Article

Recommendations for Effective and Sustainable Regulation of Biopesticides in Nigeria

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Abstract: The global trend towards increased demand for organic food, greener environments, and the integration of biological control agents into pest management strategies has greatly enhanced the need for biopesticides. Biopesticides are made from micro-organisms or other natural substances and are, hence, generally environmentally friendly. However, despite their great potential—and in part due to regulatory challenges—relatively few biopesticides have been registered and commercialised in Nigeria compared to other African countries, such as South Africa and Kenya. Biological active agents are so diverse that applying the same safety standards to all of them is almost impossible. A comparative review of risk assessment processes of Nigeria’s biopesticide regulations with other developing African countries (South Africa and Kenya) and developed regions (the European Union and the United States of America) was conducted. Prolonged field testing, lack of bridged risk assessments, and technical checklists were identified as key factors hampering the research and development of biopesticides in Nigeria. Suitable amendments to the existing regulations guiding biopesticide formulation and utilisation in Nigeria are recommended. Risk assessment matrices for microbial and biochemical pesticides and a scientific/technical checklist have also been developed. It is apparent that harmonisation and data exchange among countries in the region could enhance the advancement of scientific and technical knowledge for sustainable regulation of, and cross-border trade in, biopesticides.

Keywords: biopesticides; regulations; risk assessment; regulatory challenges; sustainability; Nigeria

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1. Introduction

It has always been necessary to protect plants from pests and pathogens to provide the human population with quality and sufficient food. Conventional synthetic pesticides have been used effectively over the years to ensure food safety and security. However, there has, over the last few years, been a global drive towards more organic food production and greener environments—and consequently, a strong push for the integration of biopesticides into pest management strategies [1].

There is no single, internationally agreed-upon definition for biopesticides. The Food and Agriculture Organisation (FAO) describes biopesticides as products with active substances that are based on botanicals, semiochemicals, or microbials [2]. The Organisation for Economic Cooperation and Development (OECD) refers to biopesticides as biocontrol agents that include microbials, pheromones, and other semiochemicals and invertebrates [3]. Despite the great potential of these products, the associated regulatory processes for their authorisation are generally lengthy, time-consuming, and costly [4]. Disproportionate data requirements associated with extended assessment processes can present a

significant challenge that deters biopesticide companies from applying for registration in some jurisdictions [5].

Ideally, regulations should not be an obstacle to the development and commercialisation of biopesticides, but rather a scientific tool or process to ensure safety of environment, human, and animal health. The different definitions and classifications of biopesticides, with variations in data requirements and regulatory frameworks, remain an issue of concern for biopesticide research and development. While some countries or regions (e.g., European Union (EU)) have adopted the conventional pesticide regulatory models for the regulation of biopesticides [6], others have customised regulations (e.g., Nigeria and the United States of America (USA)).

The fact that biologically active agents are so diverse makes it almost impossible for regulators to apply the same consumer safety criteria or environmental conditions to all of them [7]. The issue of multiple modes of action is one of the concerns related to the regulation of biopesticides [8]. For example, even though *Trichoderma* species are used as biopesticides against soil-borne plant pathogenic fungi [9], they are also known to enhance the absorption of micro- and macronutrients from the soil [10]. They also function as cell wall degrading enzymes, parasitise plant pathogenic fungi, and also produce antibiotics [9,11]. Fluorescent *Pseudomonas* can also be used as both biocontrol agents as well as plant growth promoting agents [12]. The OECD is making concerted efforts to promote harmonised data requirements. This action will enable companies to easily submit applications for registration and, on the other hand, create a mutually beneficial platform for regulatory agencies to benefit from each other [13].

The National Agency for Food and Drug Administration and Control (NAFDAC) is the national regulatory authority responsible for regulating biopesticides in Nigeria. Prior to the licensing of any biopesticide product in Nigeria, NAFDAC conducts technical and documentary regulatory reviews to ensure the safety and efficacy of the product. However, despite the availability of regulatory procedures, and the interest to promote the development and commercialisation of biopesticides, only a few have been registered in Nigeria, compared to other African countries, such as South Africa and Kenya (Figure 1). This may be due to the requirement for extensive field testing and screening procedures, inadequate risk assessment techniques, and low public awareness.

Figure 1. Registered biopesticides (as at July 2021) in Nigeria [14], South Africa [15], and Kenya [16].

The objective of this study was to review Nigeria's biopesticide regulatory system and make recommendations to facilitate the development of a more sustainable regulatory approach to enhance their development and commercialisation.

Regulatory Challenges to Biopesticide Registration

Assessment of the safety and efficacy of a biopesticide product is an essential prerequisite for its authorisation. However, many investors view regulatory oversight as an impediment to the timely development and commercialisation of their products. The extended field trials and risk assessments conducted (usually over two different growing seasons) are seen as a key challenge for the research and development of biopesticide products. A further challenge is the multiplicity of modes of action of certain microorganisms. This often leads to regulators requiring a lot of data to enable them to better establish safety and efficacy criteria for these products. In addition, most applicants who intend to register Plant Incorporated Protectants (PIPs) as biopesticides do not often return to finalise their registration process. This is probably due to their inability to comply with the relevant GMO safety assessments at the responsible Biosafety Agency (e.g., the National Biosafety Management Agency in the case of Nigeria). The successful commercialisation of biopesticides after registration is also another major challenge for investors. Biopesticides are expected to compete with existing conventional pesticides in terms of cost, market acceptability, and mode of action. Compared to biopesticides, conventional pesticides have been on the market for decades—and are thus well known to the public and less expensive. They also have a faster mode of action, compared to biopesticides. Political, social, and societal pressures also pose a significant challenge to the effective marketing of biopesticide products in Nigeria.

2. Methodology

To achieve the objectives of this research, three distinct, but related, strategies were employed.

i. Comparative assessment of biopesticide regulations:

A comparative assessment of the Nigeria biopesticide regulations versus those of select African developing countries (South Africa and Kenya) and developed regions (EU and USA) were carried out. This was done to identify regulatory gaps and, consequently, make recommendations to improve the Nigerian biopesticides regulatory system. The available online biopesticide-related regulations with summary of the assessments for each of the countries and regions are shown in Table 1.

Table 1. Overview of the regulatory framework comparison between EU, USA, South Africa, Kenya, and Nigeria.

Indicators	Regulatory Frameworks				
	EU	USA	South Africa	Kenya	Nigeria
Biopesticide Regulations	Regulation (EC) N0. 1107/2009 [17]	40 CFR Part 158 [18]	Guidelines for Registration of Biological\Agricultural Remedies in South Africa 2015 [19]	Pest Control Products Act [Act No. 4 of 1982, L.N. 89/1983, Act No. 6 of 2009) [20]	Biopesticide Registration Regulations 2019 [21]
Authorities	EC, EFSA RMS	USEPA	DALRRD	PCPB	NAFDAC

Table 1. Cont.

Indicators	Regulatory Frameworks				
	EU	USA	South Africa	Kenya	Nigeria
Definition	A pesticide is something that prevents, destroys, or controls a harmful organism (pest) or disease, or protects plant or plant products during production, storage, and transport.	Pesticides derived from such natural materials as animals, plants, bacteria, and certain minerals.	Any biological remedy or mixture or combination of any substance excluding any biological remedy controlled under the medicines or the hazardous substance act.	Biological pest control agents that are naturally occurring or genetically modified agents or derived from natural materials.	Pesticides derived from such natural materials as animals, plants, and microorganisms.
Major Classification	Pesticides: (Insecticides, Fungicides, Rodenticides, etc.)	Biochemical, Microbial Plant Incorporated Protectants.	Microbial, Biochemical and Semiochemical, Macrobial, Enzymes, Hormones and Plant extracts.	Biochemical, Microbial, Macrobial.	Biochemical, Microbial, Plant Incorporated Protectants.
Data Requirements					
Product Chemistry (Including Identity, Composition, Analysis and certified limits, Physicochemical properties)	✓	✓	✓	✓	✓
Risk Assessments (Human Health and Environmental)	✓	✓	✓ (Accepts existing scientific toxicological data).	✓	✓
Residue Data	✓	✓ (Required if: microbial biopesticide (MBP) has a significant potential to produce a mammalian toxin; and if use pattern is such that residues may be present in or on food or feed crops).	✓	✓	✓
Efficacy (Performance Data)	✓	Not required unless claims to control public health pest.	✓	✓	✓
Quality Control (Methods of Analysis, Manufacturing, Stability Test, Determination of shelf life)	✓	✓	✓	✓	✓

European Commission (EC), European Food Safety Authority (EFSA), Member/Rapporteur Member States (RMS), United States Environmental Protection Agency (USEPA), Department of Agriculture, Land Reform and Rural Development (DALRRD), Pest Control Products Board (PCPB), National Agency for Food and Drug Administration and Control (NAFDAC).

ii. Review of the Nigerian biopesticide regulations and guidelines:

The Nigerian biopesticide regulations/guidelines were reviewed to generate recommendations needed for amendment. The documents assessed were: Biopesticide Registration Regulations 2019, Guidelines for Issuance of Permit to Import Field Trials Samples (Doc. Ref. No: VMAP-GDL-016-06) and Guidelines for Listing as Pesticides, Agrochemicals, Fertilisers, Biopesticides and Bio-fertilisers Marketers (Doc. Ref. No: VMAP-GDL-016-05)-Table 2.

Table 2. Outcome of the review of the Nigerian biopesticide regulations.

Regulations	Section	Regulation Comment	Observation/Recommendations
Biopesticide Registration Regulations 2019	4(5)	The Agency shall, from time to time, publish the list of registered biopesticides on the Agency's official website, notifying the registration of a biopesticide.	Technically, specificity is important, the word "time to time" can be replaced with more specific words like: The Agency shall update the list of registered biopesticides following each approval (or de-registration) of a new biopesticide.
	5(i)	Efficacy assessment of a biopesticide to be introduced into the market shall be carried out to ensure that biopesticide approved would be efficacious for its intended use.	If the Agency is of the view that relevant data of good quality has been generated in other countries, then it may waive the requirement for local data generation, especially when importing from countries with similar environmental and climatic conditions.
	5 (iv)	The assessment shall be monitored by the Agency at an approved research institute(s).	It is necessary to have a list of approved research institutes as an appendix. The needed capacities of the research institutes may also be stated to serve as a template for upcoming institutes.
	11 (2)	A manufacturer or importer engaged in the manufacturing, importation, distribution, sale, or storage of biopesticide shall submit preliminary and final reports to the Agency of any adverse effect on non-target organism and environment, loss of effectiveness associated with biopesticide occurring in Nigeria or elsewhere.	It will be more appropriate to immediately notify the agency of any adverse effects on environment, human, and animal health. Submission of reports may come later. This is to ensure timely mitigation of any adverse impacts.
Guidelines for Issuance of Permit to Import Field Trials Samples (Doc. Ref. No: VMAP-GDL-016-06) [22]	8(2)	The trial should be carried out according to the approved protocol for experimental/efficacy trial.	It is important to specify the approved protocols, e.g., OECD guidelines, etc.
Guidelines for Listing as Pesticides, Agrochemicals, Fertilisers, Biopesticides, and Bio-fertilisers Marketers. (Doc. Ref. No: VMAP-GDL-016-05) [22]	2.2.6	Appointment and acceptance letters, passport photographs of the technical officer including all credentials (Degree, National Youth Service Corps (NYSC) certificates, etc.). The technical officer should have scientific background with minimum of Ordinary National Diploma or its equivalent.	Technical officer with relevant training in biotechnology, or biopesticide research and development, may also be considered in lieu of academic degree qualifications. It is important to have a separate guideline for listing of biopesticide, different from other agrochemicals, such as fertilisers, pesticides, etc.

iii. Review of the FAO pesticide risk assessment guidelines:

Risk Assessment is a valuable tool in evaluating the potential for possible health and environmental effects of both new and existing biopesticides. The potential toxicity (hazard) and exposure scenarios help in determining the overall level of risk in a qualitative and/or quantitative manner.

The bridging risk assessment matrices in Tables 3 and 4 were developed following the review of pesticide risk assessment techniques of the FAO. This, if implemented, is expected to help speed up the evaluation and authorisation process for biopesticides in Nigeria.

Table 3. Bridged risk assessment matrix for a microbial biopesticide.

		Reference Country Risk Assessment	
Assume that Toxicology is Similar in Two Situations		Risk Considered Acceptable	Risk Considered Unacceptable
Local Situation	Product Strain	Sufficiently similar to reference	Less similar, conduct local risk assessment
	Content of Relevant Metabolites	Complies with maximum limit as Reference and no metabolites of concern present	Complies with maximum limit but shows presence of metabolites of concern
	Content of Microbial Contaminants	Content complies with reference using internationally approved protocols	Content complies with reference using other protocols, conduct data integrity
	Product Efficacy	Similar or better than reference	Lower than reference
	Product Use Pattern	Similar to reference	Different from reference
	Product Withholding periods (If any)	Similar to reference	Not similar, conduct residue analysis
	Human and Environmental Exposures	Similar to reference	Different from reference
	Environmental Conditions	Similar to reference	Different from reference

Table 4. Bridged risk assessment matrix for a biochemical biopesticide.

		Reference Country Risk Assessment	
Assume that Toxicology is Similar in Two Situations		Risk Considered Acceptable	Risk Considered Acceptable
Local Situation	Minimum Purity of Active Ingredient	Sufficiently similar or higher than reference	Less than reference
	Relevant Metabolite	Content complies with maximum limit as reference and no metabolites of concern present	Content shows presence of metabolites of concern, conduct local risk assessment
	Max. Content of Impurities	Relevant impurities are similar and/or lower to reference	Relevant impurities are higher than reference
	Product Efficacy	Similar or better than reference	Lower than reference
	Product Use Pattern	Similar to reference	Different from reference
	Product Withholding periods (If any)	Similar to reference	Different from reference, conduct residue analysis
	Human and Environmental Exposures	Similar to reference	Different from reference
	Environmental Conditions	Identical to reference	Different from reference

Sources: All information and documents reviewed were sourced online from the corresponding authority's website as listed in the reference lists.

3. Results

3.1. Comparative Assessments of the Biopesticide Regulatory Frameworks

An overview of the regulatory framework comparison between EU, USA, South Africa, Kenya, and Nigeria were summarised in Table 1.

3.2. Review of the Nigeria Biopesticide Regulations and Guidelines

The observations made on the corresponding Nigeria biopesticide regulations and guidelines were shown in Table 2.

4. Discussion

4.1. Definition and Classification of Biopesticides

The definition of biopesticides varies between countries and it seems to influence their classification and regulatory mechanisms. The biopesticide definition adopted by the USEPA is quite similar to that of Nigeria [21,23]. This identical definition between the two might be responsible for the similarity in their classification (Table 1). Kenya defines biopesticides as biological pest control agents that are naturally occurring or genetically modified [24], while South Africa recognises biopesticides as any biological remedy or any mixture or combination of any substance or remedy intended or offered to be used for the destruction, control, repelling, attraction, or prevention of any undesired microbe, alga, nematode, fungus, insect, plant, vertebrate, invertebrate, or any product thereof [19]. Unlike Nigeria and the USA, South Africa and Kenya do not recognise Genetically Modified Organisms (GMOs) as a biopesticide category. Rather, they have adopted the Microbial, Macrobial, and Biochemicals classifications. However, South Africa includes Semiochemicals in its biochemicals class, and has a separate class for Enzymes, Hormones, and Plant Extracts. The EU does not recognise biopesticides as a separate regulatory category from conventional chemical pesticides. It considers biopesticides as Plant Protection Products (PPPs) of biological nature [25] whose classification is mostly based on target organisms. The EU's definition for biopesticides is the same for pesticides [26]. This different biopesticide classifications might be responsible for some of the challenges faced by companies in moving their products across jurisdictions.

4.2. Overview of Data Requirements for Biopesticide Registration

The baseline data requirements and general regulatory processes for the licensing of biopesticides in Nigeria are not substantially different from those in the other reviewed countries. Generally, the basic, and common, data required by most authorities relate to product chemistry, health and environmental risk assessments, efficacy, quality control and residue information (Table 1). Even though product performance data must be developed for all biopesticides, the USEPA does not typically require applicants to submit efficacy data unless the product bears a claim to control public health [27]. It also requires residue data for microbial pesticides only if such products have significant potential to produce a mammalian toxin, and if the use pattern is such that residues may be present in or on food/feed crops [27]. Contrary to the USEPA position, efficacy and residue data are considered vital components for the registration of biopesticides in Nigeria, South Africa, Kenya, and the EU. However, the South African regulatory authority may issue provisional registration for applicants with toxicological assessment reports containing new active ingredients, which are already registered in developed countries (like the US, UK, EU, Australia or Japan) alongside a toxicological assessment from an independent accredited toxicologist in South Africa [19]. Nigeria, on the other hand may, considers provisional approval for applicants after successful field trial assessment for one crop season. Data on human health and environmental risk assessments, product chemistry, and quality control are required by all the countries and regions examined.

4.3. Overview of Regulatory Framework for Biopesticides

The main aim of regulation is to ensure the safety of humans, animals and the environment. Regulation should not in any way be seen as a barrier to the development and commercialisation of biopesticides but rather, as a scientific process, tool, or path to ensure that all biopesticides placed on the market are safe, efficacious, and do not pose unacceptable risks to humans, animals and the environment. Different regulatory frameworks exist for the regulation of biopesticides. The EU has three main regulatory authorities while

the USA, South Africa, Kenya, and Nigeria have one each (Table 1). The EU adopted the conventional pesticide regulatory model for the regulation of its biopesticides while Nigeria and the US have customised their regulations. Biopesticides that fulfil the EU low-risk criteria are, however, considered as low-risk pesticides and hence benefit from low-risk incentives, which include faster authorisation processes and a longer license validity period compared to chemical pesticides [28]. Applicants seeking approval or registration for PIPs as biopesticides in South Africa, Kenya and Nigeria must first comply with the provisions of the national GMO Act before applying to the biopesticide regulatory authorities for registration. However, USEPA self-regulates PIPs and ensures that they meet federal safety standards before approval [29]. Plant Protection Products containing GMOs in the EU are regulated in accordance with Directive 2001/18/EC in addition to the regulations governing placement of PPPs on the market [17]. The license validity for biopesticides varies across the examined countries: EU (15 years), US (15 years), South Africa (3 years), Kenya (3 years), and Nigeria (5 years). The need for license renewal enables regulatory authorities to determine whether license holders are still complying with the approval conditions. License validity periods appear to be longer in developed countries where there may be, arguably, a higher commitment to regulatory compliance.

4.4. Overview of Risk Assessment

Complete local Risk Assessments (RA) are sometimes time consuming and expensive. Regulators may therefore need to consider the bridging and equivalence approach. This approach is suitable if it can be determined or established that the data or dossier submitted for evaluation of local (new) biopesticide products is similar to a registered reference product—in terms of toxicological profiles, impurities, and physicochemical properties [30]. Bridging often requires good knowledge of the principles and procedures of risk assessment, bearing in mind that a detailed local exposure estimation or full-fledged assessment of toxicity data is not required. When clear and unequivocal conclusions are achieved in a bridging process, further local assessments are no longer needed, but if otherwise, bridging may still be employed to facilitate the overall risk assessments by focusing the local risk assessment technique on specific issues of concern [31]. Bridging assumes that since the reference product is a registered biopesticide, the quality, efficacy, and risks are already acceptable in the reference country and it is, therefore, an obligation of the local authorities to decide if the same risk will be acceptable in their own situation. The product use pattern, application rate, timing, withdrawal periods, potential adverse effects, and environmental conditions are important factors when considering the bridging approach [30]. Allergenicity, genotoxicity, and biological properties are also significant when assessing potential risks. It should however be noted that bridging will not be possible if the characteristics of the biopesticide products deviate too much from the reference product or if the exposure scenarios between the two situations cannot be compared. Bridging can only be done if the active ingredient is the same for the reference and local product [32]. If risk assessments indicate a high likelihood of hazard, additional testing maybe required and approval for use may then be restricted or completely rejected.

The tiered approach assists regulatory agencies to make scientifically sound regulatory RA decisions in a timely and cost-effective manner. Tiered testing entails structuring the assessments or evaluation methods in such a way that unnecessary or more complicated lines of assessment are minimised or completely avoided. It is designed to first consider unrealistic ‘worst case’ scenarios and if these are unlikely (do not pose any hazard), then further testing or RA is not necessary. However, if Tier-1 screening indicates that unacceptable effects are possible or probable, (i.e., fail to prove adequate certainty of acceptable risks), then further testing must be carried out [33]. For example, if a biopesticide product is formulated with inert substances or materials of no toxicological concern, RA can reasonably be based on the active ingredients alone as it represents the worst-case scenario. Also, RA data may only be required for the end use products if no scientific distinction exists between active ingredients and the final product. The tiered approach

has the goal of achieving adequate certainty of acceptable risk. It should be noted that uncertainty and variability are critical factors when conducting RA. Since uncertainty stems from lack of knowledge, it cannot be eliminated but can rather be minimised, characterised, and managed via the use of more reliable data. Variability, on the other hand, cannot be minimised or reduced as it is an inherent characteristic of a population.

5. Recommendations for Sustainable Regulation of Biopesticides in Nigeria

The following recommendations were developed to promote sustainable regulation of biopesticides in Nigeria.

5.1. Amendment of the Current Biopesticide Regulations

The sections of the Nigeria biopesticide regulations and guidelines identified for amendments are highlighted in Table 2. Additionally, the separate/standalone document suggested for the listing of biopesticides (Section 2.2.6 in Table 2), will allow for improved data requirements as new knowledge becomes available. It will also not in any way be seen to undermine the integrity or assume less priority for the other regulated agrochemical products.

5.2. Checklist for Evaluation by Equivalence

The checklist in Table 5 was developed using the template from the FAO pesticide tool kit [30] and the Kenya guidance on dossier for pest control products [32]. This checklist will speed up the initial document evaluation and decision-making process by identifying potential areas of concern at the early stages of the application screening process.

Table 5. Checklist for biopesticide evaluation by equivalence.

Checklist: Evaluation by Equivalence			
Product Name:		Registration File Number:	
Name of the Assessor:		Date of the Assessment:	
Comparison of Parameters for the Local Situation Under Review and a Reference Country			
Describe/Quantify the Parameter for:			
	Parameter	Local Situation (Application)	Reference Country (Registration)
			Remarks
	Country		
1	Country		
	Applicant/registrant		
2	Name and address of applicant/registrant		
3	Name of manufacturer		
4	Registration status in reference country		
	Pesticide product		
5	Product name		
6	Active ingredient common name		

Table 5. Cont.

Checklist: Evaluation by Equivalence			
Product Name:		Registration File Number:	
Name of the Assessor:		Date of the Assessment:	
Comparison of Parameters for the Local Situation Under Review and a Reference Country			
Parameter	Describe/Quantify the Parameter for:		Remarks
	Local Situation (Application)	Reference Country (Registration)	
7	Formulation type		
8	Active ingredient concentration in the product (cfu/g or mL, g a.i./kg)		
9	Declaration by applicant that the product is identical or equivalent to the one in the reference country		
	If not:		
10	Active ingredient manufacturing source		
11	Min. Purity of A.I (biochem/semio)		
12	Max. Content of relevant impurities		
13	Impurities from Manufacturing		
14	Strain (MCP)		
15	Max. Limit of relevant metabolites		
16	Content of microbial contaminant		
17	Efficacy		
18	Toxicological properties		
19	Co-formulants triggering a hazard classification		
20	Conclusion with respect to the pesticide product:		
	Use		
21	Crop or use situation		
22	Pest		
23	Dose rate (g a.i./ha)		
24	Number of applications per growing season		

Table 5. Cont.

Checklist: Evaluation by Equivalence			
Product Name:		Registration File Number:	
Name of the Assessor:		Date of the Assessment:	
Comparison of Parameters for the Local Situation Under Review and a Reference Country			
Parameter	Describe/Quantify the Parameter for:		Remarks
	Local Situation (Application)	Reference Country (Registration)	
25	Withholding period		
26	Conclusion with respect to the use:		
	Human health risks		
27	Use restrictions (human health)		
28	Required/ recommended PPE		
29	Level of training/experience of operator		
30	Conclusion with respect to the human health risks: Risks similar or less when compared to the reference country:		
	Environmental risks		
31	Use restrictions (environment)		
32	Rainfall, temperature, soil		
33	Sensitive ecosystems/organisms		
34	Conclusion with respect to the environmental risks:		
35	Overall conclusions:		

This checklist was adapted from the FAO pesticide registration tool kit [30] and Kenya guidance on dossier evaluation [32].

5.3. Regional Data Sharing and Harmonisation of the Regulatory Process

Data sharing and joint review processes amongst other African countries (especially those with similar environmental condition) will help promote simultaneous access to new knowledge, improved technical networking initiatives, and increased efficiency of the regulatory process. Harmonisation of biopesticide regulations will also promote mutually comparable standards, protocols, norms, and ease transboundary trade either within the African region or across the continent.

5.4. Bridged Risk Assessment Matrices for Microbial and Biochemical Biopesticides

Two bridged risk assessment matrices were developed to help improve scientific regulatory decision making in a more timely and effective manner, viz:

- Bridged risk assessment matrix for a microbial biopesticide as shown in Table 3
- Bridged risk assessment matrix for a biochemical biopesticide as shown in Table 4

5.5. Capacity Building and Public Awareness

Capacity building of regulators, risk managers, and increased public awareness on the benefits of biopesticides will help promote the effective regulation of biopesticides.

6. Summary

Biopesticides are known to include a wide range of both living and non-living natural substances that vary widely in their bioproperties, mode of action, composition, and toxicities—hence the need for a sustainable regulatory approach for maximum protection of animal and human health and the environment. The different biopesticide regulatory frameworks and variations in the data requirements across countries and regions are some of the leading factors inhibiting the sustainable development and transboundary trade of biopesticides.

The regulatory challenges facing the development and commercialisation of biopesticide products in Nigeria were identified to include protracted or extensive field trials and risk assessment methods and inability of applicants to fulfil the GMO requirements for registration of PIPs. Low public awareness and high market cost of biopesticides also inhibits its commercialisation in the region.

Although the biopesticide regulatory system in Nigeria is not significantly different from those in other countries, amendment of the current Nigeria biopesticide regulations, use of technical checklists, and bridged risk assessment matrices will enhance the scientific decision-making process. Data (Efficacy and Toxicity) sharing and harmonisation of regulatory processes between countries/regions (especially those with similar ecologic conditions) will undoubtedly promote mutually comparable standards, inter data acceptability, norms, and protocols for sustainable regulation.

It is pertinent to note that a no risk situation does not exist, not even for biopesticides. Tiered RA approaches and data waivers should always be substantiated with sound scientific and technical arguments. Non-regulatory factors, such as political, social, and societal pressure also influence the development and commercialisation of biopesticides. Capacity building of regulators, developers, risk managers, and public awareness will help smooth the path of transboundary trade and easy, effective commercialisation across regions.

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