



**REPORT ON THE STATUS OF DOMESTICATION AND IMPLEMENTATION OF
THE EAST AFRICAN COMMUNITY HARMONIZED PESTICIDE GUIDELINES**

REPUBLIC OF KENYA

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Alliance for A Green Revolution in Africa (AGRA)

Email : BKeizire@agra.org

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ABBREVIATIONS

AGRA	The Alliance for a Green Revolution in Africa
CBI	Confidential Business Information
EAC	East African Community
GHS	Global Harmonized System of Classification and labelling
KALRO	Kenya Agricultural & Livestock Research Organization
PCPB	Pest Control Products Board
USDA	United State Department of Agriculture
R&D	Research and Development
TWG	Technical Working Group
FAO	Food and Agriculture Organization of the United Nations
EUP	Experimental Use Permits
WHO	World Health Organization
JASCOM	Joint Agriculture Sector Consultation and Cooperation Mechanism
SWAG	Sector Technical Thematic Working Group

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EXECUTIVE SUMMARY

An assessment was conducted to establish Kenya's status of adoption and domestication of the East African Community (EAC) pesticides harmonized guidelines that were scheduled for full adoption by May 2020 in all the six Partner States. This report aims to present the findings of the assessment; highlight the status, gaps and any interventions required for full implementation of the EAC guidelines..

Following the endorsement of the guidelines by both the Sectoral Council on Agriculture and Food Security (SCAFs) and the Extra Ordinary Council of Ministers (EOCMs), Kenya developed a roadmap for the implementation. However, this was interrupted by the occurrence of the Covid-19 pandemic. The information on the status of implementation and experiences on the domestication were collected from Pest Control Product Board and selected private sector companies through desk review and questionnaire. Reference was made to licensed importers as per PCPB registered and licensed companies during 2020. The study utilized purposive sampling during identification and selection of sampling in the private sector. A sample of 10 were drawn from estimated population of 80. The guiding principle for selection of the private sector participants was to select a representative sample that reflect structure of the industry (R&D, agents of generic pesticide manufacturers and local companies). Only companies that had applied for registration of products in Kenya in the past 18 months or known to have applied for registration using EAC guidelines even in other EAC countries were eligible for selection.

The main findings indicate that the Republic of Kenya has made fair progress in the domestication and implementation of the EAC harmonized guidelines on the legislation front. A new bill to replace the current Act that has been in place since 1982, was awaiting approval by Cabinet before presentation to the National Assembly for debate. In addition, draft regulations have been revised to incorporate the EAC guidelines and are awaiting publishing in the Kenya Gazette to give them legal status.

Challenges identified in the assessment include the length of time and financial resources that the Pest Control Products Board needs for the successful implementation of the roadmap as stipulated by the 2010 Constitution. The legislation is required to provide the regulatory authority the needed mandate to implement the provisions in The Pest Control Products Bill, 2018 and Seven (7) draft regulations, in which the provisions of the EAC guidelines have been captured. Recommendations have been organised around policy, general infrastructure development and capacity building in registration and post registration as well as private sector activities

1 BACKGROUND AND INTRODUCTION

The East African Community (EAC) pesticides harmonized guidelines were scheduled for full adoption by May 2020 in all the six Partner States following endorsement by both the Sectoral Council on Agriculture and Food Security (SCAFs) and the Extra Ordinary Council of Ministers (EOCMs) in 2018 and 2019.

Specifically, SCAFs and the Council of Ministers directed:

1. Partner States to domesticate the guidelines by 30th May 2020.
2. Partner States to pilot implementation of the efficacy guidelines for the first three years (2019 to 2021) subject to annual reviews prioritizing potential products that could be used to control the Fall Armyworm (FAW).
3. Partner States to prioritize coordinated capacity building and support to facilitate implementation of these harmonized guidelines, including dossier evaluation and risk assessment, at the country level; and
4. the EAC Secretariat and Partner States to establish a secure online system for submission of dossiers.

The Republic of Kenya prepared a road map to effect the implementation but like other EAC partner states, the envisaged steps were since disrupted by the COVID-19 pandemic from March 2020.

The project designed by the Alliance for a Green Revolution in Africa (AGRA) and the EAC Secretariat is a response to the challenges faced by Partner States in domestication of the guidelines and envisages to fast tracking the domestication during the first half of 2021. The overall goal of the project is to facilitate increased farmer access to effective conventional pesticides and bio pesticides in EAC Partner States through and implementation of the harmonized pesticide registration system.

1.1 OBJECTIVES

The overall project aim was to assist Kenya achieve implementation of the EAC pesticides harmonized guidelines. The capacity assessment was aimed at establishing the existing regulatory processes; the status of implementation of the guidelines and identifying the gaps and challenges to the implementation of the guidelines to determine the road map for support to improve capacities for enhanced implementation of the guidelines.

The specific objectives were:

- 1) To appraise the Kenya's pesticide regulatory framework and Environment for adoption of the EAC harmonized guidelines in terms of:

- i) Infrastructure to manage registrations;
 - ii) Human Resources and Technical capability to undertake pesticide registration;
 - iii) Financial Resources and
 - iv) Governance
- 2) To establish the status of the domestication of the EAC harmonized guidelines
- 3) To understand the general pesticide registration process and other pesticide management practices in Kenya
- 4) To establish Kenya Private sector buy-in and experiences in:
 - i) Pesticide dossier application under the EAC harmonized guidelines
 - ii) Efficacy trials implementation of EAC Harmonized Guidelines
- 5) Established the gaps and recommendations for fast-tracking the implementation of the guidelines.

2. METHODOLOGY

2.1 DESK REVIEW

The required information was partly gathered through a desk review of information obtained from the relevant websites and from published literature. Also reviewed were available documents relevant to the country's adoption of the EAC harmonized pesticide registration system. Most of the documentation was provided by the EAC, AGRA and USDA among other stakeholders. These were in the form of minutes of the technical working group, reports on any previous activities related to the domestication of the EAC harmonized guidelines such as training and or survey reports. Reference was made to the desk assessment conducted by Joseph Huesing and Luis Suguiyama in August 2020 under USDA support. The assessment focused only on the domestication and implementation of harmonised guidelines, whilst the current assessment went further and deeper by looking at the entire regulatory system as well as the interactions of private sector actors in the Republic of Kenya.

2.2 ASSESSMENT TOOLS

Two assessment tools in the form of questionnaires were developed and administered. One was for assessment of the national regulatory approval system and the other for assessment of the country's private sector involvement in and challenges encountered in the harmonization of the guidelines.

The tool for the regulatory approval assessment was responded to by government officials responsible for registration of pesticides and running of trials in the country. The tool was designed to capture target information as per the assessment objectives. Two focus group discussions were held with officials from the Pest Control Products Board of Kenya (PCPB) to gain in-depth understanding of the information provided in the questionnaires.

The private sector assessment tool was self-administered by pesticide dealers identified by CropLife Kenya, an association of agrochemical dealers in the country.

2.3 SELECTION OF KEY RESPONDENTS.

For PCPB, all the officials in the departments of registration, inspections and compliance and those from analysis department were involved in the assessment. Whilst on the efficacy trials, only institutions that participated in the EAC pilot trials were selected to provide their experiences with the implementation of the EAC guidelines.

Purposive sampling was employed in the identification of the respondents. The selection targeted companies with presence in multiple EAC member states agents or registrants who had had interactions with the regulatory authority and indicated preparedness to respond to the questionnaire. Pesticide dealers who had not applied for registration of pesticides with PCPB in the past 18 months were not eligible for selection. Those who had participated in the pilot registration under the EAC guidelines were all provided with the questionnaire to complete. A total of 10 questionnaires were sent to as many companies.

2.4. ANALYSIS

The information gathered from the respondents was sorted, organized and subjected to descriptive analysis to inform the drawing of conclusions in line with the assessment objectives.

Considering that full implementation of the EAC harmonised guidelines required alignment of the country's legal framework with the guidelines, the level of the alignment was rated using a combination of Likert Scale and Ordinal Scale models. The information obtained relating to legal and administrative measures so far taken, was assigned a value to depict the extent of alignment to the guidelines in a scale of 1-5 defined as follows:

- 0 No action taken
- 1 Process initiated (25%)
- 2 Process at 50%
- 3 process at an advanced stage (75%)
- 4 Process at finalization stage (90%) and
- 5 Process completed(90-100%)

The analysis was designed by the assessment team based on the Likert Scale, which measures attitude, perception and opinion (Robinson, 2014), because most of the information gathered on legal frameworks were based on perceptions of the respondents. The scale was combined with the ordinal scale rating to permit quantification of the levels of alignment of the legal frameworks with the EAC guidelines. A continuum ranging from "No Action Taken" to "Process Completed" and values assigned based on how the assessors perceived the extent of the alignment was used.

3. FINDINGS

3.1 REGULATORY FRAMEWORK FOR REGISTRATION OF PESTICIDES

The findings reveal that there is no policy to guide the sound management of pesticides in the country. However, Pesticides in Kenya are regulated under the Pest Control Products Act Cap 346 enacted in 1982 and revised in 2009 through a miscellaneous amendment. The subsidiary laws within the realm of pesticide law regulation include:

1. Registration regulations, 1984 (L.N. 43/2006);
2. Importation and exportation regulations, 1984 (L.N. 146/1984, L.N. 125/2006)
3. Licensing of premises regulations 1984 (L.N. 45/1984, L.N. 124/2006);
4. Disposal regulations, 2006 (L.N. 126/2006);
5. Labelling, packaging and advertising regulations, 1984 (L.N. 89/1984, LN 127/2006);
6. Fees and other charges regulations, 2006 (L.N. 128/2006)

The survey noted that a procedure for application for registration was in place as per the law, and pesticide registration involves evaluation of comprehensive scientific data and conducting of local efficacy trials are a pre-requisite requirement to registration. Similarly, local and regional residues trial data are required for registration. The survey revealed that local residue trials can be conducted where data from internationally accepted sources were not available.

The survey also revealed that there is a provision for registration of a product under emergency use. However, the procedure has not been formalised and therefore remains unclear especially when there are emergencies that need to be responded to.

3.1.1 INCORPORATION OF EAC GUIDELINES IN THE LEGAL FRAMEWORK

Full implementation or domestication of the guidelines in the legal framework requires each Partner State to take necessary and appropriate legal, administrative and other measures which may include the following five key measures:

1. Development and or review of a Policy on pesticides management
2. Development and or review of legislation on pesticides (Law (Act/Decree)
3. Development and or review of legislation on pesticides regulations to implement.
4. Establishment and or review of a system (authority, office of the registrar, review committee) for regulation of pesticides – registration and post registration management
5. Establishment and or review of Mechanisms for public awareness, education and participation.

Kenya made efforts to incorporate EAC harmonized pesticides guidelines in the draft Bill and regulations . A road map to effect the implementation was prepared as follows:

1. EAC harmonized guidelines were presented to the Pest Control Products Board which cleared them for onward transmission to the Ministry of Agriculture, Livestock, Fisheries and Cooperatives (MOALF&C) and the Attorney General's Chambers in 2019.
2. PCPB and the MOALF&C jointly developed a roadmap to guide finalization of the Pest Control Products Bill and Regulations by July 2020.
3. PCPB presented the draft Regulations on pesticides to the Intergovernmental Joint Agriculture (JASCOM) Sector Thematic Working Group (SWAG) on Policy, Regulations and Standards in January and February 2020 who granted the go ahead for public participation on the revised regulations to be conducted in March and April 2020.
4. However, a new road map was drawn when there was a decline in incidents of Covid-19 in the month of September 2020. The stakeholders' consultations were conducted between 28th September, 2020 and 26th October, 2020 covering a total of 37 counties and a target of 740 participants drawn from various stake holding interests.
5. The next step is for the experts to internalize the comments from the stakeholders from the counties and incorporate them into the PCP Bill and regulations. The experts will be drawn from Kenya State law office (Attorney General's office), Ministry of Agriculture, among others. This process including conducting national validation exercise requires that remain a challenge.
6. It was noted that regulations become effective if Parliament assents. The draft regulations were revised so as to include all the provisions of the six EAC pesticides harmonized guidelines. Therefore, the gazettment of these revised guidelines will result in full domestication and implementation of the EAC harmonized pesticide guidelines.

In view of the above, Kenya's status of domestication of the EAC guidelines stands at 14 out 25 or 56% as shown in table 1.

TABLE 1: STATUS OF ALIGNMENT OF LEGISLATIVE FRAMEWORK TO EAC GUIDELINES.

Legal Framework	Existence (Yes)/No	EAC alignment score	Comments
Development and or review of a Policy on pesticides management	No.	0	No policy in place
Development and or review of legislation on pesticides (Law (Act/Decree)	Yes	3 (75%)	Present act 35yrs ago. Bill aligned to EAC is pending approval
Development and or review of legislation on pesticides regulations to implement	Yes	4(90%)	New regulations developed to align to EAC pending approval
Establishment and or review of a system (authority, office of the registrar, review committee) for regulation of pesticides – registration and post registration management	Yes	3 (75%)	Creation of the authority is included in the Bill
Establishment and or review of Mechanisms for public awareness, education and participation	Yes	4(90%)	Public participation as provided for in the constitution has been undertaken.
Scale: 0-No action taken; 1-process initiated (25%); 2 process at 50%; 3-process at an advanced stage (75%); 4-Process at finalization stage (90%) and 5-process completed (90-100%)			

3.2 ENABLING ENVIRONMENT FOR PESTICIDE MANAGEMENT AND ADOPTION OF THE HARMONIZED GUIDELINES

3.2.1 ADMINISTRATION AND FUNDING FOR REGULATORY ACTIVITIES

Overall administration of regulatory approval systems, including the power to issue regulations, rules and guidelines relating to pesticide management rests with the parent ministry; Ministry of Agriculture, Livestock, Fisheries and Cooperatives. Pest Control Products Board (PCPB) which started its operations in 1985 has the power to issue licenses and permits. The institution is established under the Pest Control Products Act, Cap 346, Laws of Kenya, overseen by a Board established since 1984.

Regarding funding of the regulatory approval system, the Board, receives payments for statutory fees (registration fees, licenses, permits etc.) accounting for 35 percent of the PCPB budget and government grants accounting for 65 percent. It was noted that internally generated funds were retained by the regulator for funding its activities.

All the six EAC guidelines have been ideally implemented on paper as PCPB awaits the finalisation of the draft regulations; in which the guidelines have been incorporated by reference. The subsequent gazettment of the regulations will bring them into effect. In the interim, Kenya Agricultural Livestock and Research Organization (KALRO) has been designated as a pilot efficacy testing centre in as far as the guidelines on efficacy trial centres is concerned.

Kenya has thus taken measures to review legislative provisions, in this case the draft law and regulations, as well as current practice in registration of pesticides espousing the EAC guidelines. The Pest Control Products Bill, 2018 and the seven (7) draft regulations, adequately capture the provisions of the EAC guidelines¹. The draft regulations capture import and export fees and other charges, inspection, labelling, Confidential Business Information and registration. The registration regulations encompass the EAC guidelines' data requirements for conventional products, for microbial, macrobial, biochemicals, semiochemicals as well as prescribed application forms. Like other countries, there is also no policy on pesticide management.

A number of aspects currently with gaps will be addressed once the Bill and Regulations are passed. These include the creation of the office of the Pesticide Registrar; proposed for establishment in the Bill. Table 2 summarizes the status and gaps in Kenya's pesticide registration system and the recommendations arising from the assessment.

TABLE 2: STATUS, GAPS AND RECOMMENDATION ON PESTICIDE MANAGEMENT SYSTEMS IN KENYA

Capacity Area	Status	GAPs	Recommendation
1. Infrastructure	<ul style="list-style-type: none"> • Spacious offices, board rooms equipped with internet in place, • Staff have computers connected to the internet. • Lockable rooms for keeping dossiers. • Analytical Laboratory exists for testing sample for registration and post registrations. • PCPB has pool vehicles but none is dedicated to the registration and post registration monitoring process. 	<ul style="list-style-type: none"> • Additional equipment required in the laboratoru • The available laboratory space is not sufficient. • There is no library • The current ICT- infrastructure cannot support electronic dossier submission 	<ul style="list-style-type: none"> • fast-track the completion of new laboratory, under construction • Equip the laboratory to facilitate pesticide formulation and redsidue analyses;
2. Human Resources	<ul style="list-style-type: none"> • A total of 7 experts are responsible for dossiers evaluations with support from 3 support staff. • The experts are spread out to toxicology, ecotoxicology, chemistry and efficacy. • 3 members of staff are available for laboratory analysis. 	<ul style="list-style-type: none"> • Insufficient number of staff in registrations and laboratory 	<ul style="list-style-type: none"> • There is need to increase and train the number staff for registrations and laboratory.
3. Funding & Financial Resources & governance	<ul style="list-style-type: none"> • The Board receives funding from statutory fees (registration fees, licenses, permits etc.) accounting for 35% of the PCPB budget and government grants accounting for 65%. • It was noted that internally generated funds were retained by the regulator • The current PCP Act is 35 years old, and theres is no policy guiding the sector. • pesticide registration board and committee meet at least four times in a year as provided for in the law, depending on availability of funds.Its composition enshrined in the law 	<ul style="list-style-type: none"> • Insufficient funds for implementation of the harmonized guidelines • Lack of policy on pesticides may make it difficult for a regulatory authority to deliver on its mandate • The current law is outdated and does not address emerging issues 	<ul style="list-style-type: none"> • Increase funding to support implementation of the harmonized guidelines • Development of a pesticide management policy and expediting the enactment of the PCP Bill and Regulations

	includes representatives from health, environment, water, national standards body, agriculture, livestock and trade.		
4. Pesticide Registration process and data requirements	<p>Elaborate procedures of registration exist:</p> <ul style="list-style-type: none"> • Registration pre-consultations; elaborate dossier evaluation based on requirements for conventional and biopesticides respectively; local efficacy. • There are application forms and procedure for registration under emergency use and low risk products (biopesticides and bio-control agents) • Board has mandate to approve, defer or reject registration as well as revoke a registration or deregister a product upon recommendations by the technical committee. 	<ul style="list-style-type: none"> • Dossier evaluation process is not standardized with registration officers sometimes making conflicting decisions; • EAC guidelines on data requirements yet to be adopted 	<ul style="list-style-type: none"> • These gaps will be resolved once the PCP Bill and Regulations are enacted.
5. Post registrations Import & Export & Licensing	<ul style="list-style-type: none"> • The law prohibits the import of pesticides that have not been registered. • The law establishes equal standards for imported and domestically produced products as required under WTO agreements. • There is a licensing scheme including procedures and requirements for obtaining a license to ensure proper storage, handling, packaging and use. 	<ul style="list-style-type: none"> • The post registration surveillance inspectors are not adequate. • Counterfeits, unregistered products, substandard products enter the country through porous borders. 	<ul style="list-style-type: none"> • Increase the number of inspectors to undertake post registration surveillance to enhance compliance.
6. Record keeping and Confidentiality including CBI protection	<ul style="list-style-type: none"> • Procedure for receiving and handling Confidential CBI in place (separation of CBI) and secure under lock and key. • Also, a register containing basic information of all the registered 	<ul style="list-style-type: none"> • The current practice is not hangered in law • Inadequate storage space. 	<ul style="list-style-type: none"> • The enactment of the new law and regulation should expedited • Developed systems & enhance capacity for e-submission.

products, is kept by the registration agency.

- This register of pesticides is available to the public on the website.

- there is need for further improvement on the physical storage.

3.2.2 RECORD KEEPING AND CONFIDENTIAL BUSINESS INFORMATION

A register containing basic information of all the registered products, is kept by the registration agency. This register is available to the public on the website at no cost. Registers of banned and severely restricted products were also published on the official website and accessible to the public.

The assessment revealed that there was a procedure for receiving and handling CBI and that PCPB kept and updated important registers. The procedure involves among other practices; submission of CBI separately from the rest of the dossier. It is then kept secure under lock and key and made accessible to authorized persons only. All employees in accordance to oath and secrecy act signs a commitment to keep in confidence all the information that comes in their possession during employment.

In practice therefore, PCPB utilises the above in absence of the explicit regulation on the protection of CBI by ensuring all staff handling CBI sign confidentiality agreement with the applicants.

However, there is need for further improvement on the physical storage capacity so as to have bulk files and safes. This can also be resolved by implementation of e-submission systems.

It is noteworthy that unless the Bill and Draft Regulations are enacted, the current primary law and respective regulations do not have an explicit legal cover or provision for the protection CBI, neither do they identify which information could be made public and which was confidential. Penalties for breaches of confidentiality were found not to be sufficiently high to act as an effective deterrent and to assure industry members that the registration process would not compromise their business interests.

Improved provisions for protection of CBI in line with EAC guidelines have been fully incorporated in the draft 2018 regulations on CBI, awaiting enactment.

3.3 THE STATUS OF THE EAC PILOT TRIALS IN KENYA

Conducting local efficacy trials is a prerequisite for pesticide registration for use in Kenya. In this regard, PCPB has accredited over 40 institutions to conduct efficacy trials on its behalf drawn from both government and private bodies. The major government body accredited is KALRO that has various centers countrywide with each having a well-defined mandate. Applicants are at liberty to choose any of the accredited institutions as long as the accreditation scope covers the proposed situation(s) of use. Trials are currently conducted for 3 seasons. PCPB have developed guidelines for the establishment and conduct of the trials

On the status of the EAC pilot trials, it was established that six (6) pesticides were approved for testing in Kenya under EAC pilot efficacy trials. The trials were carried out to test the efficacy of the insecticides against the Fall Armyworm infestation on maize by the Kenya Agricultural and Livestock Research Organization (KALRO). All efficacy trials for the products tested under the pilot programme were run for two seasons as required and the efficacy reports submitted to PCPB. Table 3 shows the status of the pilot trials conducted in Kenya.

TABLE 1: STATUS OF PILOT EFFICACY TRIALS IN KENYA

Product	Company	Status report as of 30th June, 2020	Status as of March 2021
Mazao Achieve (Met 78)	Real IPM	Season 1 trials concluded. Season 2 trials have not started	Trials finalised. Awaiting submission of trial report to PCPB for consideration for registration
Mazao Detain (78)	Real IPM	Trials have not commenced.	Season 1 trial completed. Season 2 trial has started
Gaicho FS 600	Bayer	Season 1 &2 trials completed	Final report submitted to PCPB and awaits consideration for registration
Provivi Pherogen dispenser	Provivi	Season 1 and season 2 trials completed.	The two seasons trials were completed and report send to PCPB. The product is registered.
Fawligen	AgBitech	Season 1 trials concluded. Season 2 trials have not commenced	Trials completed and the product registered
Nomax.	BASF	Season 1 and 2 trials concluded	The trials were completed and report submitted to PCPB awaiting consideration for registration

4. PRIVATE SECTOR EXPERIENCES

This section provides experiences and challenges cited by private sector respondents, vis a vis dossier submission, efficacy trials and the entire registration process. The following experiences from the private sector were noted. Ten (10) respondents out of the 80 currently registered with PCPB were approached to complete they questionnaire and they all completed and returned; a response rate of 100%.

PCPB in consultation with the private sector as required by law incorporated the newly introduced EAC harmonized guidelines in the draft regulations that were submitted to the Parent Ministry for gazettelement.

4.1 DOSSIER APPLICATION UNDER THE EAC HARMONIZED GUIDELINES

The registration process was noted to be fairly straightforward though the procedure is not properly documented. The process took on average 2-3 years; a duration considered “too long” by the private sector.

Regarding application dossier submission, Pest Control Products Board (PCPB) charged Kenyan Shillings (Kshs.) 10,000 for introduction of a new product (trial permit) as per the Pest Control Products (Licence Fees and other Charges) Regulations, [L.N. 128/2006) (as revised in 2012). Additional payments are required whenever there are data gaps. Partial e-submission process currently in place eased dossier submission since a pre-consultation option on the alignment of information granted with the assigned PCPB officer had been added to the process.

4.2 CONFIDENTIAL BUSINESS INFORMATION

Both the regulatory agency officials and private sector actors understood what entails confidential Business Information. The applicants on their part are required to indicate what Confidential Business Information (CBI) is when submitting a dossier for consideration of application for registration of a product. Applicants confirmed the requirement for signing a confidentiality declaration obliging for nondisclosure of propriety information.

4.3 EXPERIENCES IN EFFICACY TRIALS.

The private sector had also actively participated in the EAC Pilot efficacy trials, with, a total of 36 dossiers submitted for review during the 2019 – 2021 period by the respondents. The assessment revealed that there is adequate feedback mechanism in place. This explains that the private sector actors somewhat receive sufficient

clarification on the requirements for registration. During 2021, a total of 41 dossiers applications are planned for submission among the respondents.

The assessment revealed that EAC trials protocols and requirements were generally followed in conducting efficacy trials. Additionally, the locations of the testing facilities and institutions were convenient and accessible and capacities of the institutions conducting the efficacy trials were fairly adequate with highly competent staff and fairly equipped facilities. However, the time frame for conduct of local efficacy trials and costs were not uniform for the various institutions. On the cost accredited government efficacy trial institutions were reportedly more expensive than their private counterparts.

Private sector actors suggested possible solutions around their respective experiences and challenges on the dossier review process, protection of CBI and efficacy trials as highlighted in Table 4:

TABLE 4. PRIVATE SECTOR RECOMMENDATIONS ON THE PESTICIDE REGISTRATION PROCESS IN KENYA

Area	Recommendations
Review of dossiers	<ul style="list-style-type: none"> • Reduce the current time it takes for reviews (2-3 years) and timely communication to applicants on registration decisions. • Review the additional costs associated with data gaps • Standardisation of review processes/ provision of clear procedures to avoid varied interpretation that may arise during dossier reviews or dependence on the reviewer’s discretion. • Adherence to service charters established by PCPB
Communication with regulatory authorities	<ul style="list-style-type: none"> • Regulatory authority to assign an officer to be responsible for communication with the stakeholders; this aspect requires improvement; • No feedback on requests/approvals unless the applicant makes a follow up and it takes quite some time to get an answer
Efficacy trials	<ul style="list-style-type: none"> • Cost are varied depending on the institutons. Standardisation is required. • Consider reduction of the current timeframe. PCPB considers two season trials instead of three for new product registration as per the EAC guidelines as they await for the gazettelement of the draft Bill. • Timely sharing of progress reports with applicants • Accreditation of more testing institutions for public health products
CBI Handling , Storage and e-submission	<ul style="list-style-type: none"> • Only authorized personnel should have access to the confidential business information, however the need to improve on storage through implementation of esubmission • Improved efficiency in e-submission to avoid double submissions in both paper and electronic.

5. CONCLUSIONS AND RECOMMENDATIONS

5.1 CONCLUSIONS

Kenya has implemented 45% of the EAC harmonised guidelines, albeit administratively. This is a result of the fact that even prior to the onset of the development of the harmonised guidelines, the regulatory authority; PCPB proactively, over time improved pesticide management including adoption of some best practices including data requirements, adoption of mechanisms for protection of IPR, review of biologicals, equivalence and Globally Harmonized System of Classification and Labelling of Chemicals among others.

Furthermore, in an effort towards the domestication and implementation of the harmonized EAC guidelines Kenya drafted a law and Regulations awaiting finalisation for some time now. This delay could be attributed to the fact that after the promulgation of the Constitution of Kenya 2010, the process of law review became a complex process involving different levels of stakeholder consultations and engagements at the County and National Governments and stakeholder groups outside of Government.

Kenyan law also requires that a Regulatory Impact Assessment (RIA) be conducted. This has since been done and submitted. Once completed, the process involves will forwarding final draft regulations to the Office of the Attorney General. The next stage is a parliamentary review and approval before its official publication in the Kenya Gazette to give it legal status. The draft Regulations were aligned to the six (6) EAC pesticide harmonised guidelines. In view of the highlighted developments, publishing of the regulations shall facilitate the implementation of the EAC guidelines. The following steps are required to be covered in order to approval proposed PCPB bill and Regulations. This will also enable the full domestication of the EAC guidelines:

- a) Consolidation of stakeholders' views.
- b) Assessment of the legislative impact of the proposed PCPB bill and Regulations.
- c) Presentation to Parliament for deliberation by the law makers.
- d) Enactment of the law and regulations.
- e) Stakeholder sensitization.
- f) Training of technical staff.
- g) Adequate funding for the process.

It is envisaged that at the end of this process Kenya will have fully domesticated and advanced the implementation of the EAC pesticides harmonised guidelines.

5.2 RECOMMENDATIONS

In view of the challenges and gaps identified, the following recommendations for full domestication of the EAC pesticides harmonised guidelines and further improvement in efficient pesticide management for both the public and private sector have been derived:

5.2.1 PUBLIC SECTOR

1. Fast track enactment of the Bill and gazettment of draft Regulations. PCPB has revised the road map for the implementation of the EAC guidelines
2. Increase of exchequer support to PCPB: The funding to PCPB from the exchequer is inadequate for the proper functioning of the institution to effectively deliver on its mandate. Recommendations in parliamentary PCPB budget puts the required deficit at Kshs. 200 million
3. Development of a pesticide management policy to guide the sector.
4. Continue capacity building of officials in the required skill and competency set in order to support pesticide management including human and environmental risk assessments.
5. Capacity build of electronic mechanisms for registrations including handling CBI
6. Enhance public awareness and sensitization on the EAC harmonized guidelines

5.2.2 PRIVATE SECTOR

1. Sensitization and training of private sector actors to raise awareness and comprehension of the EAC harmonised guidelines. Private sector comprehension of the guidelines and participation will result in more utilisation and improvement of the harmonised system of registration.

5.3 INTERVENTION MATRIX

As an outcome of this assessment, key interventions are summarised in table 5 below:

TABLE 5: INTERVENTION MATRIX

No.	Intervention required	Proposed Activities	Suggested Resp Organization	Proposed Timelines
1.	Pesticide legal framework	Development of a pesticides management policy	FAO/EAC / /Industry /Ministry of Agriculture	Medium term
		Fast track the Approval of PCP Bill 2018 and Regulations	/Ministry of Agriculture and other Govt agencies	Short term
2.	Capacity enhancement	Completion and equipping of laboratory for support pesticides analysis (quality and residue)	MoA and other developing agencies	Medium to long term
3.		Expansion of human resources along the required skill set ²	EAC / FAO MoA/AGRA/Industry	Medium to long term
4.	Training and Sensitization (including private sector actors)	Training of new and existing personnel in <ul style="list-style-type: none"> • risk assessment <ul style="list-style-type: none"> ○ Dietary risk ○ Non-dietary ○ Environmental • Post registration surveillance (residues monitoring and counterfeits inspections) • CBI handling 	EAC / FAO MoA/AGRA/Industry	Regular
5.	Capacity enhancement on dossier review and trials	Standardisation of dossier review and trial processes	PCPB/EAC/AGRA/ FAO MoA Industry	Medium to short term
	Digitalisation of registration process (include private sector)	Support infrastructure for digitalisation of the registration process- including handling of CBI	EAC / FAO MoA/AGRA/Industry	Medium to short term

² chemistry, toxicology, ecotoxicology, environmental toxicology, residues and consumer safety, bio pesticides, biocontrol agents and efficacy.

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ANNEX 1: REPUBLIC OF KENYA LIST OF KEY STAKEHOLDERS

Government Ministries, Departments and Agencies and public agricultural research organizations involved in carrying out biological efficacy trials of candidate pesticide products

1. Ministry of Agriculture
2. Kenya Bureau of Standards (KEBS)
3. Ministry of Trade and Industry
4. Agricultural Sector Committee, Parliament
5. Ministry of Environment - National Environment Management Authority (NEMA),
6. Ministry of Justice – The State Law Office
7. Pest Control Products Board (PCBP)
8. Kenya Plant Health Inspectorate Service (KEPHIS)
9. Agriculture and Food Authority
10. Kenya Agricultural & Livestock Research Organization Coffee Research Foundation,
11. Potato Research Center-Tigoni,
12. Horticultural Crop Research-Thika),
13. University of Nairobi,
14. JAL Agriculture Research and Consultancy,
15. Horticro Research

Pesticide companies- manufacturers/dealers in the region (including manufacturers, formulators, importers, distributors, commercial farmers, famers' cooperatives

- | | |
|---|----------------------------------|
| 1. Agrichem Africa Limited | 1. Murphy Chemicals E.A. Ltd |
| 2. Agriscope (Africa) Ltd | 2. Nairobi Veterinary Center Ltd |
| 3. Amiran Kenya Ltd | 3. Nordox As (K) Ltd |
| 4. Anset International Ltd | 4. Norbrook Kenya Ltd |
| 5. Anspa E.A. Limited | 5. Oak Medica Ltd |
| 6. Arysta Life Science Corporation | 6. Osho Chemical |
| 7. Bimeda Ltd | 7. Orbit Chemical Industries Ltd |
| 8. Basf East Africa Ltd | 8. Organix Ltd |
| 9. Bayer E. A. Ltd | 9. Pestgon Ltd |
| 10. Bell Industries Ltd. | 10. Pytech Chemicals Gmbh |
| 11. Biomedica Laboratories Ltd | 11. Rentokil Initial Kenya Ltd |
| 12. Chemraw E.A. Ltd | 12. Rockem Limited |
| 13. Cooper K Brands Ltd | 13. Rotam Sub-Saharan Africa |
| 14. Dera Chemical Industries | 14. Safina (Ea) Limited |
| 15. Dow Agrosiences/Corteva | 15. Sineria East Africa Ltd |
| 16. Dupont International | 16. Syngenta E. A. Ltd |
| 17. East African Business Co. | 17. Topserve E.A. Ltd |
| 18. Elgon Kenya Ltd | 18. Tropical Farm Management |
| 19. Export Trading Co. Inputs Kenya Ltd | 19. Twiga Chemical Industries |

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| 20. Greenlife Crop Protection Africa Ltd | 20. Turbo Highway Eld Ltd |
| 21. Corteva | 21. Ultravetis E.A. Ltd |
| 22. Fedo Agencies Ltd | 22. Unga Farmcare E.A. Ltd |
| 23. Hangzhou Agrochemical Industries | 24. Willowood Africa Ltd |
| 25. Highchem Essentials Ltd | 26. Botachem Enterprises Ltd |
| 27. Flamingo Horticulture Ltd | 28. Koppert Biological Systems |
| 29. Impact Chemicals | 30. Lachlan (K) Ltd |
| 31. Insecta Ltd | 32. Laibuta Chemicals Ltd |
| 33. Juanco Sps Ltd | 34. Mea Ltd |
| 35. Kapi Ltd | 36. Kilimo Centre Ltd |
| 37. Kenagro Suppliers Ltd | |

Farmers Associations and Organisations

38. Kenya Farmers Association Ltd.,
39. Kenya National Farmers Federation,
40. Kapi Limited
41. Pyrethrum Board of Kenya
42. Fresh Produce Exporters – Flowers, fruits, vegetables
43. Kenya Flower Council

International Research and Intergovernmental Institutions

1. Food and Agricultural Organization (FAO) – Kenya country office.
2. Centre for Agriculture and Bioscience International - CABI
3. International Centre of Insect Physiology and Ecology - ICIPE
4. International Potato Center - CIP
5. Centre of Phytosanitary Excellence (COPE) in Eastern Africa
6. African Agricultural Technology Foundation - AATF
7. International Institute of Tropical Agriculture - IITA