MUNYAO, MUTHAMA & KASHINDI

REGULATORY IMPACT ASSESSMENT (RIA) REPORT

THE PEST CONTROL PRODUCTS REGULATIONS, 2021

FOR

PEST CONTROL PRODUCTS BOARD (PCPB)

FEBRUARY, 2022

TABLE OF CONTENTS

LIST OF ABBREVIATIONS

AAK	Agrochemicals Association of Kenya
AFA	Agriculture and Food Authority
ASDS	Agriculture Sector Development Strategy
BAF	Business Advocacy Fund
Cap.	Chapter of the Laws of Kenya
CABI	Centre for Agriculture and Bioscience International
CBA	Cost Benefit Analysis
CBI	Confidential Business Information
E.A	East Africa
EAC	East African Community
EMCA	Environmental Management and Coordination Act
EU	European Union
FAO	Food and Agriculture Organization
GAHP	Global Alliance on Health Pollution
GDP	Gross Domestic Product
GHS	Globally Harmonized System
ICIPE	International Center of Insect Physiology and Ecology
JKUAT	Jomo Kenyatta University of Agriculture and Technology
KALRO	Kenya Agriculture Livestock and Research Organization
KALRO	Kenya Agricultural and Livestock Research Organization
KARI	Kenya Agriculture Research Institute
KENTRADE	Kenya Trade Network Agency
KEPHIS	Kenya Plant Health Inspectorate Service
Kgs	Kilograms
KLRC	Kenya Law Reform Commission
KRA	Kenya Revenue Authority

KSH	Kenya Shillings
L.N	Legal Notice
MLND	Maize Lethal Necrosis Disease
MMK	Munyao Muthama and Kashindi
MOALF	Ministry of Agriculture, Livestock, Fisheries and Irrigation
MRLs	Maximum Residue Levels
NEMA	National Environment Management Authority
NPRMP	National Pesticide Residue Monitoring Programme
OECD	Organization for Economic Co-operation and Development
OSHA	Occupational Safety and Health Act
PCBs	Polychlorinated biphenyls
PCP	Pest Control Products
PCPB	Pest Control Products Board
RIA	Regulatory Impact Assessment
RIS	Regulatory Impact Statement
USAID	United States Agency for International Development
WHO	World Health Organization

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EXECUTIVE SUMMARY

Pest Control Products Board (PCPB) and Agrochemicals Association of Kenya (AAK) engaged the firm of Munyao, Muthama and Kashindi (MMK) Advocates to undertake a Regulatory Impact Assessment (RIA) of the Pest Control Products Regulations 2021 to determine if the gains to be obtained from the regulations, outweigh the costs imposed to the industry by the regulations as provided by sections 6 and 7 of the Statutory Instruments Act, 2013. The RIA sought to evaluate the impact and the effects of the proposed regulations both on the public and private sectors to inform the choice of the most appropriate way to achieve objectives of the proposed regulations by evaluating the major feasible alternatives of intended regulatory action and other practical non-regulatory options.

The approach to the assignment entailed a detailed desk review and synthesis of the draft Pest Control Products Regulations 2021 against Pest Control Products Act (CAP 346), the draft Pest Control Products Bill 2021, Crops Act, 2013, AFA Act (2013). The Consultants also reviewed relevant agricultural policies and strategies, Vision 2030, the Big 4 Agenda, and other key policy documents for qualitative analysis, quantitative analysis, comparative analysis, trend analysis of data from these documents, trend analysis of judicial decisions on regulatory impact assessment and public participation and key informant interviews and focused group discussions to validate secondary data obtained from the documents.

The review of the draft PCP Regulations found that the proposed regulations shall have a positive impact on the public sector by enhancing coherence and streamlining the management and supportive strategies towards the improvement of the pesticide industry. It also found that the proposed regulations shall make the use of pest control products cleaner and healthier and lead to increased agricultural production, quality, increased alternative niche markets and exports and increased foreign exchange earnings.

The proposed regulations shall have a positive impact on the fundamental rights and freedoms through the promotion of the right to a clean and healthy environment as envisaged under article 42 of the Constitution 2010. As a result, it will lead to the promotion of food production which will be geared towards satisfying the socio-economic rights of the citizenry as envisaged under Article 43 of the Constitution and further promoting the consumer rights as contemplated under Article 46 of the Constitution.

The analysis, therefore, recommends the passing and operationalization of the proposed regulations after subjecting them to adequate and proper public participation.

1.0 INTRODUCTION AND BACKGROUND

1.1 Introduction

Agriculture is an important sector in Kenya. It provides food and nutrition security, offers employment and provides primary agricultural products for the manufacturing industry. However, as the agricultural sector grows, it faces many constraints chief among them being pests and diseases which are mainly managed with pesticide products. The need for pest and disease management is directly related to the provision of food for the increasing population and maintenance of human and animal health by suppressing disease vectors (Mwaja, 2008).

Pesticides have been widely used in controlling pests and diseases in agriculture, forestry, veterinary and public health. They also play a major role in maintaining weed-free lawns, sports grounds and in clearing roadsides. Pest-induced losses due to plant diseases, arthropod and vertebrate pests as well as weed infestations are estimated to be as high as 30-35% while in the field post-harvest losses were estimated at 40-50%. It was estimated that without pesticides, world losses caused by pests in agriculture annually are about 35% of potential production (FAO, 2014).

These losses can be controlled or reduced by the effective and responsible use of pesticides. The pesticides kill or deter the destructive activity of the target organism and they possess inherent toxicities that endanger the health of the farmers, consumers and the environment. In Kenya, a wide array of products in different classes of pest control products are readily available and widely used in farms, and are particularly extensively used on small and large farms, largely concerned with export crops. Some of these products are extremely and highly hazardous while others though less hazardous expose farmers and product consumers to health risks (Epstein and Bassein, 2003).

Pesticides have been an integral part of increasing productivity by reducing significant losses that would have otherwise been realized without the agrochemicals. Most of the pesticides are used in the agricultural sector to reduce the impact of pests and diseases on crops and livestock, preservation of food and materials and prevention of vector-borne diseases. In public health, pest control products (PCPs) are used to control the vectors of disease pathogens such as mosquitoes and tsetse flies. The pesticide industry in Kenya consists of agrochemical firms that mainly import the formulated pest control product or active ingredient to formulate, repack, distribute and sell for retail purposes. Demand for PCPs has increased with the increased adoption of new agricultural technologies and reports of emerging pests.

However, as the farmers expand/improve their production, they are faced with several challenges. These include climate change that has influenced rainfall patterns, aridity of arable lands and interact with living organisms within the ecosystem and as such more pests and diseases are now emerging (Dora, 2016).

Research by Centre for Agriculture and Bioscience International (CABI) in 2017 revealed that just five invasive alien pest species are causing US$0.9 - 1.1 billion in economic losses to smallholder farmers across six Eastern African countries including Kenya each year, equating to 1.8% - 2.2% of total agricultural Gross Domestic Product (GDP) for the region. These losses are expected to grow to $1.0 – 1.2 billion per year over the next 5-10 years highlighting the urgent need for coordinated responses at regional, national and international levels (CABI, 2017).

The research published in the Global Food Security in 2017 points out the alarming level of economic losses suffered by smallholder farmers each year in Eastern Africa to a handful of species that have become damaging crop pests since their introduction to the region. These few invasive species can have devastating impacts on important staples such as maize, but also high-value crops including tomatoes, peas and green beans.

The pests and diseases included in the study are the spotted stem borer, Maize Lethal Necrosis Disease (MLND), the famine weed, three species of *Liriomyza* leaf-mining flies and *Tuta absoluta*, The recent invasion of the Fall armyworm (*Spodoptera frugiperda*) significantly add to these losses as it is known to cause great damage to maize and other crops in its native range (CABI, 2018). Assessment of the impact of pesticide use on human health and environmental hazard in Kenya shows a clear effect on both human health and environmental degradation. However, limited studies have been undertaken to quantify this impact (CABI, 2017).

Pesticides have numerous beneficial effects including crop protection. Even though pesticides are toxic by design, they are biocides, designed to kill, reduce or repel insects, weeds, rodents, fungi or other organisms that can threaten public health and the economy. Their mode of action is by targeting systems or enzymes in the pests which may be identical or very similar to systems or enzymes in human beings and therefore, they pose risks to human health and the environment.

Globally, there is growing concern about human exposure to pesticides. Pesticides are ubiquitous in the environment and most of them are synthetic. The use of pesticides has risen in developing countries and the fastest-growing markets for PCPs are in Africa, Asia, South and Central America, and Eastern Mediterranean where there is high pesticide use on crops grown for export. Although developing countries only use 25% of the pesticides produced worldwide, they experience 99% of reported PCP-related deaths. This is because their use of pesticides tends to be more intense and unsafe. Additionally, the regulatory, health and education systems are weaker in developing countries (WHO, 2012).

As an agricultural economy, Kenya's demand for pesticides is relatively high. The import demand is further fueled by regional consumption in land-locked countries like Uganda, Rwanda and Burundi. These pesticides are an assortment of insecticides, fungicides, herbicides fumigants, rodenticides, growth regulators, defoliators, proteins, surfactants and wetting agents. Of the total pesticide imports, insecticides account for about 40% in terms of volume and 50% of the total cost of pesticide imports (Ngaruiya, 2004).

Kenya has a relatively developed pesticide regulatory framework. The pesticide industry is regulated by a government statutory board, called the Pest Control Products Board (PCPB). The Board is established under section 5 of the Pest Control Products Act Cap 346 Laws of Kenya. The functions of the Board are stipulated in the regulations that guide the importation, manufacture, formulation, sale and distribution of pest control products. Notwithstanding, there is a need for continuous review of the regulatory framework to ensure an efficient and well-regulated pesticide industry.

The Agrochemical Association of Kenya (AAK) is an important private institution that self regulates the agrochemical firms whose members are mainly the manufacturers, importers, formulators, re-packers and distributors of agrochemicals. AAK promotes responsible, safe and profitable use of pest control products. They strive to raise awareness of the stakeholders about responsible use of agrochemicals and keep the genuine supply chain clean through the accreditation of all those involved in handling agrochemicals from importation, through distribution to sales to the end-users (Dora, 2016).

1.2 Background

Pesticides were first brought to Kenya by the colonial government early in the 1920s. In 1921 the British government enacted the Public Health Act to protect human beings and regulate the use of pesticides by farmers in Kenya. The toxic effects of pesticides were observed very early, soon after their application in the environment. It must be concluded that the early observed adverse effects of pesticides on humans necessitated the regulation of their use and handling (Shem, 2001). In Kenya and globally, concern has been growing that improper agrochemical use can cause risks for humans and the environment. Along with the green revolution policy around the world, the use of pesticides has skyrocketed over the past 40 years (Harris, 2000).

One of the main challenges facing the agricultural industry in Kenya is the production of pest/damage-free products which are also pesticide residue-free. The only way to address this challenge is to employ effective regulation in the pesticide industry. The Kenya horticultural industry is the major pesticide use area and is the country's leading foreign exchange earner. The value of horticulture exports in 2018 increased by 33.3 percent from Kshs. 115.3 in 2017 to Kshs 153.7 billion (Economic survey, 2019).

PCPB has fully registered a total of 2,200 pest control products as of August 2021 for agriculture (crops), public health and technical grade material for manufacturing and industrial use. As of the end of 2020, the volume of pest control products imported into Kenya was estimated to stand at 19,932 metric tons (PCPB, 2021).

Kenya is a net importer of pesticide control products which include both technical grade materials and end-use products. Although there has been a general increase in the volumes of pesticides imported into the country for the last 10 years, the increase in import volumes have been marginal especially over the last five years with an exception of year 2020 as shown in the Table 1 below.

Approximately 14.2 million Kgs of pesticides valued at K.shs. 11 Billion were imported into the country in the Financial Year 2018/2019 compared to 15.81 million Kgs valued at K.shs. 12.7 Billion in the previous year, representing a 10% and 13% decrease in volume and values, respectively. In 2017/2018 the volume of pesticides imported grew and this could be due to the emerging pests in the country such as the Fall Army Worms against maize and *Tuta absoluta* in tomatoes (PCPB, 2019). This trend continued in the year 2020 where 19.9 million Kgs of pesticides were imported.

The values and quantities of pesticides imported in the country in the past ten years have fluctuated within a narrow range as presented in Table 1 below:-

Table 1: Pesticide imports and value trends 2009-2019

Year	2009/ 10	2010/ 11	2011/12	2012/ 13	2013/ 14	2014/ 15	2015/ 16	2016/ 17	2017/ 18	2018/ 19
Import Value (Kshs, Billion)	9.34	9.29	10.71	11.06	11.2	12.69	11.32	11.02	12.7	11
Import quantity (Million Kgs	10.11	11.96	12.98	13.84	13.2	16.33	15.5	14.64	15.81	14.2

Source: PCPB

The horticultural industry, one of the main pesticide use areas in Kenya is also a major source of employment to both the rural and the urban populations estimated at 500,000 and over 2 million people respectively (Economic survey, 2019). Kenya is the largest flower exporter to the European Union (EU), with 25% of the market share. The export market customers now demand a reduction in pesticide use (Mehrad, 2004). This market, however, also demands no presence of pests in the export produce requiring very effective pest management both during production and in post-harvest handling. Insecticides are the most utilized pesticides, followed by herbicides and fungicides. Personal protection equipment and personal hygiene are generally inadequate among users/farmers as shown by different studies on the handling of pesticides by rural farmers (Burleigh et al., 1998; Berg, 2001; Matthews *et al*., 2003; Isin and Yildirim, 2007).

1.3 Rationale and Justification for a Regulatory Impact Assessment (RIA)

Regulatory Impact Assessment (RIA) is a systemic approach to critically assess the positive and negative effects of proposed or existing regulatory and non-regulatory alternatives. It is an evidence-based approach to policy making. RIA requirements apply to proposals for new and amending regulation and to policy proposals that may result in new or amending regulation

(regulatory proposals). It is an instrument that authorizes the determination and consequences of introducing a new regulatory regime. The systematic use of RIA has been recognized as a key means to improve the efficiency, transparency and accountability of decision making.

Pesticides abuse and misuse are common in Kenya and Africa, although the use of pesticides in Africa represents a small fraction of the global total, misuse is disproportionately high. Factors that lead to these high misuse rates include high illiteracy levels, unfair trade practices in the industry and inaccessibility to reliable protective clothing. Smuggled products, unregistered products, open-air sales, sale of a banned product, cases of decanting and reweighing, faking of pest control products using counterfeit labels, sale of expired products with modified expiry dates are among the misuse cases that have been reported in Kenya. Spraying mistaken products have led to the death of hundreds of flock (Nyakundi, *et al*. 2012). To promote the appropriate use of pesticides and applications, it is critical to develop an efficient and well-regulated pesticide industry in the country.

Proper pesticide waste disposal is also an important part of responsible pesticide use. Accidental release or uncontrolled discharge of pesticide waste into the environment can harm people and contaminate the environment (Damalasb *et al*., 2008). Empty pesticide containers often retain unacceptable quantities of pesticide residue if not rinsed properly (Miles et al, 1983). Thus, to promote appropriate use of pesticides and applications, it is important that all aspects of pesticide management including; manufacturing, formulating, re-packaging, handling, storage, trading, transportation, use and disposal be regulated and guided.

This would require comprehensive regulatory interventions to change farmers' pesticide use patterns, tackle determinants of inappropriate pesticide use holistically and empower farmers to safer choices for pest management. This should include knowledge of chemical hazards which should be disseminated to all farmers and knowledge regarding personal protective equipment should be propagated.

1.4 Objectives of the Assignment

Section 15 of the Pest Control Products Act empowers the Cabinet Secretary to make regulations for the better carrying into effect the provisions of the Act. The Act provides for the implementation of various regulations to operationalize the Act.

The Ministry provided the Consultants with seven pieces of regulations for purposes of the regulatory impact assessment. On 11th November 2021, the drafting team from AAK, PCPB and Ministry held a workshop with the Consultants in Naivasha. The team in consultation with various Chief Executive Officers resolved that the provisions of the Pest Control Products (Confidential Business Information) 2021 should form part of the Pest Control Products (Registration) Regulations, 2021.

The main objective of the assignment was to undertake a Regulatory Impact Assessment (RIA) of the draft Pest Control Products (PCP) Regulations 2021 to determine if the gains to be obtained from the regulations outweigh the costs imposed on the industry by the regulations as provided by sections 6 and 7 of the Statutory Instruments Act, 2013. The RIA sought to evaluate the impact and effects of the proposed regulations both on the public and private sectors to inform the choice of the most appropriate way to achieve objectives of the proposed regulations by evaluating the major feasible alternatives of intended regulatory action and other practical non-regulatory options.

The specific objectives of the following assignment were to:-

i. Review the Pest Control Products Act (CAP 346) and the proposed PCP regulations.
ii. Review RIAs on the pesticide industry globally to determine appropriate considerations to be made in the preparation of RIAs and document key lessons learned from the global review of RIAs.
iii. Conduct a Regulatory Impact Assessment (RIA) on the proposed regulations with a specific focus on;
    - Preparing a cost-benefit analysis of the proposed regulations with a focus on economic, environmental and social impact on all stakeholders.
    - The costs of administration and compliance on all stakeholders.
iv. Prepare a Regulatory Impact Statement (RIS) for the proposed regulations.
v. Prepare an Explanatory Memorandum for the proposed regulations.
vi. Prepare notices on the Regulatory Impact Statement for publication in the Kenya Gazette and 2 other daily newspapers of wide circulation.
vii. Submit a draft report containing the findings of the review, the draft RIS and an Explanatory Memorandum for consideration and approval by PCPB and before subjecting the draft to a stakeholders' forum.
viii. Conduct stakeholders' fora to collect comments from stakeholders on the draft report.
ix. Submit a final report after incorporating the views and suggestions of stakeholders.

1.5 Project Deliverables

The assignment resulted in the following deliverables:-

i. Inception report.
ii. Regulatory Impact Statements for the proposed Regulations.
iii. Draft Regulatory Impact Assessment report for the proposed Regulations.
iv. Final Regulatory Impact Assessment report for the proposed Regulations.
v. Explanatory Memorandum for the proposed Regulations.
vi. Notices on the Regulatory Impact Statements for publication.
vii. Certificate of Compliance for the proposed Regulations.

1.6 Methodology and Approach

The approach to the assignment entailed detailed desk review and synthesis of the draft PCP Regulations 2021 against Pest Control Products Act (Cap 346), the draft Pest Control Products Bill 2019, Crops Act, 2013, Agriculture and Food Authority Act (2013). The Consultants also reviewed relevant Agricultural policies and strategies, Vision 2030, the Big 4 Agenda, and other key policy documents for qualitative analysis, quantitative analysis, comparative analysis, trend analysis of data from these documents, trend analysis of judicial decisions on regulatory impact assessment and public participation and key informant interviews and focused group discussions to validate secondary data obtained from the documents.

1.7 Objectives of Pest Control Products Regulations

The general objective of the regulations is to streamline the practices and management in the pesticides industry through effectively addressing the industry's emerging issues, pesticides safety concerns and market requirements. It intends to reduce exposure and the possible acute and chronic health effects and environmental hazards resulting from pesticides. The regulations seek to address the registration of pest control products, licencing of premises and businesses handling pest control products, importation, exportation and re-exportation of pest control products, labeling, advertising and packaging of pest control products, use and disposal of pest control products and prescribe specific license fees and charges applicable to pest control products in Kenya.

The proposed regulations specifically seek to address the following key pest control products industry concerns:-

i. To strengthen the legislative framework by addressing consumer and environmental protection.

ii. To facilitate market access: The international markets access for the horticultural produce requires adherence to strict food safety standards, and Maximum Residue Limits (MRL). The current law does not adequately provide for regulation on residues.

iii. To accommodate the international and regional best practices in the pesticide industry including pesticide guidelines approved by the East African Community.

iv. The regulations also address the Recommendations of the Departmental Committee on Health- of Public Petition No.70 on withdrawal of harmful pesticides in the Kenyan market.

The Pest Control Products Regulations 2021 comprise six proposed regulations. Each proposed regulation named below aims at achieving specific objectives in the pesticide industry. If passed, they will repeal and replace the current Pest Control Products regulations first gazetted in 2004.

i. The Pest Control Products (Registration) Regulations, 2021,

ii. The Pest Control Products (Licensing of Premises and Business) Regulations, 2021,
iii. The Pest Control Products (Labelling, Advertising and Packaging) Regulations, 2021,
iv. The Pest Control Products (Importation and Exportation) Regulations, 2021,
v. The Pest Control Products (Disposal) Regulations, 2021, and
vi. The Pest Control Products (Licence Fees and Other Charges) Regulations, 2021.

The specific objectives of the proposed PCP Regulations are stated below:-

A. Registration Regulations

The regulations seek to streamline the registration of pest control products in the country, promote efficiency and fair trade in the industry and align the registration process to the harmonized guidelines for data requirements for registration of pest control products under EAC guidelines.

The proposed registration regulations are aimed at achieving the following specific objectives:-

i. To provide clarity on agency matters to reduce agency related litigation;
ii. To provide for a termination notice (6 months) for agency agreements by either party;
iii. To facilitate data extrapolation and crop grouping;
iv. To accommodate regulatory documents for the paint industry and post-harvest products;
v. To provide for the submission and the protection of confidential business information;
vi. To eliminate the double submission of dossiers;
vii. To criminalize submission of incorrectly translated certificates;
viii. To specify valid registration periods (5 years, and 3 years renewal);
ix. To provide for the suspension of registration certificate if not renewed within 6 months after expiry;
x. To provide for the period of appeal to the Cabinet Secretary upon receipt of a notice under the regulations (30 days);
xi. To provide for instances of temporary registration and emergency registration; and
xii. To accommodate new EAC guidelines on pest control products.

B. Labeling, Advertising and Packaging Regulations

These regulations seek to enhance information access on pest control products, to ensure that users of PCPs and other stakeholders have an in-depth understanding of these products including the recommended application rates and procedures, storage, inherent risks of their usage, post-harvest intervals and disposal of the products' containers.

The proposed labeling, advertising and packaging regulations are aimed at achieving the following specific objectives:-

i. To clearly define pest control products advertisement;
ii. To clearly separate requirements for packaging, labeling and advertising in different sections;
iii. To describe the Globally Harmonized System of classification and labeling of chemicals;

iv. To describe requirements for labeling of small packs, display of information on the label, information where the product is shipped in bulk and the requirement for reporting adverse effects; and
v. To describe the requirements for experimental labels.

C. Importation and Exportation Regulations

These regulations provide for guidelines to be adhered to in the importation and exportation of pest control products in Kenya. The proposed import-export regulations are aimed at achieving the following specific objectives:-

i. To provide for authorization for importation, exportation and re-exportation of pest control products;

ii. To provide for a general prohibition on smuggled products and pest control product that has not been imported in accordance with these Regulations;

iii. To extend the permit validity period to 6 months from date of issues from the current 3 months; and

iv. To provide for immediate cancellation of permits for products dangerous to the public or environment.

D. Licensing of Premises and Business Regulations

The regulations set the minimum requirements for licensing of premises and businesses of pest control products in the country. It also introduces the role of County governments in the process of licensing and registration of the premises. The proposed licensing of premises and business regulations are aimed at achieving the following specific objectives:-

i. To provide for licensing of premises and businesses handling pest control products;

ii. To provide for a provisional license after payment of license fees before inspection of premises;

iii. To introduce penalties for licenses not renewed within stipulated timeframe;

iv. To ensure Compliance with occupational health and safety regulations for manufacturers, formulators re-packers and storage,

v. To provide for minimum requirements for distributors and retailers of pest control products; and

vi. To provide for conditions for handling, using, distributing, transporting or dealing in class 1 or restricted pest control products.

E. Disposal Regulations

These regulations seek to establish safe and effective mechanisms for the disposal of pest control products or their containers to avoid any detrimental effects to man, animals and the environment. The specific objectives of the proposed regulations are:-

i. To prevent the disposal of any pest control products or their containers in a manner detrimental to man, animals and the environment.

ii. To require persons carrying out any disposal of pest control products, pest control products containers, pesticide waste or treated seeds for commercial purposes to be licensed under the Regulations.

iii. The regulations also provide for the procedure for application of the pest control product disposal license, cancellation or suspension of the license.

F. Licenses Fees and Other Charges Regulations

The regulations seek to harmonize and rationalize license fees and other charges applicable in the industry for services rendered by the Board. The proposed regulations are aimed at achieving the following specific objectives:-

i. To provide for new revised fees and charges to support regulatory services and product stewardship;
ii. To provide for inspection upon request to ascertain compliance; and
iii. To allow for application for the registration fee to be paid at the beginning of the process rather than at the end.

2.0 ASSESSMENT OF THE NATURE AND EXTENT OF THE PROBLEM

This section describes the nature and extent of the problem in the pest control products sub-sector which calls for a better regulatory framework.

2.1 Nature of the Problem

Pesticides abuse and misuse are common in Kenya. Factors that lead to these high misuse rates include high illiteracy levels and inaccessibility to reliable protective clothing. Smuggled products, unregistered products, open-air sales, sale of the banned product, cases of decanting and reweighing, counterfeit pest products, sale of expired products with modified expiry dates are among the misuse cases that have been reported in Kenya (W. O. Nyakundi *et al*, 2012). Usually, such sale of expired products is done without any revalidation to confirm reusability which is a standard /international practice to revalidate a product using set guidelines at the expiry date to check if it is still reusable or obsolete.

The proposed Labelling, Advertising and Packaging Regulations seek to enhance pesticide users' information access through elaborate labels that will provide detailed information on recommended product use areas, rates, safety, expiry dates and will contribute to the reduction of counterfeit and fake products in the market. The Licensing of Premises and Business Regulations set minimum requirements for licensing of premises and businesses and will eliminate any rogue pesticide operators and further enhance access to product information and recommendations to users through the use of technical experts in all licensed pesticides products outlets.

The proposed Registration together with the importation and exportation Regulations will ensure that only registered pest control products and those legally imported into the country will be accessed in the market and thus will contribute to the elimination of smuggled products, unregistered products, open-air sales, sale of a banned product, as well as cases of decanting and reweighing counterfeit products and expired products in the country.

Pesticides are a necessity in crop production, however, they pose risks to the environment and humans ranging from low to high if not properly used. Most small-scale commercial growers use pesticides without adequate appreciation of the risks to the environment and people. This has resulted in environmental pollution and health concerns in applicators, farming families, neighbors and consumers. For export markets, Kenya's horticultural produce is facing restrictions in European markets due to MRL interceptions and restrictions on the use of locally registered pesticides that are not allowed for use in the EU due to health and environmental risks posed by their usage and handling. Some pesticide distributors driven by the desire to drive up their sales down to the retail outlets (Agrovets), farmer advisors and farmers who do not have adequate knowledge on pesticide use and pesticide resistance management all add to the problem. If not addressed, this is likely to leave the farmers with limited pesticide options that are more expensive,

increased field losses and increased market restrictions for Kenyan agricultural products (USAID, 2014).

The enhanced access to information by pesticide users envisaged from the implementation of the Labelling, Advertising and Packaging Regulations will provide users with recommended use procedures for the products and details of possible human and environmental hazards of each product which will include the globally harmonized system, hazard symbols and signal words. This information in addition to expert advice will be available at all pesticide outlets as envisaged by the Licensing of Premises and Business Regulations and pesticides through the engagement of technical personnel in these outlets. The pesticide containers disposal guidelines proposed in the disposal regulations will enable pesticide users to minimize risks to the environment and people as well as promote the proper and safe use of these products to meet the markets' food safety expectations.

In addition, the pesticide industry problems are also further compounded by counterfeit pesticide products which are on the increase, especially in developing countries. Counterfeits are estimated to amount to 5-7% of the pest control products traded in Europe and 20-30% in developing countries (FAO, 2008). Apart from causing economic losses to the legitimate pesticide industry, forged pesticides may endanger farmers' livelihoods and health, put the food chain and consumers at risk, and may cause damage to the environment. Counterfeiting also undermines the national regulatory systems (Dora, 2016). According to a recent study by the Anti-Counterfeit Authority on National Baseline Survey on Illicit Trade, the volume of illicit trade in the pesticide industry is estimated at K.shs 11.8billion in 2017 and rose by 23% to K.shs.14.6billion in 2018 (ACA, 2020).

The threat that counterfeits pest control products pose to any economy is well known and has been a subject of research since 2010. These include environmental degradation, risks to human health, loss of productivity, unfair competition, sales losses, loss of investments, food insecurity, loss of government revenues, among many other negative effects (ACA, 2020).

A study on counterfeit products commissioned by the Agro-Chemical Association of Kenya in 2020 stipulates that the magnitude of counterfeit and illicitly traded pest control products can be measured through the seizure of counterfeit products or estimated industry firms' sales losses. The counterfeit pest control products seized from PCPB inspections between 2017 and 2019 in Kenya was K.shs 4.82million while the industry firms' firm sales losses between 2017 and 2019 were estimated to be K.shs 607.94million. This shows the level of counterfeiting pest control products is much higher than indicated by seizure data from the PCPB. The full magnitude of illicit trade in pest control products (which by definition includes counterfeits and all other illegally imported pest control products) between 2017 and 2019 was estimated to be about K.shs11.3billion (Integrated Development consultants, 2021).

The proposed registration and Importation and Exportation Regulations will to a large extent ensure that only registered pest control products and those legally imported in the country can be

accessed in the market and thus will contribute towards the elimination of counterfeit products in the country.

2.2 Extent of the Problem

In Kenya, there is limited data available concerning the use of pesticides or the concentrations of pesticides in water, soil and food and the related impacts. Most of the research focuses on persistent organic pollutants, such as DDT, lindane and endosulfan, which are rarely used anymore (Abong'o et al., 2018). This means that Kenyan consumers and farmers are not aware of the extent of pesticide use, their concentrations in food and the environment and their possible effects on the environment and ecosystem services (WHO, 2015).

Based on World Health Organization (WHO) data, the Global Alliance on Health and Pollution indicated in their annual report that 9 million deaths worldwide are related to environmental pollution (GAHP, 2015). WHO has warned in several reports, that chronic, non-communicable diseases are a major challenge, making up 86% of the total burden of disease in the WHO European region. These non-communicable diseases include diabetes, Alzheimer's, cancer, osteoporosis, chronic lung disease, stroke, and heart disease. While WHO does not provide any figures on the respective share of pesticides to environmental pollution, experts consider them as one of the principal environmental risk factors for chronic diseases (GAHP, 2015).

While farmers and rural residents are exposed most frequently and directly to pesticides, residues are found everywhere – in our food, our drinking water, in the rain and the air. Several studies in Kenya established a link between pesticide exposure and acute and chronic health effects and environmental hazards (e.g. Tsimbiri *et al*., 2015; Ohayo-Mitako *et al*., 2000). Tsimbiri et al. (2015) testified that the main health impact of pesticides on residents and workers at Lake Naivasha in Kenya were headaches and miserableness, followed by respiratory symptoms. In general, workers in horticultural farms in particular farmers that use pesticides intensively are at higher risk than those in the office or support duties within the same company (Del Prado-Lu, 2007; Issa *et al*., 2010; Strong *et al*., 2004). Sun *et al.* (2016) determined the concentration, distribution and, sources of organo halogenated contaminants in soils from Kenya and performed a risk assessment. 12% of organo chlorine pesticides were found in the samples. The human risk assessment indicated that Polychlorinated biphenyls (PCBs) were the most prominent chemicals contributing contaminants in the area studied.

Within the National Pesticide Residue Monitoring Programme (NPRMP) undertaken by KEPHIS, 10.80% of food sampled from the field under the NPRMP had exceeded EU set maximum residue levels (MRLs) (KEPHIS, 2018).

On environmental health, almost half (approximately 49%) of the products registered in Kenya are toxic or very toxic to fish (toxicity values <1), which might lead to a major threat to fish species, when pesticides enter the river and other water bodies via runoff or spray-drift. Depending on their persistence, they may have a short or long-term effect on fish populations. Additionally, farmers

are not aware of the toxicity to bees of many of the products they use and are not aware of the precautions to be taken. For example, not to spray in the morning when pollinators are out and foraging (Van Der Valk *et a*l., 2014).

Counterfeiting of agrochemicals is another major problem the world over and Kenya is not an exception. The prevalence of counterfeits in the market creates unfair competition for genuine product manufacturers and law-abiding traders. Apart from unfair trade competition, the vice also denies farmers access to genuine products resulting in health risks, economic losses, loss of reputation, strained international relations, distortion of trade, and defrauding of consumers.

A survey commissioned by the Agrochemical Association of Kenya estimated the amount of counterfeiting of agrochemicals traded in Kenya to be 18%. Counterfeited products are traded on the grey market, making it difficult to control the market and separate the illegal items from the legal. Counterfeiting activities cost the Kenyan economy billions of shillings in terms of revenue and jobs (Dora, 2016). Further, the National Baseline Survey on Illicit Trade commissioned in 2020 estimates the size of illicit trade in the country in the pesticide industry was at K.shs11.8billion in 2017, and it increased by 23% to K.shs 14.6billion in 2018 (ACA, 2020).

In addition, counterfeiting denies legitimate pesticide manufacturers returns for investment in the generation of regulatory data and use of safety studies for registration through this unfair trade practice. Manufacturers are required to conduct more than 150 safety studies – designed and validated by regulatory authorities on each potential crop protection product before its approval for commercial use. The studies are designed to evaluate all circumstances of human and environmental exposure. The crop protection industry spends an average of $71million on toxicology and environmental safety tests for every product brought to the market. These tests help ensure that pesticides only receive regulatory approval if they are safe for human health and the environment and it takes an average of 11 years to take a product from discovery to commercial use(Crop Life International, 2018).

The fee structure for registration of a pesticide in Kenya is clearly very beneficial for the applicants. Pesticide registration fees in Kenya are only paid after a positive registration decision. As a result, all evaluations conducted by PCPB for products which registration is in the end refused, are “free of charge” and at the Kenyan tax payers cost. This approach, therefore, does not incite applicants to provide complete and good quality dossiers, since there is no penalty in repeated submissions of missing or substandard data. The fee structure in many other countries across the globe is such that application and evaluation fees are paid upfront and are generally not reimbursable, irrespective of the outcome of the evaluation and registration decision.

The low registration fees also encourage “sleeping registrations”. This means that pesticides that are registered in Kenya are not for local use but mainly as a justification to obtain a registration in other countries (for example, the product is registered in Kenya, which has a reputable registration system; therefore it must be efficacious and pose only acceptable risks), making Kenya a pesticide

registration haven for dealers circumventing registration conditions in other countries reciprocating with Kenya of pesticide registration and regulation (PEAR Kenya, 2018).

Kenya's pesticide registration fees are low in comparison to other African countries with similar agriculture. They are also much lower than fees required in the regional and OECD countries as shown in table 2 below:

Table 2: Comparison of registration fees for a new pesticide product in selected countries (all in euro equivalent)

Country	Fees (Euro Equivalent)
Kenya	240
Ghana	2500
Tanzania	1740
South Africa	600
European Union	200,000
Netherlands	50,000
U.K.	9,000
Canada	95,000
U.S.A.	525,000
Australia	58,000

Source: (PEAR Kenya, 2018)

The current import levied for pesticide imports in Kenya of 0.8 % F.O.B value of imports is also way below compared to similar pesticide levies in other countries regionally and across the globe denying PCPB revenue and currently which only can recover 53% of its registration and regulatory costs from levies and fees, making it to rely on the Treasury for up to 50% support to finance the Boards' annual budget (PCPB, 2019).

Table 3: Comparison of pesticide import levies in selected countries

Country	Specific pesticide levy
Kenya	0.8% of FOB value
Tanzania	0.5% of FOB value
Mozambique	0.2% of FOB value
Guyana	3% of CIF value
St Lucia	21% of CIF value
Australia	0.63% of sales value
California	2.1% of sales value
Canada	3.0% of sales value
Sweden	3.6 euro/kg a.i.
France	0.9 – 5 euro/kg a.i.

Denmark	Specific for each product; often 20-40% of sales value
Netherlands	None

Source; PEAR Kenya, 2019)

2.3 Regulatory Contextualization

The pesticides' sector was first regulated by the Public Health Act enacted by the British Colonial Government in 1921. This is an indication that the toxic effects of pesticides were observed very early, soon after their application in the environment and thus the need to regulate their use.

Prior to 1982, pesticide regulation was domiciled in the Pharmacy and Poisons Board. The Pharmacy and Poisons Board is the Drug Regulatory Authority established under the Pharmacy and Poisons Act, Chapter 244 of the Laws of Kenya. The Board regulated the Practice of Pharmacy and the Manufacture and Trade in drugs and poisons, including pesticides on standards of safety, efficacy and quality, chemical substances and medical devices, locally manufactured, imported, exported, distributed, sold, or used, to ensure the protection of the consumer as envisaged by the laws regulating drugs than in force in Kenya.

After 1984, the Pest Control Products Board was established under an Act of parliament, the Pest Control Products Act, Cap 346, Laws of Kenya of 1982 to regulate the importation and exportation, manufacture, distribution and use of pest control products and the organic function of plants and animals and for connected purposes. This Act was amended in 2006 and 2014, and again in 2015 and mandates the Board to assess the safety, efficacy, quality, merit and economic value of pest control products, assessing the suitability of premises used for manufacture/formulation, re-packing, storage and distribution of pest control products for purposes of licensing, processing and issuing import/export permits, and advising the Minister on all matters relating to the provisions of the PCP Act, regulations and the relevant EAC regulatory instruments.

The Act also identifies other roles of the Board as creating awareness to the general public on all aspects of safety, storage, handling, disposal and use of PCPs, Monitoring and ensuring adherence of quality standards of pest control products throughout the supply chain; investigating and prosecuting contravention of the Pest Control Products Act, and Supervising the disposal of obsolete or undesired pest control products.

This Act currently regulates the registration of pesticides including public health pesticides under the Pest Control Products Act, 1982 (PCP Act). Other Acts that also relate to the safety of humans and the environment include the Occupational Safety and Health Act (OSHA) and Environmental Management and Coordination Act, 1999 (EMCA).

PCPB is responsible for the enforcement of the PCP Act. Members of the Board represent various relevant ministries (including Ministry responsible for Public Health and Sanitation) and other relevant stakeholders. The Technical Committee (TC) of the PCPB comprises members from various relevant ministries and stakeholders. It supports the PCPB on technical matters including

technical evaluations of registration applications. Risk evaluations are made before making risk management decisions; however, the technical capacity is limited.

There has been initiatives to harmonize registration requirements among the East African Community countries under The Control of Pesticides Act (E.A. Cap. 3) of the Community. The harmonization was revived in 1999 under article 108 of the Treaty for Establishment of the East African Community and provides guidelines for the EAC members on the use of common forms, efficacy trials, mutual recognition and residue data generation to facilitate trade in the region and provides for recognition of other regional blocks.

Registration requirements for pesticides (including public health pesticides) have been harmonized under the East African Community (EAC). Data from other countries are accepted except for efficacy data and public health pesticides are exempted from residue data requirements.

All imports and exports of pesticides are approved in accordance with the Pest Control Products (Importation and Exportation) Regulations, Legal Notice No. 146/1984, and Pest Control Products (Importation and Exportation) (Amendment) Regulations, L. N. 125/2006. This is aimed at ensuring that only products that have undergone the registration process are availed into the Community's market.

Regulation of imports also prevents the introduction of banned or severely restricted products into the country. Such licenses are granted to registered local agents or their approved distributors. Imports are only allowed from approved sources. The applications for Import/Export permits for pest control products are done through the single window platform, the KENTRADE system (PCPB, 2019).

Kenya is also a signatory to various International Convections of pesticides. PCPB is the Designated National Authority on matters of pesticides for the Rotterdam Convention and the Stockholm Convention on Persistent Organic Pollutants, the Basel Convention on Trans-boundary Movements of Hazardous Wastes and their Disposal and the Montreal Protocol on substances that deplete the ozone layer.

3.0 EFFECTS OF THE PROPOSED REGULATIONS

This chapter outlines the groups of persons likely to be affected by the proposed regulations and the impacts of the proposed regulation on both the public and private sectors. It also examines the likely impacts of the proposed regulations on the realization of the fundamental human rights and freedoms of the affected groups.

3.1 Pest Control Products License Fees and other Charges Regulations, 2021

These regulations seek to harmonize and rationalize pest control products license fees and other charges for services provided by the Board. The regulations propose to increase the charge fee from the current 0.8%, to 1.4% of FOB value of imports and propose 50% of the fee be payable to AAK for product stewardship and responsible use trainings; prescribes different licensing categories, i.e, retail, spray services providers, distribution/wholesale, agents, repacking, formulation, manufacture, commercial pest control operators, stores/warehouses, commercial trainers and consultants and their corresponding fees. These regulations also specify the different product registration categories and the proposed fees for registration, fees for the accreditation of institutions for pesticide research and studies, licensing fees for commercial trainers as well as fees for importation and exportation of pesticides. This will see the fees and levies collection increase from the current estimated K.shs 113 Million to an estimated K.shs. 198 Million raising an additional K.shs 85 Million annually.

Approximately 50% of the increased revenue from the import charge is intended specifically for purposes of training pesticide users, retailers and other stakeholders through AAK, thus further enhancing the safe and effective use of pesticides in the country. The other 50% will be additional revenue to PCPB to improve pesticide registration and inspection services and thus further reduce PCPB's dependency on the Treasury for resources to carry out these critical services. Currently, PCPB recovers only 53% of its costs from these services through fees and levies. The regulations will contribute to streamlining and organizing the pesticide industry and promoting the safe and effective use of pesticides in Kenya but may increase the cost of doing business for the industry player resulting from the increase and introduction of fees and levies discussed above.

The review and adjustment of registration fees to be comparable to registration rates in other countries will discourage "sleeping registrations" where pesticides are registered in Kenya not for local use but mainly as a justification to obtain a registration in other countries and which are often misused to circumvent registration in other jurisdictions.

3.3 Pest Control Products (Importation and Exportation) Regulations, 2021

The regulations seek to regulate import, export or re-export of pest control products for commercial and other purposes and will ensure that only registered products are imported into the country for resale, manufacturing purposes, for importers own use, and for research purposes, thus eliminating entry of counterfeit, fake and smuggled products in Kenya. This will ensure that the industry trades only in genuine registered and locally licensed products. Similarly, the regulations will also

eliminate exports or re-export of counterfeit, fake and smuggled products from Kenya. This will promote the use of recommended and quality products only in Kenya for effective control of pests and diseases, thus increase in production while also safeguarding human health and the environment.

3.4 Pest Control Products (Labelling, Advertising and Packaging) Regulations, 2021

The regulations require that all pesticide products have labels that are approved by the Board and provide guidelines on the Label content and layout including product name, product physical form, purpose, common name, A. I or active agents, trade mark, product class designation and colour code, instruction to read the label before use, guarantee statement & net weight, name/address of manufacturer, containers disposal instructions among others and specify that the content be presented in font 7 size in both English and Kiswahili. This will enable pesticide users to get necessary information on the product before procurement, use instructions, potential hazards, first aid instructions and toxicological instructions. The regulations will reduce misuse of pesticides while promoting good, effective and safe use of pesticides for increased agricultural production, reduced pesticide exposure and acute and chronic health effects and environmental hazards.

3.5 Pest Control Products (Licensing of Premises and Business) Regulations, 2021

The proposed regulations provide for the guidelines for licensing of premises and businesses dealing with pest control products. It identifies the parameters to be considered which include the physical facilities, protection of workers, protection of the public and maintenance of product quality and protection of the environment. These regulations will contribute to reducing pesticide exposure, and acute and chronic health effects and environmental hazards by encouraging manufacturing, formulating, handling and use of pesticide only in designated premises with acceptable safety levels.

3.6 Pest Control Products (Disposal) Regulations, 2021

These regulations seek to enforce the safe disposal of pesticides products and their empty containers. The regulations outlaw disposal of pesticides and their containers to the detriment to man, animal and the environment and requires persons carrying out the disposal to be licensed by the Board and to use approved disposal methods. The regulations also provide guidelines for transboundary movements of pesticides for disposal which shall be subject to conventions, protocols, treaties & agreements Kenya is a party to. These regulations will also contribute to reduced pesticide exposure and acute and chronic health effects especially by reducing the re-using of empty pesticide containers for food items storage and reducing environmental hazards through safe disposal of pest control products.

3.7 Pest Control Products (Registration) Regulations, 2021

The regulations seek to provide for the guidelines for the application of product registration, requirements for registration for the different classes of products including temporary and

registration for experimental purposes, corresponding fees, conditions for exemption from registration, terms, duration and renewal of certificates of registration, suspension and revocation of certificates of registration and requirements for maintenance of records on quantities of products stored, manufactured or sold among others. These regulations will ensure that all products registered for use in Kenya meet the set quality and efficacy standards for the intended use.

The regulations will enable monitoring of pesticide use data and thus will contribute to increased agricultural production through more effective pest control while also meeting the Country's acceptable environmental and health standards thus reducing pesticide exposure and acute and chronic health effects and environmental hazards as well as informing future pesticide industry planning.

These regulations also seek to introduce guidelines on the management and measures for the protection of confidential business information (CBI) by the Board, the registrant/ applicant and local agents. This will promote fair trade practices in the industry by avoiding underhand dealings where confidential business information can be used by competing firms to their advantage to produce similar products or counterfeits.

In addition, the regulations seek to align the registration of the pest control products in Kenya to the harmonized East African Community (EAC) registration guidelines and provide for the use of the common EAC forms for the process, mutual recognition of efficacy trials data, residue data generation and exempt generic products from the requirement of registration data, where technical equivalence to a registered product is proven. The mutual recognition and the exemption of generic products from the requirement of registration data are expected to reduce the time for access to pesticide products while also reducing costs for the industry actors by avoiding repetitive processes, facilitating trade in the region and promoting bench marking among the industry players in the region.

3.8 Affected Groups

The regulations will affect all actors within the value chains and these include:-

- National Government & its Agencies
- County Governments
- Small-scale farmers
- Large scale farmers
- Producers' associations/Organizations
- Pesticides Transporters
- Pesticide traders/ Agrovets
- Pesticide manufacturers
- Pesticides Formulators
- Pesticide Exporters
- Pesticide Importers
- Pesticide distributors

- Commercial spray service providers
- Pesticide storage and warehousing agents
- Pest control services providers
- Pesticide commercial trainers
- Pesticide disposal agents
- Pesticide agents
- Consumers

3.9 Effects on the Public Sector

The proposed regulations will affect the public sector in the following ways:-

i. The Government will re-establish a coherent and regulated environment for streamlined oversight and improved management of the pesticide industry.

ii. County Governments will have a specified role in the pesticide industry at the local/County level, especially for the sensitization and mobilization of farmers on PCPs use, and better coordination on pesticide product use for promoting agricultural sector development in the counties.

iii. The Pest Control Products Board will have improved sector structures, systems and implementation framework for more effective pesticide industry regulation and planning.

iv. Facilitate the development and maintenance of a database of all pesticide industry actors and their respective roles, and pesticide use for monitoring purposes.

3.10 Effects on the Private Sector

The proposed regulations will affect the private sector in the following ways:

i. Pesticide industry players such as the farmers/users, pesticides manufacturers both local and international, formulators, re-packers, pest control operators, commercial trainers and consultants, transporters, local manufacturers' agents, pesticide traders/agrovets, spray services providers, stores/warehouses, pesticide waste disposal facilities and pesticide exporters among others will stand to benefit from a streamlined, competitive and well-regulated pesticide industry protected from unfair trade practices and other malpractices including counterfeits and illegal imports.

ii. Misuse of pesticides - use of unregistered and counterfeit, fake or repackaged pesticides in Kenya especially among smallholder farmers who often depend on agrovet dealers, media advertisement and pesticide companies' sale agents for pest control advice/recommendations will drastically reduce as all pesticide outlets will employ

professional and technically qualified personnel to advise farmers on product options and use and advertising regulated.

iii. The broader agricultural sector and national economy will benefit from the increased agricultural production, improved produce quality, increased alternative niche markets access and exports; and thus increased foreign exchange earnings; whilst creating employment and improving livelihoods of farmers through increased earnings.

iv. Exposure of farmers, farm workers, other rural residents and consumers of Kenya's agricultural produce to pesticides through direct exposure to pesticides or residues in food, drinking water, in rain and the air will reduce, and thus reduce incidences of acute and chronic health effects attributable to pesticides.

v. Promotion of a healthy and clean environment due to reduced contamination from pesticides, thus preservation of biodiversity for sustainability.

vi. The cost of doing business among the different categories of the industry players may increase due to the requirement of engaging technical professionals to handle the different services in the pest control products industry, the increase of the charge fee for imports, and fees for the different classes of licenses.

vii. Sustainable business can once again thrive in the pesticide industry; this will attract new local and foreign investors to invest in the sector promoting competition to the benefit of industry clients.

3.11 Effects on Fundamental Rights and Freedoms

The proposed regulations will affect fundamental rights and freedoms in the following ways:

Article 42 of the Constitution provides for the right to a clean and healthy environment to all which includes the right to have the environment protected for the benefit of present and future generations and to have obligations related to the environment fulfilled. This right entails freedom from pollution, environmental degradation, and activities that affect the environment or threaten health, life livelihood, well-being or sustainable development. It also entails protection and preservation of the air, soil, water, flora, and fauna and the essential processes and areas necessary for diversity and ecosystems

Article 43 of the Constitution of Kenya, 2010 provides for economic and social rights. It affirms the rights of individuals and communities to an adequate standard of life including the right to accessible and adequate housing, the right to adequate food of acceptable quality and the right to clean and safe water in adequate quantities.

Article 26 of the Constitution also guarantees the right to life. Article 48 of the Constitution also provides for the right to access to justice through opening avenues for dispute resolution The State should allocate and provide resources for the progressive realization of these rights. Thus the state has a constitutional obligation to promote investment, income and wealth creation in the agricultural sectors and other sectors of the economy. In addition, the government has an international obligation to promote the right to work in the country.

The proposed regulations shall have a positive impact on human rights and freedoms. They will protect consumers from misuse of pesticides, and create and recognize the dispute resolution mechanism including an appeal to the Cabinet Secretary to ensure the determination in the sector are fair and based on a level playground for resolution of industry disputes. This will contribute to an adequate standard of living envisaged in article 43 of the Constitution.

Further, the proposed regulations seek to advance the government policy of implementing reforms in the pest control sector aimed at achieving the national goals set out in the Kenya Vision 2030 whereby the agricultural sector shall be a key driver of economic growth and value addition. The regulations will not only enhance public participation of the players in the sector but also ensure increased access to justice and access to quality pest control products to consumers of pest control products as required in article 46 of the Constitution.

4.0 REGULATORY AND NON-REGULATORY OPTIONS

This chapter highlights other regulatory and non-regulatory options that could be adopted by Pest Controls Product Board in regulating the pest control products sector in Kenya.

Alternatives to rule-based regulation are more flexible than a rule-based approach since they do not require setting the rules out in legislation which then takes more time and effort to develop and change.

4.1 Option 1: Maintaining the *Status Quo*

Before considering new interventions, it is important to consider whether the problem could be resolved by making changes to practices within the existing legislative framework, thus maintaining the status quo. Examples:-

i. Making use of existing laws, regulations and/or guidelines;
ii. Simplifying or clarifying existing regulations;
iii. Improving enforcement of existing regulation; or
iv. Making legal remedies more accessible or cheaper.

4.2 Option 2: Passing the Regulations

Government can achieve its policy objectives by using taxpayer's money or through a range of non-spending interventions, including regulation. Regulations aim to set rules to protect and benefit people, businesses and the environment, stabilizing markets and addressing market failures to support economic growth. Regulations can also create costs for businesses, third parties and the public sector. It can if overused, poorly designed or implemented, stifle competitiveness and growth. Adoption and operationalization of the proposed regulations will:-

i. Support increased participation of industry players in the pesticide industry, allowing for a more efficient industry that will support the Countries' agricultural development agenda as envisaged in the Big 4 agenda and Vision 2030.

ii. Enhance access to quality registered pesticide products to meet the increasing demand for pesticides through reduced fake, counterfeit and smuggled products in Kenya.

iii. Streamline and coordinate players within the industry and remove underhand dealings that negatively impact the industry.

iv. Develop and maintain a realistic database on the industry inclusive of a register of approved products, all industry players including agrovet outlets and pesticide handling premises in Kenya for better control and planning.

v. Increased pesticide information access to users, especially smallholder farmers who often rely on agrovet attendants and pesticide companies sales teams for pesticide recommendations, and thus reduced misuse of pesticides

These regulations are thus important for streamlining and organizing the pesticide industry.

4.3 Option 3: Other Practical Options

Alternatives to regulation include information and education, market-based structures, self-regulation and co-regulation. In addition, existing policies can be improved, without further regulation, using techniques such as behavioral insight or changing enforcement practices to improve compliance. Such approaches may be better or worse for business and the economy than an equivalent regulatory measure.

Alternatives to regulation include:

1. **No New Intervention/Do Nothing;**

This may include making use of existing laws and regulations; simplifying or clarifying existing laws and regulations; improving enforcement of existing laws and regulations; or making legal remedies more accessible or cheaper and as discussed in the section above status quo in the sector are likely to remain.

2. **Information and Education;**

Information and education can be used to empower pesticide industry players to make their own decisions, improving choice for the mutual benefit of all. There are potential risks associated with this. Information and education can take time to make an impact. Access to information and the ability to use it can vary within a community and so may not reach all equally. It may also not be straightforward to assess how people will react or change their behaviour in response to the information provided and it will increase costs for government and businesses that will be providing the information and education required.

3. **Incentive/Market-Based Structures;**

The government can use economic instruments, such as taxes, subsidies, quotas and permits, vouchers among others as initiatives to realize the desired objectives. These initiatives however are only practically possible in well-developed and efficiently functioning sectors which have well-defined structures, unlike the pesticide industry. Further, often these sorts of systems need their regulations to establish the framework and may have additional costs to the government and are unlikely to be effective in the pesticide industry.

Alternatives to regulation:

i. **Self-Regulation**

An industry or a profession can self-regulate, for example, through the use of codes of conduct, customer charters, standards or accreditation. In many cases, rules and codes of conduct will be formulated by the industry representatives or organizations under their own initiative.

ii. Co-Regulation

Co-regulation is an intermediate step between state-imposed and self-regulation that involves some degree of explicit government involvement where the industry may work with the government to develop a code of practice and enforcement would be by the industry or a professional organization and accredited by the government.

5.0 COST-BENEFIT ANALYSIS (CBA)

This chapter provides an analysis of the potential costs and benefits of using the proposed regulations in regulating the pest-control products sub-sectors. It analyses the economic, environmental and social impacts as well as the administrative and compliance costs of adopting the proposed regulations. It also assesses and quantifies the return on investments of the proposed regulations; and how the impact of the proposed regulations is likely to be distributed between the public and private sectors.

The fundamental justification for the application of cost-benefit analysis or more correctly social cost-benefit analysis is that it allows policymakers to assess whether the proposed regulations deliver gains i.e. improvements over the status quo compensate for any resultant losses. Unfortunately, due to lack of sufficient reliable data for cost-benefit analysis as is the case in Kenya's pesticide industry, valuing changes in policies such as regulations and how to establish and quantify how such changes impact the economy, society and the environment many times is a big challenge.

5.1 Economic, Environmental and Social Impacts

5.1.1 Economic Impacts of The Proposed Regulations

The economic impacts of the proposed regulations include:

Economic Benefits

i. Access and use of better quality pesticides will be enhanced.

The regulations will ensure that only pest control products that meet the set minimum standards are registered and used in Kenya, thus eliminating counterfeit, contraband and fake products in the industry and will promote good pesticides use practices. Over the past 5 years, pesticides import volumes have in general grown marginally and this trend is expected to continue at a projected rate of 4% annually. This coupled with the elimination of counterfeit and fake products, better farmers training on the safe use of pesticides, a better-regulated industry is expected to see the volume of quality pest control products imported into the country increase from 10.96 Million Kilograms (kgs) valued at 14.2 Billion shillings imported in 2018/19 to a projected 16.22 M Kgs valued at 21.02 Billion shillings in the year 2029/30 thus ensuring better access and use of quality pest control products to support the desired growth of Kenya's agricultural sector as shown in table 4 below:

Table 4: Projected pesticides imports and value trends

Year										
	2020/21	2021/22	2022/23	2023/24	2024/25	2025/26	2026/27	2027/28	2028/29	2029/30
Projected Import quantity (Million Kgs	11.40	11.85	12.33	12.82	13.33	13.87	14.42	15.00	15.60	16.22
Projected import Value (Kshs, Billion)	14.77	15.36	15.97	16.61	17.28	17.97	18.69	19.43	20.21	21.02

ii. Increased revenue generation.

The current industry fees were established in 2006 and have remained largely unchanged despite increased costs for the registration of pesticides. Besides, Kenya's pesticide registration fees are low in comparison to other African countries and are much lower than fees required in the regional and Organization for Economic Cooperation and Development (OECD) countries. The Draft regulations propose to increase key fees and levies and enhance licensing compliance in the industry. The draft regulations propose an increase of the import levy from 0.8% to 1.4% of the FOB value of pesticide imports. This will see the levy collection increase from the current estimated Kshs 113 Million to an estimated Kshs. 198 Million raising an additional Kshs 85 Million annually. The Draft regulations propose to increase other key fees and levies by between 100-150% and more than double PCPB's current revenue generation and progress towards self-reliance.

Studies have shown that 18% of products in the Kenya pesticide industry are counterfeits. Given the 10.96 Million Kgs of pest products valued at 14.2 Billion shillings imported in 2018/19, it can be interpreted that an estimated 1.86 Million Kgs of products valued at almost Kshs 2.5 Billion were counterfeits and denied the Treasury over tax revenues and denied legitimate tax remitting industry players Kshs. 2.5 Billion business opportunities.

50% of the increased revenue from the import levy is intended specifically for purpose of training pesticide users, retailers and other stakeholders through AAK, thus further enhancing the safe and effective use of pesticides in the country. The other 50% and revenues from other fees will be additional revenue to PCPB to improve pesticide registration and inspection services and thus further reduce PCPB's dependency on the Treasury for resources to carry out these critical services, making it a more vibrant and self-reliant organization while freeing the resources currently provided for its budgetary support for use in other areas for the public good.

The projected increase in imports will generate direct revenue for Government from other indirect revenues from taxes and levies from the pesticide industry. These additional taxes including other revenues resulting from the anticipated growth and services in the pesticide industry may go into the Treasury or may be destined specifically to fund pesticide registration and inspection activities or even the development of low-risk alternatives.

iii. Development of a better-regulated pest control products industry.

The draft regulations propose better regulation and compliance enforcement of the pesticide industry in Kenya through a clearly defined registration, licensing, inspections, industry confidential business information management, importation and exportation, pest control products labeling, advertising and packaging and pest control products disposal procedures and processes compared to other African countries with similar agriculture and other regional and OECD countries. The draft regulations also provide for an improved revenue base for PCPB which will allow the regulatory agency to effectively execute her mandate as outlined in the regulations and thereby foster the development of well-regulated pesticide industry in the country. Implementation of the proposed regulations will eliminate counterfeit and fake products in the market, reduce misuse of pesticides, eliminate unprofessional actors and instill professionalism in the industry and streamline business transactions and promote fair trade practices in the industry for the benefit of all stakeholders. The regulations will also address other industry challenges such as the existence of a large number of "sleeping registrations" which pesticides that are registered in Kenya not for local use but mainly as a justification to obtain a registration in other countries based on the understanding that Kenya has a reputable registration system, making Kenya a pesticide registration haven for dealers circumventing registration conditions in other countries.

iv. Reduction of the cost of production.

The regulations by ensuring only quality pesticides are used in the country will reduce the farmers' cost of production by avoiding repeated pesticides applications and use of suitable products to replace other more expensive factors of production or technologies such as labour or heavy mechanized intensive operations. The promotion of good pesticide use practices and alternative pest and disease management technologies including the introduction and use of bio-pesticides which have a lower likelihood of pests developing resistance and high efficacy will significantly contribute to reducing farmers' production costs.

v. Increased agricultural production and quality.

A well-regulated and more efficient pesticide industry and the judicious use of pesticides will support and facilitate further development of the Country's agricultural sector, increasing the sector's contribution to the GDP from the current 25% annually. This will contribute to the realization of the Kenya Vision 2030 and the Government's Big 4 agenda goals of achieving an average Gross Domestic Product growth rate of 10% per annum up to the year 2030, realizing food and nutrition security and employment creation through agro-processing. Improved quality of production will also attract better product prices with pest/disease-free products that are acceptable

even in strict markets and have longer storability. To realize the 10% economic growth by 2030 and assure the country of food and nutrition security, the agricultural sector must develop at an even higher rate as it is the mainstay of the Country's economy and this is not possible without effective pests and disease management.

The Government's Big Four Agenda seeks to achieve 100% food security by 2022 by increasing large-scale production of staple foods, a move that will see 700,000 new acres of maize, potatoes, and rice being put under cultivation and transforming smallholder production. By 2022, it is expected that maize production will increase by 27 million bags from 40 million 90kg bags to 67 million bags annually, and potatoes by 0.9 million tons to 2.5 million tons annually and increase annual rice production to 400,000 million tons. This can only be realized by among other things effective pests and diseases management.

vi. Increased agricultural exports.

Agricultural products are central to Kenya's export industry accounting for 65% of the total exports with horticultural and tea being the most important. Other important agricultural exports include coffee, fish, nuts and spices. Kenya is the world's leading exporter of black tea and cut-flowers. The effective management of pests and diseases is critical in the production of all these products and ensuring product quality to meet the different export markets safety and quality standards. To sustain and further develop Kenya's agricultural exports, the Country should be able to manage current and emerging pests and diseases, failure to which these sub-sectors would be faced by imminent collapse and thus reduced exports.

Increased production of these and other agricultural products as a result of effective pest and disease management is expected to reduce dependency on agricultural imports and especially for common food items and instead translate to the substitution of imported agricultural produce with locally produced products resulting in an improvement of the country's balance of trade.

vii. Expanded and increased alternative export markets for Kenya's agricultural exports.

Kenya's trade performance is below its potential. In 2018, 33.7% of Kenyan exports were to other African countries while 28.4% to Europe with 8.9% to in North America. Smaller percentages were sent to Oceania led by Australia and Latin America and Asia. Kenya's export growth has been driven primarily by existing products in existing markets. Overall there has been little new product/new market discovery and there is a need to increase its export competitiveness. To realize this potential there is a need not only to increase agricultural production and quality of products but also to meet the specific market requirements especially on sanitary and phytosanitary, packaging and transit standards, and Maximum Residual Levels (MRLs) of the export products and a well-regulated and efficient pesticide industry will be critical to facilitate the transformation of Kenya's export marketing.

viii. Increased earnings from agricultural exports.

Kenya has a huge but largely untapped potential to grow earnings from agricultural exports and many export crop sub-sectors which are heavily dependent on pesticide products have continued to record growth despite numerous inefficiencies in the agricultural sector including the pesticide industry. The individual products growths realized can be accelerated by addressing these inefficiencies including having an efficient and well-regulated pesticide industry. Kenya's earnings for example from fresh produce exports in 2018 grew to Ksh153.68 billion, a 33 percent increase over 2017 earnings, with flower exports contributing to Sh113.16 billion up from Ksh82.24 billion earned in 2017, representing 37.8 percent growth.

Fruits and vegetables earned Sh12.83 billion and Sh. 27.68 billion in 2018, up from Sh. 9.0 billion and Sh. 24.06 billion earned in 2017, respectively, while Tea exports grew by 5 percent in 2018 to 135 billion shillings. A better regulated and efficient pesticide industry will facilitate access only to quality, safe and/or new more effective products including biopesticides and effective agricultural advisory services from qualified technical expertise to support growth in production and product quality for even more increased earnings from agricultural exports.

ix. Increased savings and investment by farm families.

Increased agricultural production and produce quality, increased agricultural exports, expanded and new alternative export markets for Kenya's agricultural exports and increased earnings from agricultural exports will all translate to increased earnings and thus increased savings and investment by farm families,

x. Increased Foreign Direct Investment through new investments in production, value addition and marketing of Kenyan agricultural products.

Attract and promote new investments in the industry: A well-regulated and efficient pesticide industry will promote and support new foreign direct investments in production, agro-processing and marketing of local agricultural products by ensuring access to quality and friendly pesticides and quality technical expertise which are key in agricultural production processes. The new improved pesticide industry regulatory environment will also be attractive for new foreign direct investment in the industry to benefit from the anticipated growth in the industry resulting from the expected increase in demand for quality products and elimination of counterfeits, fake and contraband products.

xi. Creation of job opportunities.

The increase in agricultural production, agro-processing and trading will translate to the creation of new jobs across the sector including employment at farms level, agro-processing, trading and in the sector auxiliary services including in the pesticides industry which will require the employment of trained professionals at all levels of service in the industry. Specifically, many pesticide businesses in the country currently do not employ agricultural professionals yet they serve as an important source of information to farmers on pest and disease problems, pesticide selection, use and other pesticide use issues including health and safety.

The draft regulations require that all pesticide business points engage agricultural professionals and thus will create employment opportunities for at least 8,000 agricultural professionals in the short run assuming each business employs one trained professional but the number is likely to be higher given that some businesses have several attendants.

The draft regulations also require that farmers leave application of pesticides to trained and registered spraying service providers which will greatly enhance safe and effective use of pesticides in Kenya. This will create thousands of employment opportunities especially for the youth in rural and agricultural regions of the country in the spray teams.

xii. Information system management

Pesticides manufacturers will fully benefit and will be able to recoup their investments in regulatory data and studies for registration after the elimination of counterfeit, fake and contraband products in the market, motivating them to continuously invest in research, development and registration of new products. The crop protection industry spends an average of $71m on toxicology and environmental safety tests for every product brought to the market. These tests help ensure that pesticides only receive regulatory approval if they are safe for human health and the environment. Lack of a well-regulated pesticide industry allows the existence of fake and counterfeit products in the market as well as unfair trade practices that deny genuine manufacturers the benefit of their investment, discouraging further research and development of new and safer pest control products and technologies.

Economic Costs

The implementation of the proposed regulations will however have some economic costs including:-

i. Implementation of the regulations may result in job losses in the industry from the closure of some businesses especially small rural-based agro-vet agents unable to meet the minimum requirements set in the regulations and/or due to the increased cost of doing business.

ii. Implementation of the regulations will also increase the cost of doing business in the pesticide industry through the new licensing requirements that will require industry actors to have different licenses for the different roles and services in the sector, the charge fee of 1.4% of FOB value of pesticides imports and the requirement for employment of only trained professionals at all levels of service in the industry. The draft regulations propose to increase key fees and levies by between 100-150% a cost which will be transferred to pesticide users making pest control products more expensive.

iii. The provisions of the regulations may be viewed as bureaucratic resulting time-consuming from the many different processes and actions envisaged in the regulations including Product registration, product labeling, advertising and packaging, product importation and

exportation, licensing of premises and business, confidential business information, products disposal regulations and products License fees and other charges regulations. Effective implementation of the regulations will require investment in capacity building of industry stakeholders on among others provisions of the regulations and good pesticide manufacturing, handling and use practices i.e. Publicity costs related to countrywide awareness creation, sensitization and communication e.g pamphlets, flier, mass media (radio spots, newspaper) advertisements and programmes; hands-on training of industry actors will be significant

iv. The increased cost of industry monitoring and enforcement of the regulations will require human, physical and financial resources.

v. The increased cost of products registration - Registration data and research costs including product development, resistant varieties; novel detection, monitoring and control technologies among others which are requirements for product registration are capital intensive.

vi. Increased production costs due to increase in pesticides and application costs – product prices will increase as additional costs in levies, fees and research are transferred to the end-users; application products using specialized and registered labour (spray teams) and equipment.

5.1.2 Social Impacts of the Proposed Regulations

The social impacts of the proposed regulations include:-

Social Benefits;

i. Reduced poverty among farm families and the community in general.

Increased agricultural production and produce quality, increased agricultural exports, expanded and increased alternative export markets for Kenya's agricultural exports and increased earnings from agricultural activities will be a major contribution to the reduction of poverty among farm families who make up 80% of Kenya's rural population and the Kenyan community in general.

ii. Improved income distribution among the farm families and the community in general.

Increased earnings from agricultural activities and creation of employment across all the agricultural sector value chains right from the farm level, to agro-processing and trading, will improve income distribution in the population

iii. Improved health status and reduced pesticide-related health diseases.

Implementation of the regulations will also result in improved health status and reduced pesticide-related health disease incidences of the farm families and the community resulting from reduced

exposure directly to pesticides and pesticide residues in waters, food and air. The regulations will also enhance safety through the implementation of the Global harmonized labeling and introduction of registration of biopesticides that have better safety levels. A study published in the BioMed Research International Journal in 2015 estimates the average health cost per farmer for pesticide-related illnesses in Kenya to be US$ 3.54/farmer/year and given that Kenya has an estimated 4.5 Million farmers this cost can be extrapolated at the national level to be US$ 16M/year. However, the true health costs are likely to be much higher because the costs arising from chronic diseases resulting from long-term pesticides exposure were not considered in the study. Moreover, costs occurring to hired farm laborers were not included and other "costs" to restore health status completely and nonmonetary costs like suffering and income lost by family members assisting in seeking treatment were also not captured.

The health status of the farm families and the community will be further enhanced by improved nutrition, improved food safety and the effective management of health/disease vectors and nuisances insects.

iv. Reduced contamination of water for household use among the farm families and residents in general.

v. Better regulation of the industry, good pesticide handling and use practices and promotion of alternative pest and disease management technologies including the introduction and use of bio-pesticides as envisaged in the regulations will reduce surface and groundwater contamination, thus improving access to clean water by the population. Improved education levels and reduced illiteracy and access to other social amenities resulting from increased farm families, sector and industry workers' incomes.

vi. The creation of employment in the rural areas in the agricultural sector will contribute to stem the tide of rural-urban migration and reducing general insecurity, especially in the rural areas.

Social Costs;

The regulations implementation will however have a social cost in the form of the health costs borne by the public agencies (public health care) including public assistance to sick or disabled household members or workers from pesticide exposure expected growth in real pesticide products demand. This cost can be estimated from relevant budgets of relevant public agencies

5.1.3 Environmental Impacts Of The Proposed Regulations

The environmental impacts of the proposed regulations include:-

Environmental Benefits;

i. Reduced environmental impact as a result of reduced use, and/or use of alternative of pesticides or use of alternative pest management technologies, thus reduced environmental

costs and reduction in adverse effects of products as more toxic products are replaced by more friendly products such as bio-pesticides.

ii. Environment and biodiversity preservation - A well-regulated industry, proper pesticide handling and use and the promotion of alternative pest and disease management technologies including the introduction and use of bio-pesticides as envisaged in the regulations will reduce surface and groundwater contamination and preserve Kenya's bio-diversity including beneficial animals, insects and plants.

iii. Improved land conservation, utilization and management through the use of modern agricultural pesticide-based technologies such as minimum and zero tillage.

iv. Reduced soil degradation due to contamination by pesticides and the preservation of soil life.

Environmental Costs;

The regulations implementation will however have some environmental costs.

Irrespective of specific product safety profile, all pesticides are harmful to the environment and a country's bio-diversity, especially if not used according to the use instructions. Destruction of the environment and loss of biodiversity remains a risk requiring measures to restore and or replace what is destroyed or lost at a cost. Internationally, it is recommended that damage to non-target species be estimated from past experience/cases with similar pesticides and may constitute economic and/or aesthetic losses. Economic losses can be evaluated using market prices or replacement costs. Reversible aesthetic losses can be evaluated as the cost of restoration or replacement; while irreversible aesthetic can be partially evaluated based on relevant and specific research studies on the opportunity cost of the loss of the aesthetics experiences.

Environmental costs are borne by public agencies to correct damages from the use of pesticides.

5.1.4 Costs, Benefits Analysis and Assumptions

From the above discussions, it is quite clear that the expected economic, social and environmental benefits from the implementation of the draft regulations heavily outweigh the corresponding costs. The analysis of cost and benefits of implementation of the draft regulations is however based on the following assumptions:-

i. Implementation of the regulations will be undertaken in a holistic manner where all provisions of the regulations will be implemented and not partially selected provisions are implemented.

ii. The country's development strategies and policy environment will continue to prioritize and support the development of the agriculture sector.

iii. The climatic conditions will remain favourable for agricultural production.

iv. Kenya's agricultural products will continue to access current and other alternative global markets.

v. Pesticide industry actors including farmers' will respond rationally to the implementation of the proposed regulations and voluntarily comply with the proposed regulations.

vi. The additional revenue generated from the various fees and levies will be used for the development of the pesticide industry.

5.2 Administration and Compliance Cost

RIA notes that resources would be required for operationalization of the regulations which will include human resource and operation costs for enforcement as well as for awareness creation of the regulations to the different pesticide industry players. More resources will go to the implementation of the wider National Agriculture Policy which supports extension services for strengthening knowledge transfer and technology distribution among the farmers, implementation of the Agriculture sector growth and transformation strategy and the Big 4 agenda.

5.3 Assessment of Return on Investment (Benefit)

Passing and operationalization of the proposed regulations will be critical in facilitating the development of the pesticide industry first by streamlining Kenya's unstructured pesticide industry to allow coordinated control of the industry, create a level playfield for all industry players and promote fair trade practices for safe and effective use of pesticides to support Kenya's agricultural development and manufacturing pillars as envisioned in the Big 4 agenda.

An effective and efficient pesticide industry will support increased productivity of quality agricultural products that meet international market standards and ensure consistent provision of quality raw material for agro-industries sustainably to guarantee improved incomes for the farmer and thus improved livelihoods and social welfare for communities while guaranteeing other businesses within industry good returns and higher export earnings for the country.

In broad terms, the RIA notes the following broad benefits:

i. The regulations will streamline the unstructured pesticide industry for better functioning while allowing for fair competition, enhancing access to quality pesticides and this will result in enhanced efficiency and development of the industry.

ii. Improved access to reliable pesticide information and agricultural advisory services from the professional agents of industry players will support the farmers to improve productivity and also improve on quality.

iii. Promote alternative and integrated pest and disease management thus reducing the usage of harmful products and promoting the use of bio-pesticides that do not persist in the environment, have low or no residual effects, have reduced post-harvest intervals, minimal environmental degradation, increased safety of people and animals, lower likelihood of pests developing resistance and high efficacy.

iv. Enhance compliance of Kenya's agricultural products to international standards and consequently, increase access to alternative bigger and better export markets.

v. The regulations will promote good pesticide manufacturing, handling and use practices and provide for the registration of the much safer bio-pesticides, thus reducing incidences of pesticide exposure among pesticide handlers, users and consumers for their and community's better health.

vi. New manufacturers, processors, dealers and other pesticide industry will be attracted to invest in the more efficient industry and expanding pesticide market devoid of fake, smuggled and counterfeit products, providing users with alternative options for products and services and unfair trade practices denying manufacturers' returns from investment in regulatory data and studies for registration will be eliminated.

vii. The elimination of fake, smuggled and counterfeit products which are estimated to constitute 18% of pesticide traded in the country will translate to increased legitimate business by the same margin resulting in increased industry incomes, increased industry taxes and new jobs created in the industry.

viii. The regulations will promote the employment of trained professionals across all areas of the industry, thus will create employment for the many unemployed agriculture professionals in the country. In addition, the increased agricultural production will also translate to increased job creation through farm labour, agro-processing and products manufacturing, value addition, marketing and auxiliary services.

ix. A comprehensive sector database including pesticide traders/agrovets, re-packers, commercial pest control operators, commercial trainers and consultants, spray services providers, stores/ warehouses, manufacturers, formulators, importers, exporters, pesticide waste disposal facilities, a register of approved products research information and data, exports and market demand and use volumes, etc. will be developed and maintained to inform industry planning and future investments.

x. More efficient organized and structured pesticide industry: Adoption of the proposed regulations, implementation of the proposed Globally Harmonized System of

Classification and Labelling of Chemicals (GHS) which to provide additional features on the label, use of trained professionals in the industry and training users on good pesticide use practices will reduce misuse of pesticides, availability and use of counterfeit, fake and unregistered and/or smuggled products in Kenya.

xi. Establish clear structured mechanisms for disposal of pest control products waste, thus reducing environmental contamination and the re-use of pesticide containers.

xii. Increased agricultural national production and value addition will translate to increased farmers' incomes and agricultural exports, thus increasing foreign exchange earnings.

xiii. Pesticides manufacturers will benefit from their investment in regulatory data and studies for registration, allowing them to recoup their investments and motivate them to invest more in the development of new products.

5.4 Quantification of the Benefit

The implementation of the regulations will eliminate counterfeit, contraband and fake products in the Kenyan pesticide market which will translate to market growth. Past studies have shown that 18% of pesticides products in the market are counterfeits, thus elimination of counterfeits alone should translate to an 18% market growth. The market is also expected to realize further growth from increased demand for pesticides to substitute fake and contraband pest control products for which data on their actual levels in the market have not been conclusively established.

The regulations will ensure the use of only quality registered pesticides, promote good pesticide use practices, enhance pesticide information access and improve agricultural advisory services in the industry which will increase efficiency in pest and disease management in the country, significantly reducing pest and disease crop filed losses from the current 30-35%.

The more efficient management of pests and diseases will contribute towards increased agricultural sector production and products quality, increasing marketable volumes, improving access to quality strict markets, increasing farm families earnings, and increasing the agricultural sector contribution to the national GDP from the current 26% and agricultural export earnings from the current 65% and thus support the government goal of 10% GDP growth per year as envisaged in the Vision 2030 and the Big 4 agenda.

Implementation of the regulations will also create jobs both in the pesticides industry and across the entire agricultural sector. Specifically, within the industry, the regulations require the estimated 7,000 pesticide retailers spread across the country to engage qualified professional agents to provide services to the product's end users. Other jobs opportunities will be created across the agricultural sector to support the increased production at the farm level, agro-processing and marketing.

All these developments will result in profitable and viable pesticide industry and agricultural sector and thus increased tax revenues from the industry and the sector for both the National and County governments.

In addition, implementation of the regulations will contribute towards the betterment of farm families, consumers and pesticide handlers' health through reduced exposure to pesticides and improved food safety standards and reduced pesticides related environmental degradation. This will contribute to reducing the average health cost per farmer for pesticide-related illnesses estimated at US$ 3.54/farmer/year for the probable 4.5 million small-scale farmers in Kenya and among other farmworkers in addition to reducing cost borne by public agencies to correct environmental damages from the use of pesticides.

The crop protection industry spends an average of $71m on toxicology and environmental safety tests for every product brought to the market. These tests help ensure that pesticides only receive regulatory approval if they are safe for human health and the environment, a rigorous process that takes up to 11 years on average to take a product from discovery to commercial use. Implementation of the regulations will protect industry firms' rights on these investments from unfair trade practices usually occasioned by high incidences of counterfeit, fake and contraband products allowing them to recoup their investments and motivate them to invest more in the development of new products.

5.5 Distribution of Impact

The operationalization of the regulations will generate more positive than negative impacts/risks if the regulations are implemented with sufficient financial, logistical, technical and human resources. First, the pesticide industry will be better organized and regulated to ensure that only licensed players will be allowed to operate in the industry and will only deal in registered products meaning that the country will be able to rid the industry of unlicensed and unscrupulous pesticide traders and trading in counterfeit, smuggled and fake products. This will make the pesticide industry attractive increased pesticide investments in the country as industry players invest in additional capacity, distribution and marketing networks, research etc. to take advantage of the expected growth in real pesticide products demand. This will also translate to increased access by farmers to quality and effective pesticides which will result in more effective pest management and thus increased agricultural production and quality products.

Farmers' ability to make informed decisions on product selection and application will be much enhanced by the provision of specific product information on the prescribed form on the product labels and information provided by technically qualified professionals engaged by all pesticide outlets and service providers, which will also further contribute to increased agricultural productivity. Increased production and product quality will translate to increased incomes for farmers. Increased farm incomes will allow farmers to hire extra labour to work on their farms to support the increased farm production as well as contribute to new capital formation and thus

contributing directly to the food security and employment and processing pillars of the Government's Big 4 Agenda and Vision 2030.

The correct use of pesticide products, the use of only registered products, use of approved premises for pesticide businesses, use of approved pesticide and pesticide containers disposal and more informed users will significantly reduce cases of pesticide exposure and acute and chronic health effects and environmental hazards and thus preserve the country's biodiversity for sustainable agricultural development. Socially the farm families' livelihoods will be enhanced and sustained, allowing for better health care, education and wealth creation among the families.

Elimination of unfair trade practices which deny pesticides manufacturer's returns from their investment in regulatory data and studies for registration will be eliminated allowing them to recoup their investments

In the public sector, the regulation and coordination of a streamlined pesticide industry will be significantly improved, with the Government and its agencies' role being strictly that of regulation, monitoring and enforcing compliance of the regulations including quality while creating an enabling and level playfield for the private sector to operate in. The improved production and value addition will contribute to increased exports and earnings in foreign exchange for the country.

Industry players will, however, have to incur additional costs in running their businesses resulting from additional license fees and costs introduced by the Board, the proposed increase of charge fee to 1.4% of FOB value of pesticides imports and the requirement to recruit qualified professionals at all levels of service delivery in the industry.

6.0 REASONS WHY OTHER REGULATORY OPTIONS ARE NOT APPROPRIATE

6.1 Option 1: Maintaining the *Status Quo*

Maintaining the status-quo may only sustain the challenges facing the pesticide industry and allow a further decline in this sub-sector, including the following:-

i. The pesticide industry shall continue to remain unstructured and not effectively regulated allowing continued operation of unqualified, unscrupulous, quick-for-profit players who do not necessarily comply with the set industry standards, exposing pesticide users to poor quality, unregistered, fake, counterfeit and smuggled products which are harmful to users health and the environment.

ii. Harmful products banned in other countries may still find their way into the Kenyan market, exposing Kenyans health and the environment to harm.

iii. Pesticide products information will remain inaccessible by many users who still depend on product advertisement and pesticide companies' agents for advice on products to use, resulting in continued misuse and misapplication of products.

iv. Pests' losses which are estimated to be as high as 30% annually will remain a challenge and will even increase with the emergence of new pests such as the fall army worm while the efficiency of management of other pests will also remain a challenge due to use of wrong or poor quality products.

v. Agricultural productivity and quality of Kenya's agricultural products will decline, reducing export volumes and acceptability in some markets, thus, reduced foreign exchange earnings.

vi. Farmers' earnings will also reduce as a result of reduced productivity and product quality, thus impacting the farms' families' ability to access social services and amities including housing, health, education etc.

vii. Reduced earnings for farmers will also translate to lost employment opportunities in agricultural production in the rural areas, increasing the rate of unemployment in the country.

viii. Incidences of acute and chronic health effects attributable to pesticides due to direct exposure to pesticides or residues in food, drinking water, rain and in the air will continue to be reported.

ix. The environment will continue to be contaminated from pesticides and thus destroying Kenya's biodiversity which is important for sustainable agricultural development.

x. Farmers' cost of production will remain high due to having repeated pest control operations due to the use of ineffective poor quality pesticides.

The situation is not sustainable, and the RIA recommends that the proposed regulations be put in place to streamline and regulate the pesticide industry to support the agricultural sector to contribute to the realization of the objectives of the Vision 2030, the national Agriculture Sector Development Strategy and the "Big 4' Agenda".

6.2 Option 2: Other Practical Options

Alternatives to regulation include:-

i. No New Intervention/Do Nothing;

This may include making use of existing regulations; simplifying or clarifying existing regulations; improving enforcement of existing regulations; or making legal remedies more accessible or cheaper. But with this approach, the status quo in the pesticide industry is likely to remain to the detriment of all the industry stakeholders and the country.

ii. Information and Education;

Information and education can be used to empower stakeholders to make their own decisions, improving choices for the mutual benefit of all. However, information and education can take time to make an impact and still may not be acceptable to all. This approach may increase costs for the government and businesses that will be providing the information and education required. The desired objectives are unlikely to be realized within a reasonable time for the common good of all.

iii. Incentive/Market-Based Structures;

The government can use economic instruments, such as taxes, subsidies, initiatives to realize the desired objectives. These initiatives, however, are only practically possible in well-developed and efficiently functioning sectors which have well-defined structures and often these sorts of systems need their regulations to establish the framework and may have additional costs to the government and are unlikely to be effective in the pesticide industry.

6.3 Alternatives Models Of Regulation;

i. Self-Regulation

This requires the industry to have a well-developed industry representative that is fully acceptable to all industry players and who willingly subscribe to the representative's objectives, standards, code of regulation etc. AAK is the industry representative but its membership is not all-inclusive

and since the membership is voluntary and thus the association's rules and codes of conduct cannot be enforced to non-members and therefore self-regulation may not be a possible option.

ii. Co-Regulation

Co-regulation is an intermediate step between state-imposed and self-regulation that involves some degree of explicit government involvement where the industry may work with the government to develop a code of practice and enforcement would be by the industry or a professional organization and accredited by the government. The pesticide industry has no all-inclusive, wholly accepted industry representative currently at the moment and thus co-regulation is practically not possible.

7.0 OUTCOME OF STAKEHOLDER PARTICIPATION

This chapter examines the legal requirements for public participation. It also analyses the outcomes of the public consultations conducted in coming up with the proposed regulations to assess whether the consultations meet the statutory threshold set under the Constitution 2010 and the Statutory Instruments Act 2013 for public participation in Kenya.

7.1 Legal Basis for Public Participation

The Constitution of Kenya provides for national values and principles of good governance and participation of the people of Kenya. Article 10 provides for the involvement of the people in the enactment of any law. The national values and principles bind all state organs, state officers, public officers and all persons whenever they, *inter-alia*, apply the Constitution and enact any law.

The courts of law have in several instances provided for the modes of ensuring public participation is effective. For instance, in ***IEBC v NASA-Kenya & 6 others [Para 164*-5];** the Court of Appeal stated,

> *…the mode, degree, scope and extent of public participation is to be determined on a case by case basis. What is critical is a reasonable notice and reasonable opportunity for public participation. In determining what is reasonable notice a realistic time frame for public participation should be given. In addition, the purposes and level of public participation should be indicated. Reasonableness is also to be determined from the nature and importance of legislation or decision to be made, and the intensity of the impact of the legislation or decision on the public. The length of consultation during public participation should be given and the issues for consultation. Mechanisms to enable the widest reach to members of the public should be put in place; and if the matter is urgent the urgency should be explained.*

Further, in ***Poverty Alleviation Network & others v President of the Republic of South Africa & 19 others, CCT 86/08 [2010] ZACC 5*;** public participation was emphasized in the following terms;

> "*…engagement with the public is essential. Public participation informs the public of what is to be expected. It allows for the community to express concerns, fears and even to make demands. In any democratic state, participation is integral to its legitimacy. When a decision is made without consulting the public the result can never be an informed decision…"*

The totality of all those pronouncements therein reproduced brings forth the following cardinal points:

i. Public participation was never intended to be a superfluous or ornamental suggestion; rather, it should be implemented and enforced to have a practical substantive bite.

ii. Public participation must never be a mere cosmetic venture, formality and public relations exercise, rather it ought to be conducted in a manner that informs the public of what is at stake, how it will impact the society and the end document should mirror and reflect the spirit of the public in concern.

iii. Public participation should never be equated to mere consultations. The product of legislation ought to be a true reflection of the public participation so that the end product bears the seal of approval by the public.

7.2 Stakeholder Engagements

Section 5 of the Statutory Instruments Act, 2013 requires a regulation-making authority to, before issuing a statutory instrument, make appropriate consultations with persons who are likely to be affected by the proposed instrument. Specifically, section 5(3) (a) of the Statutory Instruments Act, 2013 requires a regulation-making authority to notify, either directly or by advertisement, bodies that, or organizations representative of persons who, are likely to be affected by the proposed instrument

The Ministry, PCPB and AAK organized and undertook public consultations covering 37 Counties to provide an opportunity for the public to participate in the making process of the proposed regulations. The Ministry also conducted high-level stakeholders' engagement which involved stakeholders from different sectors including an invitation for written comments on the proposed regulations.

Some of the high-level stakeholders who shared their comments on the proposed regulations via email or letters include; the Kenya Flower Council, Veterinary Medicine Directorate, Green Earth Bureau, International Center of Insect Physiology and Ecology (ICIPE), Biodiversity and Biosafety Association of Kenya, Resource Oriented Development Initiative, Kenya Organic Agricultural Network, Route to Food Initiative, United Nations Environmental Programme, and Consumer Federation of Kenya among others.

Through the Joint Agricultural Sector Consultation and Cooperation Mechanism Committee, the Ministry sent out invitation letters to 37 Counties across Kenya inviting at least 20 county-based stakeholders including representatives from small scale and large scale farmers, farmers' cooperatives/growers association representatives, representatives from local universities or colleges dealing with agriculture or public health, County officers from the department of agriculture and health, and representatives from National Environment Management Authority or County officers in charge of the environment.

The public participation workshops across different Counties took place in September, October and November 2020. Some of the Counties were clustered together to a centralized venue. The following Counties participated in the public fora; Nandi, Elgeyo Marakwet, Baringo, Nakuru, Narok, Uasin Gishu, Kiambu, Nairobi, Kisii, Nyamira, Siaya, Kisumu, Kwale, Mombasa, Meru, Laikipia, Kitui, Bomet, Kericho, Nyeri, Kakamega, Busia, Vihiga, Malindi, Kilifi, Taita Taveta,

Machakos, Kajiado, Murang'a, Kirinyaga, Trans Nzoia, Homa Bay, Migori, Tharaka Nithi, Makueni and Embu. Some of the workshops were held concurrently being facilitated by different technical teams from the Ministry.

The workshops were well attended with representatives of the Agrochemical Association of Kenya, Pest Controls Products Board, Kenya Law Reform Commission, Ministry of Agriculture, Livestock, Fisheries and Cooperatives, County representatives in charge of agriculture and public health, farmers, farmers cooperatives or growers associations, representatives from academia and research institutions, private sector players directly affected or likely to be affected by the proposed regulations among others. The participants discussed the contents of the proposed regulations. The Chief Executive Officer of the Board also attended the fora and explained to the participants the need to overhaul the Pest Control Products Act Cap 346 Laws of Kenya. He observed that the regulations would aid in addressing the inherent weakness of the current regulatory regime.

The records from the public forums show extensive deliberations on myriad issues that arose from the proposed regulations. For instance, the deliberations focused on the role of the County Government in the harmonization of licenses, promotion and dealings in locally produce pest control products, funding, dealing with counterfeits, creation of minor offences, registration and suspension of licenses, and appointments of agents among other issues. The stakeholders also raised issues with regards to the use of banned pesticides in Kenya, misinformation in the agrochemicals sector, licenses and different requirements for registration, counterfeit products, the confidentiality of the CBI data, definition of categories of business and inspection criteria in the checklist for licensing and inclusion of a dummy label in the schedule to the Labelling Regulations among others.

The participants were also allowed to review the regulations through the circulation of the regulations to them immediately before the consultative meetings. It was also apparent that the Board collated, reviewed and incorporated into the proposed regulations the issues raised and comments received from the public participation workshops.

7.2.1 National Level Consultations (Government)

The Ministry of Agriculture, Livestock, Fisheries and Cooperatives, Ministry of Health, Kenya Law Reform Commission (KLRC), National Environment Management Authority, and the Pest Controls Products Board members attended the public consultative forums among other national institutions.

7.2.2 County Governments/Level

There was evidence on record to show that representatives of various County governments were consulted or participated in the process of review of the proposed regulations.

The Draft Pest Control Products Regulations were discussed by the Intergovernmental Joint Agriculture (JASSCOM), Sector Thematic Working Group (SWAG) on Policy, Regulations and Standards in Naivasha in January and February 2020 and approval granted for stakeholder

consultations to be conducted. The public participation workshops across different Counties took place in September, October and November 2020.

The Ministry conducted public participation workshop in 37 counties considered to be directly or indirectly to be affected by the proposed regulations. Some of the counties were clustered together to a centralized venue. The following Counties participated in the public fora; Nandi, Elgeyo Marakwet, Baringo, Nakuru, Narok, Uasin Gishu, Kiambu, Nairobi, Kisii, Nyamira, Siaya, Kisumu, Kwale, Mombasa, Meru, Laikipia, Kitui, Bomet, Kericho, Nyeri, Kakamega, Busia, Vihiga, Malindi, Kilifi, Taita Taveta, Machakos, Kajiado, Murang'a, Kirinyaga, Trans Nzoia, Homa Bay, Migori, Tharaka Nithi, Makueni and Embu.

7.2.3 Research and Academia

The Board enlisted the services of a consultant, PestMatt consultants, who aided the participants in the review of the Regulations. There was a great representation of research and academia in the review process of the proposed regulations. For instance, representatives from Maseno University, Kenya Medical Training College, South Eastern Kenya University, Kabianga University, Taita Taveta University, Machakos University, Kenya Agricultural and Livestock Research Organization (KALRO), International Center of Insect Physiology and Ecology (ICIPE), Jaramogi Oginga Odinga University of Science and Technology, Pwani University among others attended the workshops held in different Counties and were able to present their comments on the proposed regulations.

7.2.4 Private Sector

The Agrochemical Association of Kenya (AAK) which is a key player in the pest control products industry was a participant in all the workshops that were organized by the Board. Different stakeholders from the private sector were able to attend the public fora held in different Counties. For instance, there was a representation of farmers and farm owners, Cooperative societies and farmers' unions, Community based organizations, agrovet owners, civil societies such as Route to Food among others.

7.3 Stakeholder Views

The issues raised by stakeholders included the need for the industry to self-regulate and discipline its members; the need for effective dispute resolution mechanisms; anti-counterfeit strategies; need to increase funding to the Pest Control Products Board; the multiplicity of licences to be issued by the Board; definition of the role of the Board because of the devolved system of governance; registration of pest control products; misinformation on agrochemicals; and confidentiality of information.

Other issues raised included registration in foreign countries; appointments of agents; recognition of registration of animal products under the Veterinary Act; the number of forms involved; clarification on the role of the local agency; an instance of invariability with the Act on the provision on the validity of the import permits; dealing in empty containers among others.

7.4 Assessment of Adequacy

The Ministry undertook a mapping of various stakeholders from different levels as required in the Statutory Instruments Act, 2013. AAK who is an umbrella organization for manufacturers, importers, formulators, distributors and users of pesticides in Kenya was an active and prominent participant in the workshops. It was therefore in a better position to represent myriad of interests that arise from these groups. However, membership of AAK is voluntary thus it does not represent all stakeholders in the pesticide industry. The Kenyan Law Reform Commission also participated in the consultation workshops. The Commission has a statutory role of reviewing all the laws of Kenya to ensure that the regulations are modernized, relevant and harmonized with the Constitution of Kenya 2010. The involvement of the PestMatt Consultants, the expert, was also decisive and in compliance with the requirement of the Statutory Instruments Act. Several research institutions such as Maseno University, Kenya Medical Training College, South Eastern Kenya University, Kabianga University, Taita Taveta University, Machakos University, Kenya Agricultural and Livestock Research Organization (KALRO), International Center of Insect Physiology and Ecology (ICIPE), Jaramogi Oginga Odinga University of Science participated in the public consultation fora.

Articles 1 and 6 and Chapter 11 of the Constitution recognizes Devolved Government. Paragraph 1, Part 2 of the 4th Schedule to the Constitution of Kenya recognizes agriculture which includes plant and animal disease control as a devolved function now placed under the mandate of the County Governments. The County Governments are thus significant stakeholders in the regulation of the pest control products sector. In this regard, it was noted that there was adequate consultation of the County Government. The representatives of different Counties were consulted or participated in the process of review of the proposed Regulations. The Draft Pest Control Products Regulations were discussed by the Intergovernmental Joint Agriculture (JASSCOM), Sector Thematic Working Group (SWAG) on Policy, Regulations and Standards in Naivasha in January and February 2020 and approval granted for stakeholder consultations to be conducted.

Further consultations were undertaken across 37 Counties and representatives from various County departments attended the public fora. For instance, there was the attendance of representatives from the department of agriculture, department of public health, County coffee inspectors, among others. The outcome and the comments from the workshops were useful in the review of the proposed regulations. The private sector and the civil society were also given an opportunity to participate in the workshops. The Consultants has reviewed various versions of the draft regulations and is satisfied that the versions progressively evolved to take into account suggestions and comments received from the stakeholders.

Overall, the formulation of the draft regulations was fully compliant with the law relating to public participation and stakeholder engagement in Kenya.

8.0 ENFORCEMENT AND COMPLIANCE

The Pest Control Products Board shall be responsible for regulating and coordinating activities of stakeholders and organizations within the pesticide industry. To support the implementation of the regulations, the Board shall identify and gazette suitable individuals as Pesticide Inspectors and will closely collaborate with other Government departments and agencies including the National and County Governments, other relevant complementing state agencies, and stakeholders for successful roll out and implementation of the regulations.

Assuming the draft regulations are adopted, the following regulatory tools have been proposed to aid in ensuring their compliance: issuance, cancellation and suspension of permits as is the case of the proposed Pest Control Products (Importation and Exportation) Regulations, 2021. Other regulatory tools include registration, issuance of certificates and criminal sanctions as is with the case of the proposed Pest Control Products (Labelling, Advertising and Packaging) Regulations, 2021 and the proposed Pest Control Products (Registration) Regulations, 2021. Licensing is also a tool for enforcement as spelt out in the proposed Pest Control Products (Licensing of Premises) Regulations, 2021.

The Pest Control Products Act provides for penalties of contravening the Act. Penalties set out in the proposed regulations have to be in line with the penalties set out in the Pest Control Products Act and section 24(5) of the Statutory Instruments Act, 2013.

9.0 REVIEW, MONITORING AND EVALUATION

This chapter provides for review, monitoring and evaluation techniques that could be adopted by PCPB to ensure full implementation of the proposed regulations.

It is expected that review, monitoring and evaluation will be a subject of great interest to all parties including stakeholders in the industry particularly because of its potential to make it easier for the Board to regulate the pest control products industry. It is projected that the aim will be to cause a reduction in incidences of non-compliance with the Act thus ensuring food security for Kenya and safe and efficacious products available for use by the citizens. The parent Ministry working together with the Board and County governments will thus work hand in hand to promote research, reviewing, monitoring and evaluation of the effectiveness of the draft regulations towards promoting growth and development of this sector.

The RIA deduces that the establishment and maintenance of a pesticide industry database will contain information relating to all industry players, products manufactured, imports and exports, product sales and disposal. It further notes that as part of the monitoring and evaluation framework, government technical departments and other complimenting regulatory agencies will be mandated to monitor specific issues within the counties and the sector, and maintain resultant data and information to inform the review of regulations in the future.

10.0 CONCLUSION AND RECOMMENDATIONS

This chapter provides for other laws and policies that complement the proposed regulations. It also provides for the concluding observations regarding the proposed regulations and makes a specific recommendation on whether the proposed regulations should be adopted and implemented.

10.1 Conclusion

The pesticide industry needs to be well-structured and regulated for many reasons. The main objective is to protect human health and the environment from risks associated with pesticide use. This includes; protection of pesticide users, consumers, the general public, crops, livestock, wildlife, water bodies among others. Other important objectives include ensuring the effectiveness of pesticide products for their proposed use to facilitate sustainable support for agricultural development and ensuring a fair market for manufacturers, importers and distributors of pesticide products. Legislation is one of the tools that countries use to achieve these objectives, by regulating the manufacture, importation, transport, storage, sale, use and disposal of pesticides.

10.2 Recommendations

The RIA thus recommends the passing and operationalization of the proposed regulations.

10.3 Linking the Proposed Regulation to Other Regulations

The assessment by the RIA certifies that the regulations will be complimented by other laws and regulations. The proposed PCP regulations are linked to many other laws and regulations in Kenya including:-

i. The Constitution of Kenya 2010.
ii. Agriculture and Food Authority Act, 2013.
iii. Crops Act.
iv. Environmental Management and Co-ordination Act, 1999.
v. Food, Drugs and Chemical Substances Act Cap 254 Laws of Kenya.
vi. Occupational Safety and Health Act, 2007.
vii. Pest Control Products Board Act (CAP 346, revised 2012).
viii. Public Fees Act Cap 424 Laws of Kenya.
ix. Public Health Act Cap 242 Laws of Kenya.
x. Standards Act Cap 496 Laws of Kenya.
xi. Use of Poisonous Substances Act Cap 247 Laws of Kenya.
xii. Veterinary Surgeons and Veterinary Para-Professionals Act, 2011.
xiii. Agriculture Sector Development Strategy (ASDS, 2010-2020).
xiv. Cooperatives Policy.
xv. Environment and Development Policy.
xvi. Kenya Vision 2030.
xvii. National Agricultural Research Systems Policy.
xviii. National Food and Nutritional Security Policy.

xix. National Livestock Policy.
xx. National Productivity Policy.
xxi. Water Policy.
xxii. Relevant County Policies and Legislations.
xxiii. Animal Diseases (Compulsory Foot and Mouth Vaccination) Rules, 1966.
xxiv. Animal Diseases (Compulsory Rinderpest Vaccination) Rules, 1964.
xxv. Animal Diseases Rules, 1968.
xxvi. Environmental (Impact Assessment and Audit) Regulations, 2003.
xxvii. Environmental (Prevention of Pollution in Coastal Zone and other Segments of the Environment) Regulations, 2003.
xxviii. Environmental Management and Co-ordination (Waste Management Regulations), 2006.
xxix. Environmental Management and Co-ordination (Water Quality) Regulations, 2006.
xxx. Factories and Other Places of Work (Hazardous Substances) Rules, 2007.
xxxi. Factories and Other Places of Work (Safety and Health Committees) Rules, 2004.
xxxii. Food, Drugs and Chemical Substances (Food Hygiene) Regulations, 1978.
xxxiii. Public Fees Regulations, 1999.
xxxiv. Public Health (Meat Inspection) Rules, 1956.
xxxv. Veterinary Surgeons and Veterinary Para-professionals Regulations, 2013.

11.0 PERTINENT ISSUES

The Consultants raised the following pertinent issues relating to the proposed regulations:-

The Pest Control Products (Registration) Regulations, 2021 under regulation 7provides for confidential business information. Form D1 provides for the information to be provided by the registrant seeking registration under the regulations. It is important to note that, processing of sensitive and personal information under these regulations brings into play the provisions of the Data Protection Act 2019 which imposes an obligation on the person who is processing such information. The consultant recommends that the Ministry should comply with the provisions of relevant laws relating to the privacy of data in case any information handled include personal or sensitive data.

The Consultants noted that there are a proposed Pests Control Products Bill, 2021. The Bill seeks to safeguard human health and the environment from risks associated with pest control products; provide for the issuance, suspension and cancellation of licenses and permits; facilitate research into pest control products; advise on international Conventions and Treaties relating to pest control products and regulate all matters related to pest control products covered under the Bill. Further, the Bill strengthens the regulatory framework governing pest control products in the country by establishing the Pest Control Products Authority. It also provides for expansive and elaborate functions of the Authority. The Bill strengthens the regulator to safeguard human health from risks associated with pest control products by, *inter-alia* assessing and evaluating pest control products in accordance with the provisions of the Bill and regulations; advising on maximum residue limits for pest control products in line with international standards; establishing minimum intervals between the application of pest control products and harvest in respect of various commodities, to promote good agricultural practices and other practices on matters related to pest control products; to disseminate information on matters relating to pest control products; to implement ratified international conventions relating to pest control products; safeguard the environment from risks associated with pest control products; to periodically review registered pest control products; and to regulate the handling of pest control products by issuing licenses and permits. The Bill designates a Registrar who is mandated to perform functions pursuant to the Act. In addition, the Bill establishes a Committee in the Authority as an internal dispute resolution mechanism within the industry. The proposed dispute resolution Committee shall hear and determine disputes at the first instance, thereafter, the dispute may be referred to Arbitration. The Bill further provides for offences and penalties for contravention of its provisions. Lastly, the Bill gives powers to Cabinet Secretary to develop regulations on several areas to assist in the implementation of the Bill.

The draft Pest Control Products (License fees and other charges) Regulations, 2021 increases the charge fee of FOB value of imports to 1.4%, 50% shared with AAK for product stewardship. This may not be acceptable to some industry players not affiliated with AAK who may view it as adding to their cost of doing business. Additionally, AAK’s rules and codes of conduct cannot be enforced on non-members who fail to comply with this obligation.

The introduction or restructuring of licenses and fees for different categories of industry players and the requirement to maintain technically qualified personnel will also increase the cost of doing business, and given the fact that that the cost of trained human resources in Kenya is high, this may drive some small pesticide retailers (Agrovets) especially in rural areas out of business. This may have an impact on pesticide access by farmers who may require to cover long distances to buy the products, as well as result in livelihoods losses for such traders.

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