Centre)</p> <p>Development of phytosanitary guidelines and procedures for seed</p>	<p>EAC SPS Protocol for some goods, including seeds in line with Article 108 of the EAC Treaty (excludes food safety measures) approved by EAC Summit, and, therefore, binding upon members; SPS Bill to facilitate implementation being finalized</p> <p>East African Standards (EAS) provide unified SPS standards for a number of staple foods, including seed potato (must follow International Plant Protection Convention (IPPC)) and other tubers, grains and pulses</p> <p>Countries are encouraged to review pest lists, but no universal pest quarantine list</p> <p>Quarantine pest list for Kenya, Tanzania, and Uganda</p>	<p>ECOWAS requires that seeds imported into and exported from the region are accompanied by a phytosanitary certificate issued by a Member State</p> <p>Countries are required to periodically review pest lists and exchange information on pests, but no universal pest quarantine list exists</p> <p>National agencies responsible for plant protection issue phytosanitary certificates for import and export, but national regimes vary considerably</p>

Country Case Studies (Kenya, Ghana, and Zimbabwe) – Deeper Assessment Country Level

- Deepened understanding of national level implementation of regional seed harmonization measures
- Examined legal and regulatory framework along entire seed value chain
 - Mapped regulatory processes governing variety release, seed certification, and cross-border trade
 - Focused on *implementation* of national and regional seed frameworks
- Based on legal assessment, including practical experience of industry, several recommendations emerged to enhance harmonization of seed frameworks at the national and regional levels

Case Studies: Overarching Recommendations for Implementation

- Increase awareness of regional frameworks, which is further linked to effectiveness of national regulations
- Provide regulatory guidance for regional standards
- Enhance regulatory collaboration within region
- Increase third country data sharing
- Study legal differences within and across regions
- Align different regional processes

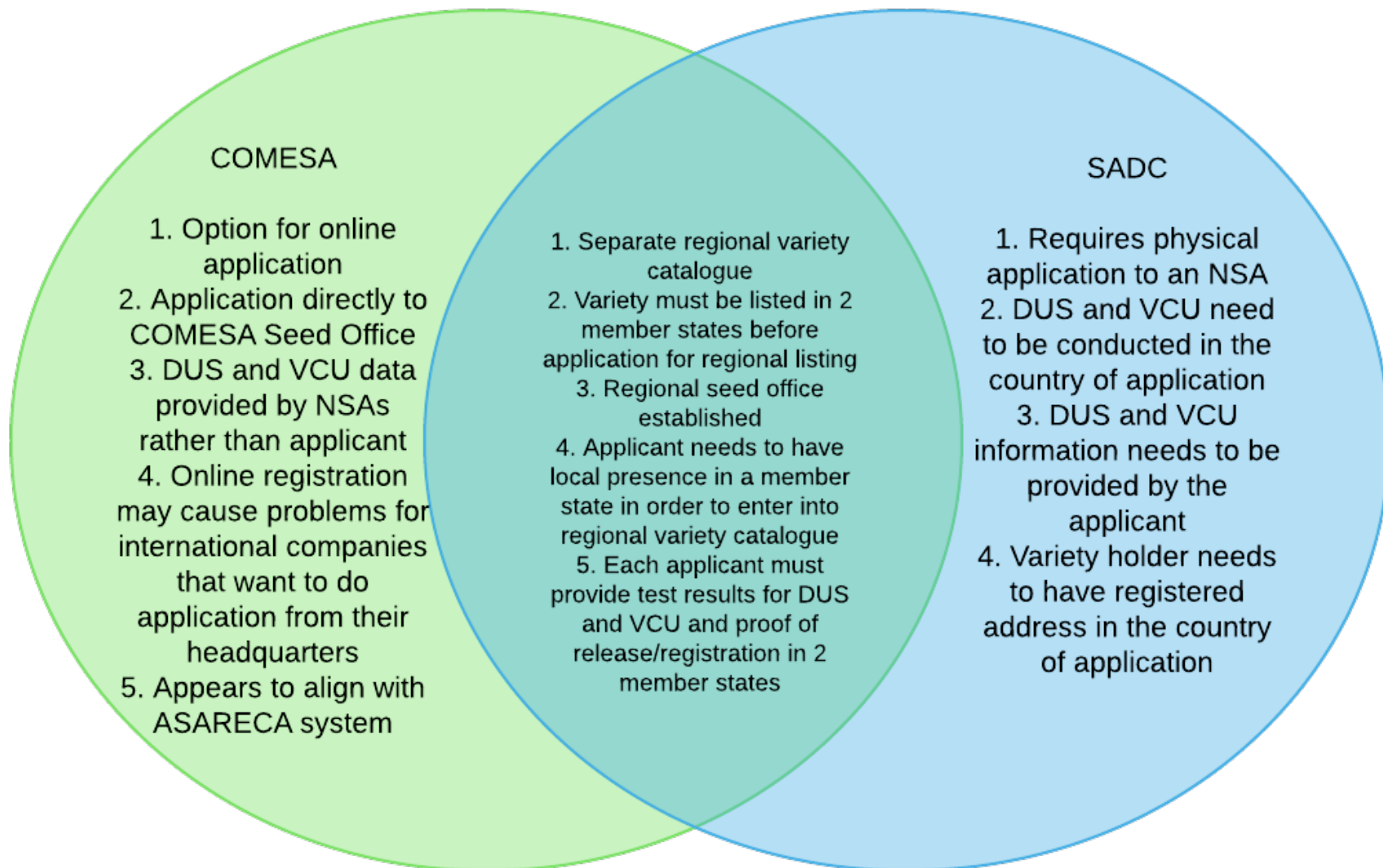
Regional Variety Release Test Cases

- Objective: Assess regional seed regulatory structures and document degree to which legal and regulatory frameworks are implemented
- Focus on EAC (beans), SADC (seed potatoes and maize), COMESA (seed potatoes and soybean) with plans to initiate test case in ECOWAS (national registration of a number of sorghum varieties, using the ECOWAS procedure, has been initiated in Mali)
 - Some Test Cases can be completed within a relatively short period of time, while others will extend for more than one year; new Test Cases will be added on an ongoing basis as the project progresses
- COMESA and SADC systems offer interesting comparison: very similar but COMESA seemingly favored by private sector

Application and Implementation of Regional Catalogue

	COMESA	SADC	EAC/East Africa	ECOWAS/West Africa
Application Process	<p>Online application directly to COMESA Seed Office</p> <p>Alternatively, physical application to COMESA Seed Office on downloadable application form</p>	<p>Application forms downloadable on the SADC Seed Centre website</p> <p>Signed applications must be submitted to the NSA of one of the two SADC countries where the variety has been released</p>	<p>Standard application for national listing in a participating country, but includes allowance for the use of trial data from another member country (along with proof of release in the other country), thereby cutting down the time a company needs to spend on in-country tests</p>	<p>No separate application for regional listing</p>
Degree of Implementation at Regional Level	<p>The COMESA Variety Catalogue was launched in November 2015 and is available online</p> <p>14 varieties (maize and potato) have been listed in the COMESA Variety Catalogue</p>	<p>The SADC Seed Centre was established in December 2011</p> <p>The first varieties were listed in the SADC Catalogue in November 2014</p> <p>Catalogue contains 24 varieties, primarily maize (online catalogue states 24 maize varieties; SADC Seed Center has noted</p>	<p>The ASARECA system has been implemented to varying degrees in the variety release and registration regulations of EAC countries</p> <p>Implementation, however, has not been fully achieved largely due to lack of awareness of the ASARECA Agreement and differences in approach and interpretation among EAC countries</p>	<p>Regional Common Catalogue of Plant Species and Varieties was validated on 30 August 2016, but is not yet available online. It includes 1496 varieties of 11 ECOWAS priority crops based on essential DUS and VCU information and replaces 2008 version</p> <p>Enabling regulations needed -- Technical regulation related to the organization of the ECOWAS-UEMOA-CILSS Variety Catalogue</p>

Comparison of COMESA and SADC Regional Variety Catalogues



Test Cases Key Findings

COMESA	SADC	EAC/East Africa	ECOWAS/West Africa
<p>The COMESA system appears, at this point, to be favored by companies</p> <p>More “user-friendly” due to factors such as option for online application</p> <p>Application directly to COMESA Seed Office</p> <p>DUS and VCU data provided by NSAs rather than applicant</p> <p>Online registration raises questions for international companies that want to do application from their headquarters</p> <p>Appears to align with ASARECA system in EAC</p>	<p>Applications not yet submitted; however, although broadly similar to the COMESA system, small differences appear to make the COMESA system more “user-friendly”</p> <p>SADC appears to require physical application to an NSA</p> <p>DUS and VCU need to be conducted in the country of application*</p> <p>DUS and VCU information needs to be provided by the applicant</p> <p>Variety holder needs to have a registered address in the country of application</p> <p>*To be confirmed through Test Case</p>	<p>Countries in the EAC are taking concrete steps to implement the ASARECA system, and companies are more willing to apply for national variety release as a result</p> <p>It is not always clear how individual countries will apply fast-track release under the ASARECA system</p> <p>There seems to be alignment between the ASARECA and COMESA systems</p>	<p>No test cases yet, but it is anticipated that companies may appreciate that regional listing does not require any additional applications or costs other than national listing in one member state</p> <p>Significant progress in implementation at national level: Regional Regulation adopted in most countries; all 17 member states have implemented a national seed law, instituted a national catalogue of species and varieties, and established a national seed committee</p>

Thank You!

- For questions or additional information please email me at kkuhlmann@newmarketslab.org
- Or visit our website at www.newmarketslab.org