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An overview of biopesticides use and analysis of the Kenyan legal frameworks regulating biocontrol agents: a review

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Plant pests and diseases caused by fungi, bacteria, viruses and plant-parasitic nematodes continue to cause substantial yield and economic losses on agricultural production systems globally and in Kenya. Management of these diseases has relied heavily on synthetic chemical pesticides; however, extensive use has raised serious concerns related to human health, environmental contamination, pesticide resistance, and compliance with increasingly stringent maximum residue limits in domestic and export markets. Biopesticides have emerged as a viable and sustainable alternative, offering target specificity, biodegradability, and reduced ecological risks. This review provides a comprehensive overview of the types, mechanisms of action, formulation processes, and global development trends of biopesticides, with particular emphasis on microbial agents, botanical extracts, semiochemicals, macrobials, and plant-incorporated protectants. The paper further examines the scientific basis underpinning botanical biopesticides, including the role of plant secondary metabolites and their modes of antimicrobial and nematicidal action. A critical analysis of biopesticide development pipeline from discovery and efficacy evaluation to formulation and commercialization is presented. In addition, the review analyzes the Kenyan legal and institutional frameworks regulating biopesticides, highlighting the roles of the Pest Control Products Board, Kenya Plant Health Inspectorate Service, and associated regulatory instruments. While Kenya has comparatively advanced regulatory mechanisms for biopesticide registration within East Africa, challenges persist related to high registration costs, lengthy approval timelines, limited farmer awareness, and formulation constraints. The review identifies key gaps, opportunities, and policy priorities needed to accelerate adoption and commercialization of biopesticides, positioning them as a central pillar of integrated pest management and sustainable agricultural intensification in Kenya and similar agro-ecological contexts.

KEYWORDS

agro-environmental safety, botanical pesticides, crop protection, microbial pesticides, pesticide regulation, plant diseases

1 Introduction

1.1 Impact of plant diseases on food security

The diversity of plant pathogens all over the globe includes fungi, bacteria, viruses and nematodes that cause severe losses in terms of economics and production in the agriculture sector (Kannan et al., 2015). Fungal pathogens play a significant role in plant health (Yang et al., 2017) and as such, played a key role in driving technological advances in agricultural sciences from 1845 when the potato famine struck Ireland following successive crop failures (from 1845 to 1852) due to infection by *Phytophthora infestans* (Goyal and Manoharachary, 2014). Coffee leaf rust caused by the fungus, *Hemileia vastatrix*, Berk. and Broome, wiped out coffee in Ceylon (now Sri Lanka) (Hindorf and Omondi, 2011) and has continued to be the most significant disease of Arabica coffee in the coffee producing countries and is one of the most studied plant pathogens (Talhinhas et al., 2017). Rust is a major disease of wheat in Kenya and has caused yield losses and thus increase in mitigation costs (Suurbaar et al., 2017; Fetch et al., 2021). To date, rust diseases such as stem, leaf and head rust have remained a major threat to wheat crops causing significant yield losses and reduced grain quality (Fetch et al., 2021). The emergence of the Ug99 race of stem rust is especially significant, as nearly 90% of wheat varieties grown in Kenya are vulnerable to this strain, with a small number of wheat varieties and breeding lines that show resistance. This poses a serious threat to wheat production and food security (Singh et al., 2011; Singh, 2014; Raja et al., 2017; Li et al., 2019).

Plant bacterial pathogens adversely caused significant agricultural impact as early as 1932 when bacterial spot was detected in peach orchards (Stefani, 2010; Ravikumar et al., 2021). The most important pathogenic bacteria species belong to genera such as *Erwinia*, *Pectobacterium*, *Pantoea*, *Agrobacterium*, *Pseudomonas*, *Ralstonia*, *Burkholderia*, *Acidovorax*, *Xanthomonas*, *Clavibacter*, *Streptomyces*, *Xylella*, *Spiroplasma*, and *Phytoplasma* (Kannan et al., 2015). Majority of these diseases have been reported in Kenya causing significant quantity and quality losses. For instance, *Erwinia* spp. has been reported as one of the most important bacterial disease in Kenya causing several diseases in several economically important plants and is referred to as the premier phytopathogenic bacterium (Kannan et al., 2015). These bacterial diseases are widespread in many production areas of Kenya. The phytopathogenic *Agrobacterium* has been reported to cause significant losses in fruit trees, nuts, grapevines, vegetables, and ornamentals such as roses and chrysanthemums (Martins et al., 2018). *Xanthomonas* spp. causes at least 350 diseases with rotting symptoms, resulting in tremendous economic losses in agriculture. *Xanthomonas* species have numerous pathovars that affect various economically significant host plants and cause important diseases (Mansfield et al., 2012).

Plant parasitic nematodes inflict damages amounting to 157 billion dollars worldwide (Singh et al., 2015). They damage the host plant by causing wounds on the plant roots forming brown spots on the root, and swelling or rotting of the tubers (Kannan et al., 2015; Bernard et al., 2017). The topmost important plant parasitic nematodes include root-knot nematodes (*Meloidogyne* spp) comprising *Meloidogyne javanica*, *Meloidogyne arenaria*, *Meloidogyne hapla*, and *Meloidogyne incognita* representing the most devastating threat to agricultural crop production. In Kenya, they have a wide host range including ornamentals and cause damage by reproducing and feeding

within plant roots thus causing galls or root-knots thus disrupt the physiology of the plant. The most important one currently is the cyst nematodes *Globodera rostochiensis* and *Globodera pallida* that is causing serious threat to potato production in Kenya (Smiley, 2015). Potato cyst nematode was first detected and confirmed in Kenya in 2015 and has since been causing serious threat to potato farmers, most of whom are smallholders in rural areas (Mburu et al., 2018).

Plant viral diseases cause nearly 50% of emerging plant disease epidemics posing a major challenge to global food security, especially in tropical and subtropical regions (Manjunatha et al., 2022). The cumulative global economic loss caused by plant viral diseases is over USD 30 billion annually (Martínez-Gómez, 2025). Cassava Mosaic Disease (CMD), caused by cassava mosaic begomoviruses, and Cassava Brown Streak Disease (CBSD), caused by ipomoviruses, are responsible for devastating effects on cassava across sub-Saharan Africa (Jones, 2021). Maize Lethal Necrosis Disease (MLND) caused by co-infection of Maize Chlorotic Mottle Virus (MCMV) and potyviruses like Sugarcane Mosaic Virus (SCMV), caused significant yield losses in East Africa (Jones and Naidu, 2019). Likewise, Banana Bunchy Top Virus (BBTV), spread by aphid vectors, poses severe threats to both commercial plantations and smallholder banana systems across Asia and Africa (Islam, 2017).

Important fruit and vegetable crop viruses include, Citrus Tristeza Virus (CTV), that killed over 100 million trees globally, most of which were citrus grafted on sour orange rootstocks in Latin America (Jiang and Zhou, 2023). Tomato Yellow Leaf Curl Virus (TYLCV), transmitted by whiteflies, causes yield losses often ranging from 20 to 100% in tropical environments (Jones, 2021). Legume crops such as common bean and cowpea are frequently affected by viruses like Bean Common Mosaic Virus (BCMV) and Cowpea Severe Mosaic Virus (CPSMV), with yield losses reaching 60–80%, particularly in low-income regions of Africa and Asia where these crops serve as vital protein sources (Hema et al., 2014). There is therefore an urgent need for integrated viral surveillance, rapid diagnostic systems, and sustainable virus-vector management approaches (Devi et al., 2024).

The management of plant diseases in Kenya has for a long time been reliant on chemical pesticides to reduce damage and yield losses (Kumar et al., 2021). However, the use of these chemicals is associated with long-term threats and risks to living beings due to their harmful side effects. Biological pesticides can effectively replace these synthetic chemicals due to their characteristic bioresponsivity, reliability, and a reliant high efficacy (Archana et al., 2022). Based on chemical usage globally and even in Kenya, it is imperative that we come up with alternative methods, especially to increase the use of biopesticides. By minimizing chemical usage we will prevent evolving pest resistance against plant hosts hence promoting the prevalent application of biopesticides. These are compounds or organisms that occur naturally with low risks and are used to control pests and diseases (Kansiime et al., 2017). According to Suman and Dikshit (2010), Kumar et al. (2021), and Thakur et al. (2020), they are a diverse group of microbial pesticides and biochemicals derived from microorganisms and natural sources which are effective and biodegradable with no residuals to the environment (Chandler et al., 2011; Sharma and Malik, 2012; Kachhawa, 2017; Kutawa et al., 2016; Arjumend and Koutouki, 2018). These are either made from parts (phytochemicals, microbial products), by-products (Semiochemicals) or whole living organisms (natural enemies) (Kachhawa, 2017; Kutawa et al., 2016; Sharma and Malik, 2012). Plant-based biopesticides were used for crop protection by the

Greeks, Romans, and Egyptians (Alburo and Olofson, 1987; Raghavendra et al., 2016) long before the agrarian revolution (Figure 1). This review provides information on various important biopesticides and legal framework in the Kenyan context for registration.

2 Types of bio-pesticides

2.1 Microbial biopesticides

Microbial biopesticides are derived from microorganisms and their metabolites (Chandler et al., 2011; Kumar et al., 2021). Over 3,000 bacteria, 1,000 viruses, 800 fungi, 1,000 protozoa and 67 nematode species are all entomopathogenic to crop pests (Arjjumend and Koutouki, 2018; Holmes et al., 2019; Kutawa et al., 2016; Ruiiu, 2018). These microbial biopesticides offer an alternative to synthetic insecticides with high specificity plus ecological safety (Kansiime et al., 2017). The most successful and widely adopted of these is the bacterium *Bacillus thuringiensis* Berliner (Bt), which produces a crystal protein during bacterial spore formation capable of causing lysis of gut cells when consumed by susceptible insects (Speckbacher and Zeilinger, 2018). Currently, around 400 Bt formulations have been registered as biological control products and may be applied directly in sprays. Other microbial biopesticides include *Trichoderma harzianum*, *Coniothyrium minitans*, the K84 strain of *Agrobacterium radiobacter* used to control crown gall, *B. subtilis*, *P. fluorescens*, and *P. aureofaciens*. Microbial biopesticides are specific, nonpathogenic to wildlife, humans and other organisms, can be established in a pest population and can also be used as root and plant growth regulators. Their utilization as biocontrol agents in commercial applications has advantages due to their ability to be readily mass-produced through both *in vivo* and *in vitro* techniques, while also being exempt from registration requirements (Kumar et al., 2021). However, these biopesticides have their limitations as well. When exposed to heat, they lose efficacy and are only toxic to specific pests. Because they require unique formulations and storage procedures, there may be complications in the production and distribution of these pest control products (Kansiime et al., 2017).

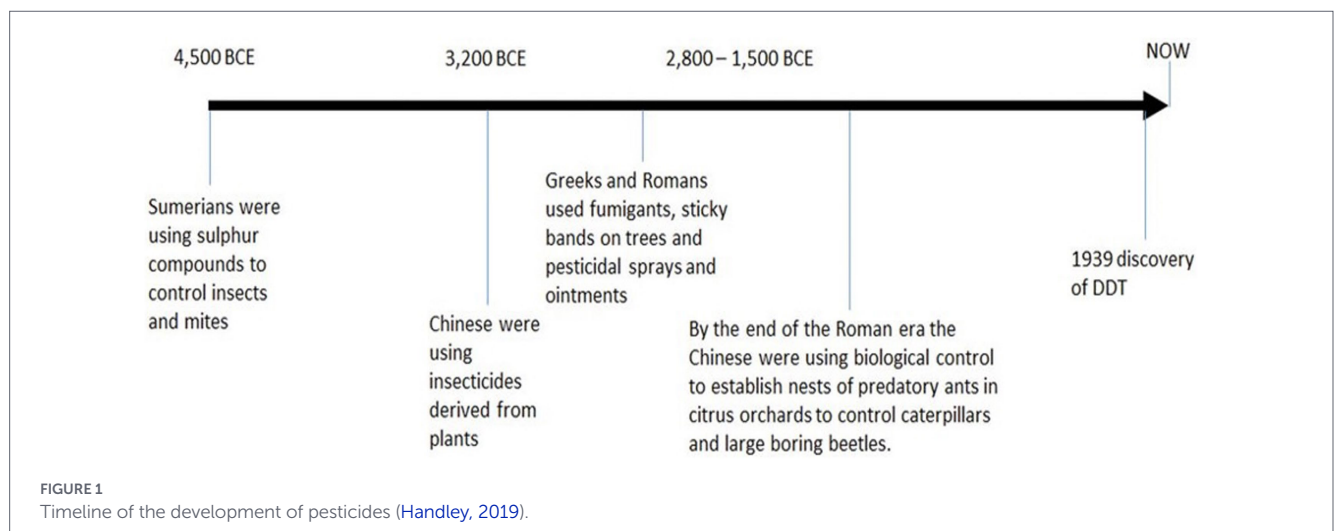
2.2 Macrobial biopesticides

Macrobial biopesticides consist of living natural enemies, including predators, parasitoids, and entomopathogenic nematodes, that suppress pest populations through direct predation or parasitism (Kutawa et al., 2016; Sharma and Malik, 2012; Kumar et al., 2021). A widely used example is the egg parasitoid *Trichogramma* spp., which has been released at large scale to control *Spodoptera*, *Helicoverpa*, and *Chilo* species in maize, cotton, and rice systems. These parasitoids reduce pest populations by preventing larval emergence, leading to significant yield protection with minimal environmental disturbance (Smith, 1996). Similarly, predatory mites such as *Phytoseiulus persimilis* are extensively used in greenhouse vegetable and flower production to control spider mites (*Tetranychus urticae*), offering rapid population suppression without pesticide residues (van Lenteren, 2012).

Entomopathogenic nematodes, particularly *Steinernema* and *Heterorhabditis* species, are effective against soil-dwelling pests such as cutworms, white grubs, and fungus gnat larvae. These nematodes carry symbiotic bacteria (*Xenorhabdus* or *Photorhabdus*) that kill the host insect within 24–48 h after infection, making them valuable tools in high-value horticultural systems (Lacey and Georgis, 2012). However, macrobial biopesticides require careful handling, cold-chain logistics, and appropriate release timing, which can constrain their widespread adoption among resource-limited farmers.

2.3 Semiochemicals

Semiochemicals are natural chemical signals produced by an organism and affects another organism of the same or different species (Chandler et al., 2011; Koul, 2011; Kumar et al., 2021). They can be volatile or non-volatile signals that operate long or short-range to modify the recipient's behavior (Singh, 2014). There are two broad groups of semiochemicals: pheromones that mediate interactions among individuals of the same species and allelochemicals that mediate interaction among individuals of different species. Allelochemicals are divided into kairomones that mediate interaction favoring recipient, allomones favoring the emitter and synomones favoring both the emitter and the recipient (Chandler et al., 2011; Kumar et al., 2021). In crop protection, semiochemicals influence pest behavior, microbial



virulence, and plant defense responses, offering environmentally benign alternatives to conventional pesticides. One of the most well-studied examples is the aphid alarm pheromone (E)- β -farnesene (E β F), a sesquiterpene released by aphids when attacked and plant-derived kairomones, including green leaf volatiles such as (Z)-3-hexenyl acetate, which repel aphid vectors (*Myzus persicae*), thereby lowering transmission rates of Potato virus Y (PVY) and Cucumber mosaic virus (CMV) in solanaceous crops (Beale et al., 2006). Beyond insect pests, semiochemicals regulate plant–microbe interactions, mainly through quorum sensing (QS) molecules produced by bacteria and fungi. Bacterial N-acyl homoserine lactones (AHLs), classical QS signals in Gram-negative bacteria, can be perceived by plants and trigger growth modulation and immune priming. Long-chain AHLs, such as oxo-C14-HSL, induce systemic resistance in *Arabidopsis thaliana*, enhancing resistance against *Pseudomonas syringae* through cell wall fortification and defense gene activation (Shrestha et al., 2020). Conversely, plants can reduce microbial virulence by interfering with microbial communication through quorum quenching, either by degrading QS molecules enzymatically or by producing QS mimics that disrupt pathogen coordination (Zhu et al., 2023). Fungal semiochemicals such as farnesol, and nematode signaling molecules like ascariosides, further expand the scope of semiochemical-mediated plant defense by modulating host immunity and pathogen behavior across kingdoms (Zheng et al., 2025). Semiochemicals are thus integral components of sustainable plant disease and pest management strategies, with strong potential for integration into regulatory-compliant biopesticide and integrated pest management (IPM) frameworks.

2.4 Plant incorporated protectants

Plant Incorporated Protectants (PIP) are biopesticide substances produced by plants from genetic material that have been added or incorporated into their genetic make-up, e.g., Bt protein (Chandler et al., 2011; Damalas and Koutroubas, 2018; Gupta and Dikshit, 2010; Kutawa et al., 2016; Sharma et al., 2018). When plants are genetically modified to produce a pesticide, they are regulated as pesticides by Environmental Protection Agency (EPA) in the United States and National Biosafety Authority (NBA) in Kenya and as plant products under EU plant protection regulations. Hence, the pesticide produced by such plants and the genetic material introduced are defined as PIPs. To date, scientists have had a lot of focus on the use of virus coat protein and replication genes for genetic engineering by incorporating them into plants. Several breeding programs across the globe have successfully incorporated genetic material into various crops for disease resistance as a long-lasting disease management strategy. Beyond insect resistance, viral coat protein-mediated resistance has been successfully deployed against plant viruses. For instance, transgenic papaya expressing the coat protein gene of Papaya Ringspot Virus (PRSV) effectively controlled the disease in Hawaii (Gonsalves, 1998). Despite these benefits, PIPs face regulatory, biosafety, and public acceptance challenges, particularly in African contexts, which have limited their deployment compared to conventional biopesticides.

2.5 Plant based extracts and essential oils

Botanicals or plant extracts are plant derivatives that can be used to control crop pests and diseases. Plant extracts were used to control crop insect pests long before the green revolution by the Greeks,

Egyptians, and Romans (Albuero and Olofson, 1987; Pavela, 2016; Raghavendra et al., 2016). However, after DDT's discovery, botanical biopesticides' use decreased significantly in the 20th century (Pavela, 2016). The intensive crop production systems led to the excessive use of synthetic pesticides negatively impacted humans and in the last three decades, global concern on the safe use of pesticides, food safety, and environmental degradation has led to a significant shift from synthetics to biopesticides (Damalas and Koutroubas, 2018). This change in preference and consumer demands has also resulted in increased adoption of plant extracts in integrated pest management (IPM) options and organic farming systems. Botanical pesticide plants are readily and commercially available, with most having multiple uses, such as medicines, spices, ornamentals, and organic soil amendments. Studies have reported antimicrobial effects of products from neem, custard apple, garlic, and ginger, among other medicinal plants. These can be applied as secondary metabolites, crude extracts or powder of dried plant parts (Choudhury et al., 2018). Commercialized pyrethrum, neem, and sabadilla biopesticides are less toxic to beneficial and non-target organisms, making them acceptable and reliable in a sustainable production system.

3 Mechanisms of pest control and development process of biopesticides

The antimicrobial activity of botanical biopesticides is reliant on plant bioactive compounds, primarily secondary metabolites, which are often influenced by genetic structure and environmental factors (Murtaza et al., 2015; Bittner Fialová et al., 2021; Liu et al., 2021). Extracts for control of phytopathogens have mainly been obtained from plant species such as *Aloe vera*, Eucalyptus (*Eucalyptus globulus*), Neem (*Azadirachta indica*), and herbaceous species like Garlic (*Allium sativum*), Mint (*Mentha spicata*), Ginger (*Zingiber officinale*). These plants synthesize aromatic secondary metabolites like phenols, phenolic acids, quinones, flavones, flavonoids, flavanols, tannins and coumarins (Bittner Fialová et al., 2021). The compounds containing phenolic structures, such as carvacrol, eugenols, and thymol, are highly active against plant pathogens and serve as plant defense mechanisms against plant pathogenic microorganisms (Table 1). However, their efficacies differ based on diversity in the chemical bio-composition, such as the secondary metabolites of plants. The antimicrobial activity of medicinal plants may be because of the synergistic activity of diverse bioactive metabolites that may act as antiseptic, cicatrizant and antiparasitic (Fyhrquist, 2007; Vaou et al., 2021). These compounds are classified into four classes: terpenoids, saponins, phenolic compounds and flavones, flavonoids and flavonols.

3.1 Global research progress on the use of plant biopesticides to control crop diseases

Various studies have been carried out on the efficacy of botanical biopesticides against plant pathogens. Though the success has been low compared to synthetic pesticides, there are some novel documented success stories across the globe and in Kenya (Table 2).

The process of biopesticide development involves two phases (Figure 2). Phase I involves the research and product development guided by regulations within the country of origin. This process is usually done under strict and controlled environments in research

TABLE 1 Common classification of phytochemicals and the modes of action.

Class	Sub-class	Description	Examples of pathogen	Mechanism of control	References
Phenolic compounds	Simple phenols	Low-molecular-weight phenolic compounds characterized by one or more hydroxyl groups attached to an aromatic ring	<i>Bacillus subtilis</i> , <i>Serratia marcescens</i> and <i>Pseudomonas aeruginosa</i> , <i>Escherichia coli</i> , <i>sclerotiorum</i> , <i>Alternaria brassicicola</i> , <i>Sclerotinia sclerotiorum</i> and <i>Cercospora carotae</i>	Disrupt microbial cell membranes through lipid interaction, denature proteins, interfere with enzyme activity, and impair energy metabolism	Bhardwaj et al. (2015), Choudhury et al. (2018)
	Alkylated phenols	Low-molecular-weight phenolic compounds characterized by one or more hydroxyl groups attached to an aromatic ring, with additional hydrocarbon side chains that increase lipophilicity and bioactivity			
	Phenolic acids	Aromatic acids that contain a phenolic ring and a carboxyl functional group, present in plants as free acids or conjugated forms		Alter cell membrane permeability, inhibit key metabolic enzymes, interfere with microbial adhesion, and disrupt proton gradients	Altemimi et al. (2017), Draz et al. (2019), Dulf et al. (2017), Kurmukov (2013)
	Phenylpropanoids, coumarins, quinines, anthraquinones, xanthenes	Phenylpropanoids contain a C6–C3 aromatic backbone, and their phenolic hydroxyl and methoxy substitutions enhance antifungal activity. Coumarins have a benzopyrone (lactone) ring system, whose planar structure and reactive carbonyl group enable interaction with fungal DNA and enzymes Quinines are characterized by a quinoline nucleus and a basic nitrogen atom, with biological activity arising from interaction with cellular membranes and enzymes. Anthraquinones contain an anthracene backbone with two keto groups. Xanthenes are based on a tricyclic dibenzo- γ -pyrone scaffold, where extensive conjugation and hydroxylation enhance binding to fungal enzymes and membranes, resulting in broad-spectrum antifungal activity		Interaction with eucaryotic DNA, interfere with nucleic acid synthesis, inhibit electron transport, induce oxidative stress, and disrupt cellular redox homeostasis	Al-Huqail et al. (2019), Gurjar et al. (2012), Monteiro et al. (2016)
	Tannins	High-molecular-weight polyphenolic compounds capable of forming strong complexes with proteins and other macromolecules; classified as hydrolysable or condensed tannins		Precipitate cell wall and extracellular proteins, inhibit hydrolytic enzymes, reduce nutrient availability, and suppress pathogen growth	Gurjar et al. (2012), Koche et al. (2016), Kurmukov (2013), Salhi et al. (2017)
Terpenoids (isoprenoids)	Sesquiterpenes, diterpenes, diterpenoids, triterpenoids	Lipophilic secondary metabolites biosynthesized from isoprene units; major constituents of essential oils and plant resins.	<i>Pletosphaerella cucumerina</i> , <i>Botrytis cinerea</i> , and <i>Alternaria brassicicola</i> , <i>Pseudomonas syringae</i> <i>Alternaria tenuissima</i>	Cell membrane disruption, increase membrane permeability, inhibit respiration, and cause leakage of cellular contents	Bhardwaj et al. (2015), Koche et al. (2016), Kurmukov (2013)

(Continued)

TABLE 2 (Continued)

Class	Sub-class	Description	Examples of pathogen	Mechanism of control	References
Alkaloids		Nitrogen-containing heterocyclic compounds whose basic nitrogen atom and rigid ring structures enable strong interactions with fungal cell membranes, DNA, and key metabolic enzymes such as morphine or caffeine, derived mainly from amino acids; and biologically active at low concentrations	<i>Aspergillus fumigatus</i> , <i>A. flavus</i> , and <i>A. niger</i>	Intercalate into cell wall, interfere with cell wall synthesis, inhibit key enzymes, disrupt nucleic acid function, and impair cellular metabolism	Koche et al. (2016), Salhi et al. (2017)
Flavonoids	Flavones, flavanones and flavonols-	Flavones feature a C2 = C3 double bond and 4-oxo group, with hydroxyl groups. Flavanones have a C2-C3 single bond. Flavonols possess both the C2 = C3 double bond and a unique 3-hydroxyl group Plants synthesize them in response to microbial infections via the phenylpropanoid pathway; involved in plant defense, signaling, and stress responses	<i>Colletotrichum coccodes</i> , <i>Phytophthora infestans</i> ,	Bind to adhesins, forms complex with the cell wall, disrupt membrane integrity, inhibit microbial enzymes, interfere with adhesion processes, and suppress pathogen development Inactivate enzymes	Kurmukov (2013), Salhi et al. (2017), Uwague (2017)
Lectins		Carbohydrate-binding proteins that specifically recognize sugar moieties on glycoproteins and glycolipids without enzymatic modification	<i>Fusarium culmorum</i> , <i>Fusarium oxysporum</i> , <i>Erwinia carotovora subsp. Carotovora</i>	Form disulfide bridges, Bind to carbohydrates on pathogen cell surfaces, causing agglutination, interference with nutrient uptake, and inhibition of growth	Freire et al. (2012)
Antimicrobial polypeptides (plant AMPs)	defensins, thionins, cyclotides, lipid transfer proteins	Short, gene-encoded cationic peptides/proteins produced by plants as part of innate defense		Inhibition of protein synthesis, enzyme inhibition, ROS induction or interfere with cell wall-associated processes	de Oliveira et al. (2025)
Glycosides	Saponins (triterpenoid and steroidal)	Amphiphilic glycosides composed of a hydrophobic aglycone linked to one or more sugar chains; constitutively present in many plant species	<i>Rhizopus stolonifer</i> , and <i>Sclerotinia sclerotiorum</i> , <i>Fusarium oxysporum</i> , <i>Fusarium solani</i> , <i>Rhizoctonia solani</i> , <i>Pestalotiopsis funerea</i> , and <i>Colletotrichum gloeosporioides</i>	The main compound produced by cayenne pepper	Kurmukov (2013), Salhi et al. (2017)

TABLE 2 Examples of plants with antimicrobial effects that have been successfully used to manage plant pathogens.

Plant	Common name	Plant part	Target pathogen	Mode of action	References
<i>Acacia saligna</i>	Golden wattle	Leaves, bark	<i>Rhizoctonia solani</i> , <i>Fusarium culmorum</i> and <i>Penicillium chrysogenum</i>	Tannins and phenolics inhibit fungal enzyme activity and cell wall synthesis	Al-Huqail et al. (2019)
<i>Acalypha wilkesiana</i>	Acalypha	Leaves	<i>Puccinia triticina</i>	Phenolics and flavonoids inhibit urediniospore germination and fungal respiration	Draz et al. (2019)
<i>Adenocallima alliaceum</i>	Garlic vine	Leaves	<i>Alternaria alternata</i> , <i>Fusarium oxysporum</i>	Organosulfur compounds disrupt membrane permeability and inhibit hyphal growth	Salhi et al. (2017)
<i>Allium cepa</i>	Onion	Seed	<i>Helminthosporium turcicum</i> and <i>Ascochyta rabiei</i>	Sulfur compounds (thiosulfates) disrupt cell membranes and inhibit metabolic enzymes	Gwa et al. (2018)
<i>Allium sativum</i>	Garlic	Bulb, leaves	<i>Pectobacterium carotovorum</i> subspecies <i>carotovorum</i> , <i>Pectobacterium atrosepticum</i> , <i>Dickeya dadantii</i> , <i>Phytophthora infestans</i> , and <i>Rhizoctonia infestans</i>	Allicin disrupts microbial membranes and inhibits thiol-containing enzymes	Ngadze (2013), Paradza et al. (2013)
<i>Artemisia herba alba</i>	White wormwood/ desert wormwood	Leaves, aerial parts	<i>Fusarium graminearum</i> and <i>Fusarium sporotrichioides</i>	Sesquiterpene lactones and essential oils disrupt fungal membranes and inhibit spore germination	Salhi et al. (2017)
<i>Asphodelus tenuifolius</i>	Onion weed/wild onion	Leaves, roots	<i>Fusarium graminearum</i> and <i>Fusarium sporotrichioides</i>	Phenolic compounds inhibit mycelial growth and interfere with enzymatic activity	Salhi et al. (2017)
<i>Azadirachta indica</i>	Neem	Leaves, bark, root, seed, fruit	<i>Penicillium expansum</i> , <i>Pectobacterium carotovorum</i> subspecies <i>carotovorum</i> , <i>Pectobacterium atrosepticum</i> , <i>Dickeya dadantii</i> , <i>Oidium anacardiae</i> , <i>Phytophthora infestans</i> , and <i>Rhizoctonia infestans</i>	The active compound azidarachtin inhibits fungal growth, spore germination and reproduction	Gwa et al. (2018), Ngadze (2013), Paradza et al. (2013), Shomari and Menge (2013)
<i>Calotropis procera</i>	Giant milkweed	Leaves, latex	<i>Helminthosporium turcicum</i> ; <i>Ascochyta rabiei</i>	Cardiac glycosides inhibit fungal enzyme activity and cell division	Gwa et al. (2018)
<i>Carica papaya</i>	Pawpaw	Leaves	<i>Colletotrichum kahawae</i> L., <i>Phytophthora infestans</i> , and <i>Rhizoctonia infestans</i>	Papain degrades pathogen proteins and hydrolytic enzymes	Ngadze (2013), Ngouegni et al. (2017)
<i>Chenopodium ambrosioides</i>	Mexican tea/wormseed	Leaves	<i>Rhizoctonia solani</i>	Ascaridole-rich oils inhibit mycelial growth and respiration	Singh (2014)

(Continued)

TABLE 2 (Continued)

Plant	Common name	Plant part	Target pathogen	Mode of action	References
<i>Chromoleana odorata</i>	Siam weed	Leaves	<i>Ustilago maydis</i> , <i>Ustilagoideae virens</i> , <i>Curvularia lunata</i> , and <i>Rhizopus spp</i>	Flavonoids and terpenoids disrupt fungal cell walls and inhibit sporulation	Singh (2014)
<i>Cotula cinerea</i>	Gray cotula	Aerial parts	<i>Fusarium graminearum</i> and <i>Fusarium sporotrichioides</i>	Essential oils impair membrane integrity and suppress spore germination	Salhi et al. (2017)
<i>Cymbopogon citratus</i>	Lemongrass	Leaves	<i>Colletotrichum kahawae</i> L., <i>Ustilago maydis</i> , <i>Ustilagoideae virens</i> , <i>Curvularia lunata</i> , and <i>Rhizopus spp</i>	Citral-rich essential oils disrupt membrane integrity and inhibit fungal respiration	Ngouegni et al. (2017)
<i>Datura stramonium</i>	Datura	Leaves, fruit	<i>Puccinia triticina</i> ; <i>Alternaria solani</i> ; <i>Fusarium oxysporum</i>	Tropane alkaloids (scopolamine, atropine) disrupt fungal cell membranes and inhibit spore germination and mycelial growth	Rahman et al. (2009), Chaudhary et al. (2015), Draz et al. (2019), Jalander and Gachande (2012)
<i>Datura stramonium</i>	Jimson weed	Leaves, fruit	<i>Globodera rostochiensis</i>	Alkaloids interfere with nematode neuromuscular activity and egg hatching	Kamau et al. (2020)
<i>Eucalyptus saligna</i>	Eucalyptus	Leaves, bark	<i>Colletotrichum kahawae</i> L.	Essential oils (eucalyptol) disrupt membrane integrity and inhibit spore germination	Ngouegni et al. (2017)
<i>Euphorbia guyoniana</i>	Euphorbia/desert spurge	Latex, aerial parts	<i>Fusarium graminearum</i> and <i>Fusarium sporotrichioides</i>	Diterpenoids inhibit fungal enzyme systems and suppress hyphal elongation	Salhi et al. (2017)
<i>Hedera helix</i> L.	Common ivy/English ivy	Leaves	<i>Erwinia amylovora</i>	Saponins increase bacterial membrane permeability leading to cell lysis	Baysal and Zeller (2004)
<i>Lantana camara</i>	Lantana	Leaves	<i>Puccinia triticina</i> Eriks	Pentacyclic triterpenoids disrupt cell membranes and inhibit fungal respiration	Draz et al. (2019)
<i>Lawsonia inermis</i>	Henna	Leaves	<i>Puccinia triticina</i> Eriks	Lawson (naphthoquinone) interferes with electron transport and fungal enzyme systems	Ambikapathy et al. (2011), Draz et al. (2019)
<i>Lawsonia inermis</i> L.	Henna	Leaves	<i>Pythium debaryanum</i>	Lawson (naphthoquinone) interferes with electron transport and fungal enzyme systems	Ambikapathy et al. (2011)
<i>Leonotis nepetifolia</i> L.	Lion's ear/christmas candlestick	Leaves	<i>Phoma exigua</i>	Phenolic diterpenes inhibit mycelial growth and spore germination	Singh (2014)
<i>Melia azedarach</i>	Chinaberry	Leaves	<i>Puccinia triticina</i> Eriks	Limonoids inhibit fungal growth and disrupt membrane integrity	Draz et al. (2019)

(Continued)

TABLE 2 (Continued)

Plant	Common name	Plant part	Target pathogen	Mode of action	References
<i>Mimosa pudica</i> L.	Sensitive plant/touch-me-not	Leaves, roots	<i>Pythium debaryanum</i>	Tannins and flavonoids inhibit zoospore motility and mycelial development	Ambikapathy et al. (2011)
<i>Morinda morindoides</i>	African mulberry	Leaves	<i>Oidium anacardii</i>	Anthraquinones inhibit fungal growth and disrupt conidial germination	Shomari and Menge (2013)
<i>Nicotiana tabacum</i>	Tobacco	Leaves	<i>Penicillium expansum</i>	Nicotine and alkaloids disrupt cell membranes and inhibit respiration	Gwa et al. (2018), Jangam et al. (2014); Rahman et al. (2016)
<i>Ocimum gratissimum</i>	African basil	Leaves	<i>Phoma exigua</i> , <i>Ustilago maydis</i> , <i>Ustilaginoidea virens</i> , <i>Curvularia lunata</i> , and <i>Rhizopus</i> spp.	Eugenol disrupts membrane permeability and inhibits fungal enzymes	Singh (2014)
<i>Ocimum tenuiflorum</i>	Holy basil/tulsi	Leaves	<i>Xanthomonas axonopodis</i> pv. <i>punicae</i>	Eugenol disrupts bacterial membranes and inhibits protein synthesis	Sherkhane et al. (2018)
<i>Opuntia cactus</i>	Prickly pear cactus	Cladodes	<i>Oidium anacardii</i>	Mucilage and phenolics inhibit spore adhesion and germination	Shomari and Menge (2013)
<i>Opuntia vulgaris</i>	Common prickly pear	Cladodes	<i>Oidium anacardii</i>	Bioactive polysaccharides suppress fungal growth and sporulation	Shomari and Menge (2013)
<i>Origanum compactum</i>	Moroccan oregano	Leaves, flowers	<i>Erwinia amylovora</i> , <i>Pseudomonas syringae</i> pv. <i>Syringae</i> , <i>Pseudomonas fluorescens</i> , <i>Pantoea dispersa</i> , <i>Pantoea agglomerans</i>	Carvacrol and thymol disrupt bacterial cell membranes and inhibit respiration	Kokoskova et al. (2011)
<i>Origanum vulgare</i>	Wild oregano/common oregano	Leaves, flowers	<i>Pseudomonas syringae</i> pv. <i>garcea</i>	Phenolic monoterpenes cause membrane destabilization and leakage of cellular contents	Kokoskova et al. (2011)
<i>Pelargonium odoratissimum</i>	Apple geranium	Leaves	<i>Erwinia amylovora</i>	Essential oils inhibit bacterial growth by damaging membrane integrity	Chiriach and Ulea (2012)
<i>Chenopodium ambrosioides</i>	Mexican tea/wormseed	Leaves (aerial parts)	<i>Rhizoctonia solani</i>	Ascaridole-rich essential oils disrupt fungal cell membrane integrity, inhibit mycelial growth, and interfere with respiratory metabolism	Singh (2014)
<i>Phyllanthus niruri</i> L.	Gale of the wind/stonebreaker	Whole plant	<i>Pythium debaryanum</i>	Phenolics suppress zoospore germination and hyphal growth	Ambikapathy et al. (2011)
<i>Piper nigrum</i>	Black pepper	Seed	<i>Penicillium expansum</i>	Piperine interferes with membrane function and mitochondrial activity	Gwa et al. (2018)

(Continued)

TABLE 2 (Continued)

Plant	Common name	Plant part	Target pathogen	Mode of action	References
<i>Punica granatum</i>	Pomegranate	Fruit peel	<i>Puccinia triticina</i>	Tannins and polyphenols denature fungal proteins and inhibit spore germination	Draz et al. (2019)
<i>Salvia officinalis</i>	Sage	Leaves	<i>Erwinia amylovora</i> , <i>Xanthomonas arboricola</i> pv. <i>corylina</i> , <i>Xanthomonas arboricola</i> pv. <i>juglandis</i> , <i>Pseudomonas syringae</i> pv. <i>Syringae</i> , <i>Agrobacterium tumefaciens</i>	Thujone and camphor disrupt bacterial membranes and metabolic pathways	Chiriac and Ulea (2012), Mikiciński et al. (2012)
<i>Senna occidentalis</i>	Coffee senna	Leaves	<i>Oidium anacardii</i>	Anthraquinones inhibit spore germination and fungal growth	Shomari and Menge (2013)
<i>Syzygium aromaticum</i>	Clove	Flower bud	<i>Erwinia amylovora</i> , <i>Xanthomonas arboricola</i> pv. <i>corylina</i> , <i>Xanthomonas arboricola</i> pv. <i>juglandis</i> , <i>Pseudomonas syringae</i> pv. <i>Syringae</i> , <i>Agrobacterium tumefaciens</i>	Eugenol damages bacterial cell membranes and inhibits protein synthesis	Mikiciński et al. (2012)
<i>Tagetes minuta</i>	Mexican marigold/ French marigold/ marigold	Leaves, flower	<i>Erwinia amylovora</i> , <i>Phytophthora infestans</i> ; <i>Rhizoctonia infestans</i>	Thiophenes interfere with fungal respiration and nematode nervous systems	Chiriac and Ulea (2012), Ngadze (2013)
<i>Tephrosia purpurea</i>	Wild indigo/purple tephrosia	Roots, leaves	<i>Pythium debaryanum</i>	Rotenoids interfere with mitochondrial respiration of pathogens	Ambikapathy et al. (2011)
<i>Thymus vulgaris</i>	Thyme	Leaves, oil	<i>Erwinia amylovora</i> , <i>Pseudomonas syringae</i> pv. <i>Syringae</i> , <i>Pseudomonas fluorescens</i> , <i>Pantoea dispersa</i> , <i>Pantoea agglomerans</i>	Thymol disrupts bacterial membranes and inhibits enzyme activity	Kokoskova et al. (2011), Mikiciński et al. (2012)
<i>Vinca rosea</i>	Periwinkle	Leaves	<i>Pythium debaryanum</i> , <i>Phytophthora infestans</i> and <i>Rhizoctonia infestans</i>	Indole alkaloids (e.g., vincristine, vinblastine) inhibit hyphal growth and spore germination by disrupting mitotic processes and cellular metabolism	Ambikapathy et al. (2011), Ngadze (2013)
<i>Xylopiya aethiopia</i>	African pepper/ Ethiopian pepper	Fruits (pods), bark	<i>Rhizoctonia solani</i> , <i>Ustilago maydis</i> , <i>Ustilagoidea virens</i> , <i>Curvularia lunata</i> , and <i>Rhizopus</i> spp.	Diterpenes and alkaloids disrupt fungal cell membranes and inhibit sporulation and hyphal elongation	Singh (2014)
<i>Zingiber officinale</i>	Ginger	Rhizome	<i>Penicillium expansum</i>	Gingerols and shogaols disrupt membrane integrity and inhibit fungal enzymes	Gwa et al. (2018); Parveen et al. (2014)

facilities. The experimental step begins with collecting and isolating potential microbes or fortifying the microorganisms, followed by identification, characterization and performance of efficacy bioassays (Mandakini and Manamgoda, 2021). Once a potential microorganism

is identified for biopesticide production, it is accurately identified and characterized. Efficacy bioassays can be *in vitro*, *ex vivo*, or *in vivo*, depending on the target pathogen or pest organism, and pilot trials under actual application conditions. Phase II entails mass production,

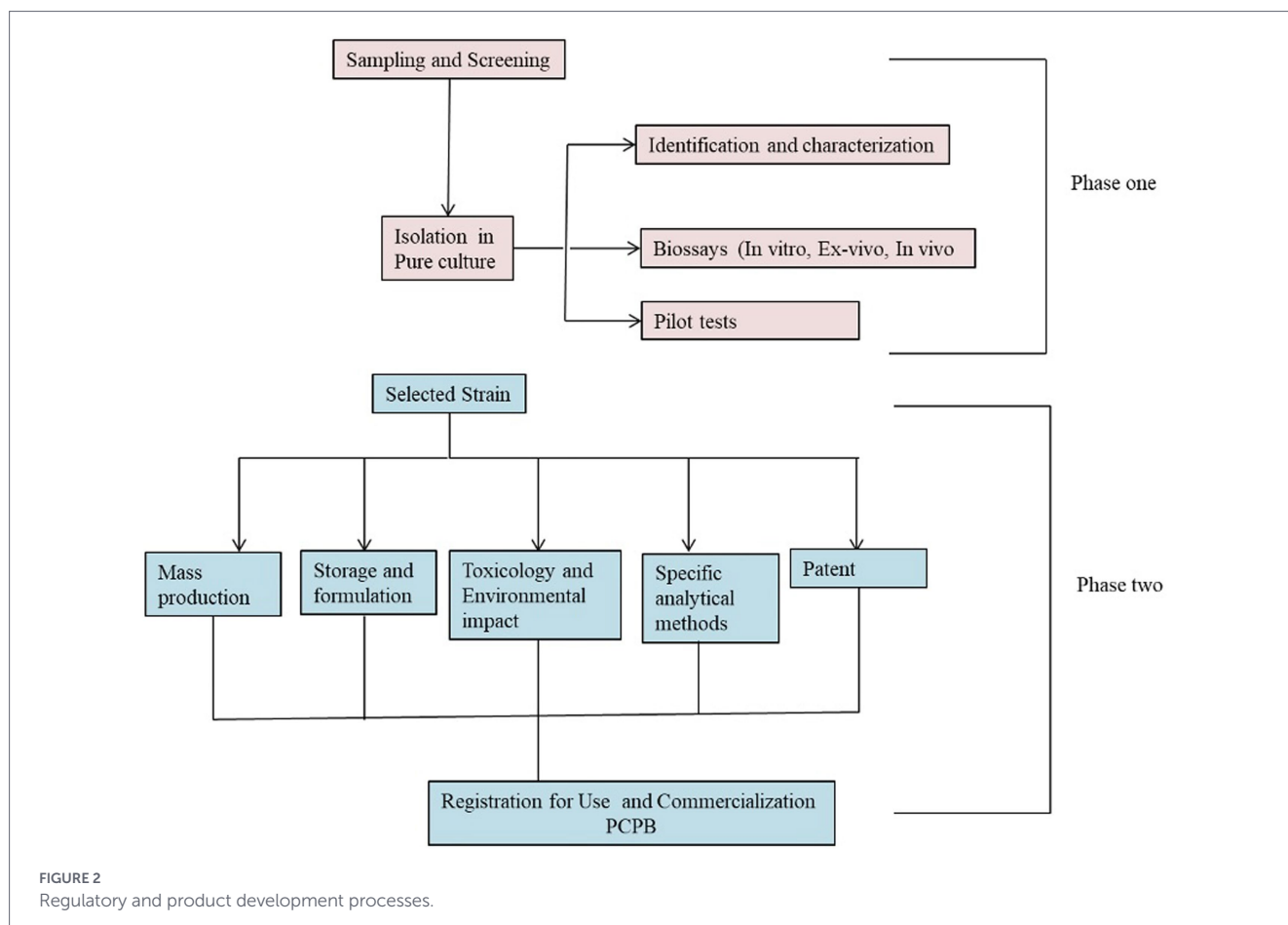


FIGURE 2
Regulatory and product development processes.

formulation, field testing and safety evaluation. Here several steps are involved with product and process development. Formulations are developed in the laboratory and pilot facilities which are scaled in manufacturing facilities (Strobel and Daisy, 2003; Kumar et al., 2019). Field studies are conducted and data are gathered for the regulatory submissions supporting product registration (USDA, 2017). Finally, biopesticides can be registered and introduced to the market upon completing safety evaluation and regulatory approval.

4 Formulation of botanical biopesticides

Over 20% of known plants have been used in pharmaceutical and crop protection studies across the globe. This has been facilitated by the high number of diverse bioactive compounds found in plants (Altemimi et al., 2017). For these products to be successfully utilized, they have to be extracted and formulated into forms that can be easily applied on plants as well as increase their shelf life (Marrone, 2007). However, according to Gašić and Tanović (2013) acceptable formulations are difficult to develop and this is mainly because the formulated product must keep its original biological function throughout storage and application. The formulation process leads to a final product by mixing with different carriers and adjuvants for survival as well improved bioactivity and storage stability (Hynes et al., 2011). Many of these biopesticides are based on living organisms and their viability must be maintained at levels that are acceptable during formulation

and storage (Gašić and Tanović, 2013). The development of biopesticide formulations that are both effective and safe is an important step in integrating this technology into IPM systems (Hynes et al., 2011). However, the formulation type is determined by the biocontrol agent's mode of action and the stage at which the host plant is most vulnerable to the agent. Formulation can be done through extraction methods by use of solvents such as methanol, hexane, ethyl alcohol; microwave-assisted extraction which involves the use of electromagnetic radiation in the range of 300 MHz to 300 GHz; and the most efficient and effective being ultrasonic assisted extraction which uses ultrasound (>20 kHz) to lyse cell walls.

Isolation and purification of bioactive plant compounds are achieved through a stepwise application of chromatographic techniques selected according to extract complexity and target compound abundance. Column chromatography and flash chromatography, including recycling preparative high-performance liquid chromatography (prep-HPLC), are routinely used for true purification of secondary metabolites to analytical or preparative purity (Sarker and Nahar, 2017; Wolfender et al., 2019). In contrast, paper chromatography and thin-layer chromatography (TLC) are primarily employed as analytical screening tools to rapidly assess the presence, number, and polarity of components in crude extracts (Sasidharan et al., 2017).

After purification, the structures of isolated compounds are elucidated using complementary spectroscopic techniques. The most common are ultraviolet-visible (UV-Vis) spectroscopy, infrared (IR) spectroscopy, and one- and two-dimensional nuclear magnetic resonance (^1D and ^2D NMR), including ^1H , ^{13}C , COSY, HSQC, and HMBG experiments. Mass spectrometry (MS) is used to determine molecular

mass and fragmentation patterns, while single-crystal X-ray crystallography, where suitable crystals are available, provides definitive three-dimensional structural confirmation (Claridge, 2016; Poupon and Nay, 2011; Wolfender et al., 2019). Most biopesticides are then formulated as dry (solid) formulations for direct application and they include dusts (DP), wettable powders (WP), and Granules (G). Liquid biopesticides formulations for dilution in water with adjuvants, protectants and nutrient and they include emulsions, suspension concentrates (SC) (Teicher, 2017; Bharti and Ibrahim, 2020).

5 Regulation and policy framework of biopesticides

Globally, various regulatory bodies and agencies such as International Organization for Biological Control (IOBC), the European and Mediterranean Plant Protection Organization (EPPO) and Organization for Economic and Co-operative Development (OECD) have been involved in resolving registration impediments faced by countries (FAO, 2012). Over the past 10 years, there has been an increase in the usage of bio-based products among farmers to manage pests and diseases in crops (Arora et al., 2016). However, the commercialization of these plant protection products is a rigorous process that necessitates testing and registration, which can be difficult with underdeveloped regulatory frameworks (AATF, 2013).

Even in countries with well-developed regulatory frameworks, issues persist since existing regulations mainly apply to conventional chemicals rather than biological pesticides. Establishing competent biopesticide guidelines is critical for safety and ensuring minimal restrictions on biopesticide commercialization (Guest, 2015). According to AATF (2013), it is crucial to develop robust systems for the registration of biopesticides based on scientific data, standards and working registration systems. Registering these biopesticides is critical to such regulatory regimes, ensuring that only approved pesticides are registered.

Biopesticides are utilized worldwide, although the regulatory processes and agencies involved differ at the regional and national levels. Various African countries have developed or are developing regulatory systems for biopesticides as part of an IPM strategy. In each of these countries, various organizations have the authority to regulate emerging biopesticides. For instance, in South Africa, laws and guidelines for regulations of registration and commercialization of biological control agents are under the Department of Agriculture, Forestry and Fisheries (DAFF) under the Act 36 of 1947 (DAFF, 2010). Under this act any product used as an agricultural input must be registered.

The act provides for all the micorganisms and metabolites contained within a product to be identified using accepted procedures and should be deposited in Agricultural Research Council (ARC) culture collection and be accompanied by an approved risk assessment indicating that the microbes that are not yet released in the South African environment are not potentially harmful to humans, plants, animals or the environment. In Nigeria, relatively few biopesticides have been registered and commercialized compared to South Africa and Kenya (Ashaolu et al., 2022). The National Agency for Food and Drug Administration (NAFDAC) is the agency mandated to regulate manufacturing, selling and distribution of fertilizers, biofertilizer and biopesticides (Ashaolu et al., 2022). Before granting a license for any biopesticide product in Nigeria, NAFDAC performs technical and

documentary regulatory evaluations to verify the product's safety and effectiveness. The NAFDAC classifies biopesticides as either microbial, biochemical and plant incorporated protectant pesticides. Closer home, in East Africa, Tanzania and Uganda have relatively registered fewer biopesticides as compared to Kenya. The regulatory body in Tanzania is the Tanzania Plant Health and Pesticides Authority (TPHPA) under the Ministry of Agriculture established by Act No. 4 of 2020 (Stadlinger et al., 2013). In Uganda, the National Agricultural Chemicals Board (UNACB) and the Agricultural Chemical Control Committee (ACCTC) are mandated by Ugandan laws to inspect and certify agrochemical trade (Arora et al., 2016).

6 Analysis of the Kenyan legal framework on biocontrol agents

6.1 Conceptual and legal positioning of biocontrol agents in Kenya

In Kenya, biocontrol agents are not regulated under a single stand-alone statute but are governed through an interlinked legal architecture anchored primarily in the Pest Control Products Act (Cap. 346) and subsidiary regulations. The Act adopts a functional definition of pest control products, covering substances, organisms, or devices intended to control pests, including insects, fungi, bacteria, viruses, weeds, and other harmful organisms (Pest Control Products Act, 2022). This expansive definition legally situates microbial, macrobial, biochemical, and semiochemical agents within the national pesticide regulatory regime.

Biological control agents are further distinguished through the Pest Control Products (Registration) Regulations, 2022, which explicitly recognizes microbial and macrobial biopesticides as separate categories, while genetically modified organisms (GMOs) fall under biosafety governance (Biosafety Act, 2009). This differentiation reflects Kenya's precautionary approach, ensuring that living organisms with potential for environmental establishment undergo heightened scrutiny.

6.2 Institutional mandates and regulatory authorities

6.2.1 Pest Control Products Board

All pesticides, for use in Kenya, are regulated by the Pest Control Products Board (PCPB), a statutory organization established in 1985 under Cap 346 Laws of Kenya. The Board is mandated to oversee all matters related to pesticides, including but not limited to regulation on importation and exportation, manufacture, distribution, sale and use of pest control products while mitigating their harmful effects on human health, animal health and the environment. The PCPB remains the principal authority responsible for the registration, evaluation, importation, manufacture, distribution, use, and advertising of biocontrol agents in Kenya. Its statutory mandate includes hazard and risk assessment, approval of labels, enforcement, and post-registration controls (Pest Control Products Act, 2022).

Under the 2022 Registration Regulations, PCPB evaluates biocontrol agents using EAC-harmonized guidelines, emphasizing quality,

safety, efficacy, and economic value before granting registration [Pest Control Products (Registration) Regulations, 2022]. The Board also administers temporary and emergency registrations, a critical provision for managing invasive pests and emerging phytosanitary threats.

Among the East African countries, Kenya has a well-developed biopesticides-specific registration legislation and mechanisms that ensure accurate assessment of the safety and dangers associated with microbial pesticides (Kabaluk et al., 2010; Arora et al., 2016). The PCPB is supported by stakeholders such as the UK DFID (Kabaluk et al., 2010) and was created through an act of Parliament, the Pest Control Products Act, Cap 346, Laws of Kenya which was enacted in 1982 (Pest Control Products Act, 1984). The Pest Control Products Act also provides for registration and regulations for microbial pesticides (Wabule et al., 2004; Kimani, 2014).

6.2.2 Kenya Plant Health Inspectorate Service

The Kenya Plant Health Inspectorate Service (KEPHIS), through the Act, Cap 512 of 2013, and Plant Protection (Biological Articles and Control Agents) Regulations, Draft (2020), regulates the imports and exports of live organisms. The act provides for application for introducing microbial and macrobials through KEPHIS, where the Kenya Standing Technical Committee on imports and exports (KSTCIE) operates under Cap 324 and advises the importer of the requirements and the areas to be addressed by the applicant.

KEPHIS plays a complementary role, particularly for introduction, release, and movement of biological organisms. Applicants introducing live biocontrol agents must demonstrate compliance with phytosanitary and plant protection requirements, including controlled release protocols and post-release monitoring (KEPHIS, 2020). This dual oversight ensures that biological agents do not compromise plant health or biodiversity.

6.2.3 National Biosafety Authority

Where biocontrol agents involve genetically modified microorganisms, regulatory jurisdiction shifts to the Biosafety Act, Cap. 320 (2009). The Act mandates prior approval, environmental risk assessment, public participation, and post-release monitoring, reinforcing Kenya's adherence to the precautionary principle (Biosafety Act, 2009).

6.3 Registration, data requirements, and evaluation procedures

The registration process of pesticides in Kenya is governed by the Pest Control Products Act Cap 346 of the Laws of Kenya. The act defines a pest control product as a product, device, organism, substance or thing manufactured, sold or used to directly or indirectly control, destroy, attract or repel any pest. Biopesticides can be categorized into five major classes: microbial pesticides, biochemical pesticides, botanical pesticides, natural enemies and plant-incorporated protectants. The board considers pest control products' safety, efficacy, quality, and economic value in line with the registration regulations LN46/1984.

Kenya's regulatory framework requires biocontrol agents to undergo scientific and regulatory evaluation proportionate to their risk profile. The Registration Regulations (2022) specify distinct summary dossiers (Forms B1-B4) for microbial, macrobial, biochemical, and semiochemical products, reflecting product-specific data needs.

Applicants must submit:

- i Taxonomic and strain identity, including national collection numbers for microbial agents;
- ii Local efficacy data, generated under EAC or national trial guidelines;
- iii Human and environmental safety data, including pathogenicity, infectivity, and non-target effects; and
- iv Labeling information, aligned with statutory labeling and advertising rules [Pest Control Products (Registration) Regulations, 2022].

Notably, classical biological control agents released by authorized government institutions are exempt from registration, though still subject to institutional oversight and biosafety considerations. This exemption reflects policy recognition of public-good biological control programs while maintaining safeguards [Pest Control Products (Registration) Regulations, 2022].

To facilitate the registration and adoption of biopesticides, a face-to-face pre-submission consultation between the applicant/registrant and the registration authority (PCPB) is recommended. The registrant provides summary data containing details of the biopesticide, origin of the active agent, deposition of culture in a nationally recognized culture collection, any non-microbial active ingredients, and proof of ownership of the microbial biopesticides to be registered. A decision must be made on whether to grant registration according to the completeness of the data and a satisfactory outcome of risk assessments. In the case of an application for a complete registration, the registration authority may decide to grant provisional approval if further data are required. This situation may arise with a new product with insufficient field use experience. For regulation purposes, local efficacy trials should be conducted following the laid down procedures and data generated.

6.4 Labeling, advertising, and market controls

The Pest Control Products (Labeling, Advertising and Packaging) Regulations, 2024 strengthen consumer protection and stewardship by requiring accurate representation of product composition, use instructions, and safety precautions. Biocontrol products are expressly prohibited from being labeled or advertised in a misleading manner, including unsubstantiated claims of safety or efficacy [Pest Control Products (Labeling, Advertising and Packaging) Regulations, 2024]. These provisions are particularly important for biological products, which are often perceived as inherently "safe," despite potential risks to non-target organisms and ecosystems if misused.

6.5 Importation, trade facilitation, and digital governance

The National Electronic Single Window System Act (2022) integrates PCPB and other regulatory agencies into a digital trade facilitation platform, streamlining import and export approvals for pest control products, including biocontrol agents. This reform enhances transparency, traceability, and regulatory coordination while reducing administrative bottlenecks (National Electronic Single Window System Act, 2022).

6.6 Enforcement, compliance, and sanctions

The PCPB is empowered to appoint inspectors, seize non-compliant products, and prosecute offenses related to unauthorized manufacture, importation, labeling, or sale of pest control products (*Pest Control Products Act, 2022*). Penalties include fines, imprisonment, forfeiture of products, and revocation of registration certificates. These enforcement mechanisms apply equally to both biological and conventional products.

The Kenya regulatory framework requires extensive data on the safety and efficacy of biocontrols which is costly and time consuming (*Hamer, 2003*). Biocontrol agents, while generally considered safer than chemical pesticides, can still have unintended ecological impacts. Regulatory frameworks may lack robust mechanisms for assessing and mitigating these risks. To address these gaps, regulatory authorities, policymakers, and stakeholders in the agriculture and biotechnology sectors need to work together to develop flexible, science-based regulations that balance the need for safety with the desire for innovation and sustainability.

6.7 Current status of registration of biopesticides

The Pest Control Products Board (PCPB) has registered various pest control products. Over the last decade, there has been an increase in the number of applications for registration of biopesticides because of the maximum residue limits concerns locally and in the European and other export markets (*Ngaruiya, 2004*). As at now, 91 biopesticides are listed at the PCPB website as fully registered.¹

7 Challenges, drawbacks and opportunities to uptake of botanical biopesticides

Development, utilization, and promotion of plant-based protectants, like other crop protection products, face challenges at various levels. Development is hampered by high costs of product development, legal restrictions, limited availability of germplasm, product formulation and short shelf life of the products (*Chandler et al., 2011; Holmes et al., 2019*). Utilization is minimal among farmers because the products are usually specific to pests, while the users prefer broad-spectrum products to minimize the costs of applications. This is further curtailed by the ability of the products to control pests at only specific growth stages and specific dosages. This, therefore, renders them less preferred as farmers have to buy and apply several products as opposed to synthetic pesticides (*Arjjumend and Koutouki, 2018; Kutawa et al., 2016; Marrone, 2007*). There is a need for coordination in developing biopesticides to address the challenges through research, which requires skilled human resources and adequate physical infrastructure. There is also a need for greater interaction and collaboration between various disciplines and sectors. The adoption can be enhanced through advocacy and integration with other pest management practices.

¹ <https://www.pcpb.go.ke/biopesticides-on-crops/>

The biopesticides industry is experiencing rapid growth driven by increased environmental and health consciousness, a focus on sustainability, regulatory mandates, and heightened demand from retailers (*Ndolo et al., 2019*). Multinational agricultural chemical corporations are making substantial investments in this sector, leading to the anticipated expansion of the biopesticide market. Projections suggest that biopesticides could conceivably rival chemical pesticides in market size over the next 20–30 years (*Olson, 2015*). According to *Glare et al. (2016)*, *Glare et al. (2012)*, and *Koul (2011)*, biopesticides are set to increase worldwide. An assessment by *Glare et al. (2016)* put the increase to 15% annually worldwide; as such, biopesticides may be entering a new era of mainstream use. In the last decade, there has been an increase in the range of registered biopesticides. Many countries have or are developing regulatory processes for microbial-based requirements. Harmonization of regulations and development of particular guidelines for biopesticides assessment hamper the development and commercialization of biopesticides. As demonstrated by the increasing sales, the future of biopesticides is promising; however, there is a need to develop a policy framework that will support commercialization and remove barriers to commercialization on a global scale.

7.1 Policy framework and business environment

Policy changes in Europe and elsewhere requiring more detailed safety data and maximum residue limits for synthetic pesticides may have changed the commercial interest in plant-based pesticides. Some countries such as China, India and Brazil have created favorable regulatory frameworks and have subsequently observed considerable growth in registered and commercialized plant-based pesticides (*Arjjumend and Koutouki, 2018*). Similar efforts need to be pursued by other countries worldwide. In Africa, strong heritage and ongoing use of plants as pesticides exist, particularly in small-holder agriculture (*Singh, 2014*). In addition, until relatively recently, East Africa was the leading global provider of crude pyrethrum. Therefore, there is great potential for natural pesticide development in Africa, toward which many African governments, policymakers and scientists can create the enabling regulatory and promotional environments required to encourage and facilitate entrepreneurs wanting to develop local practices into sustainable value chains for commercialized natural pest control products.

7.2 Research and development

Though research on plant-based pesticides has been ongoing for decades in Kenya, there has been limited focus and support for research in this area. Most of the research work has not been moved from the laboratory to the field due to a lack of suitable infrastructure, equipment and motivation to facilitate this level of research. Most of the research has been on using crude extracts of the plants and whole plant parts. However, this is not practical when it comes to adoption and application by farmers due to low efficacy and shelf life. There is a need to invest in the research and development of commercial products by refining research outputs into suitable formulations and toxicity studies. Governments must also deliberate efforts to facilitate the process of intellectual property protection, research enablers/incentives to researchers and entrepreneurs, and public-private partnerships to accelerate the uptake of research outputs by the industry.

8 Future perspectives

The biopesticides are seen as a vital component of integrated pest management (IPM) strategies, which aim to minimize chemical pesticide use and promote sustainable agricultural practices. Research into the identification and isolation of plant bioactive compounds will continue to advance. There is need for harnessing the most effective secondary metabolites from various plant sources. This will lead to the development of more potent and targeted botanical biopesticides with improved efficacy in pest and disease control. The development of new technologies, such as nanotechnology and genetic engineering, will enhance the formulation and delivery of botanical biopesticides which will improve the stability and shelf life of these products, making them more attractive to farmers. The production and commercialization of botanical biopesticides will create economic opportunities, particularly for rural communities involved in farming and the collection of plant materials. As demand for these products increases, it will stimulate job growth in the agricultural and biopesticide industries. The future of plant pathogen management in agriculture is expected to be increasingly shaped by botanical biopesticides as the world moves toward more sustainable and environmentally friendly farming practices. These products will play a vital role in ensuring food security, preserving ecosystems, and promoting healthier and safer food production. However, addressing the challenges and seizing the opportunities in this field will require collaborative efforts from various stakeholders, from researchers to policymakers to farmers.

9 Conclusion

In conclusion, botanical-based pesticides offer promising potential for the management of plant diseases. Formulations have yielded various active compounds that are capable of effectively managing plant diseases when applied in appropriate doses. Nevertheless, until now the development and adoption of these products encounter challenges across different stages. In light of the need for safe and sustainable pest control solutions, biopesticides present a growing opportunity for the industry's expansion. To foster the growth of commercial botanical pest control products, it is essential for governments and policymakers to establish a conducive regulatory framework. Simultaneously, consumers can play a pivotal role by creating a lucrative market segment that incentivizes the utilization of these eco-friendly products.

Author contributions

GA: Conceptualization, Methodology, Writing – review & editing, Investigation, Writing – original draft, Data curation. EG:

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