 doi:10.20944/preprints202110.0270.v1

*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 biological pesticides (biopesticides). Biopesticides are generally environmentally friendly and are made from micro-organisms or other natural substances. Despite their great potential, relatively few have been registered and commercialised in Nigeria compared to other African countries such as South Africa and Kenya. Biological active agents are so diverse such that applying the same safety standards or environmental conditions to all of them is almost impossible. A review of risk assessment processes and comparative assessments of Nigeria's biopesticide regulations with other developing African countries and developed regions was conducted. Prolonged field testing, lack of bridged risk assessments and technical checklists have been identified as key factors hampering the timely development and commercialisation of biopesticides in Nigeria. Recommendations on necessary changes to the existing Nigeria biopesticide regulations have been made. Risk assessment matrices for microbial and biochemical biopesticides and a scientific/technical checklist have also been developed. Harmonisation and data exchange among other countries in the region will also enhance the advancement of scientific and technical knowledge for sustainable regulation and cross-border trade.

**Keywords:** Biopesticides; Regulations; Risk Assessment; Regulatory Challenge, Sustainability; Nigeria.

## 1. Introduction

It has always been necessary to protect plants from pests and pathogens in order to provide the human population with quality and sufficient food products. Conventional synthetic pesticides have been used effectively over the years to ensure food safety and security. Recently, there has been a global drive towards more organic food production, greener environments; and consequently, a strong push for the integration of biopesticides into pest management strategies (1). There is no single internationally agreed definition for biological pesticides or biopesticides. Biological pesticides or biopesticides in the Food and Agriculture Organizations (FAO) definition include products with active substances that are based on botanicals, semiochemicals or microbials(2). The Organization for Economic Co-operation and Development (OECD) refers to biological pesticides as biocontrol agents which include microbials, pheromones, and other semiochemicals and invertebrates(3). Despite the great potential of biopesticides, the associated regulatory processes for authorising these pest control products are generally lengthy, time-consuming, and costly (4). Disproportionate data requirements associated with extended assessment processes can present a significant challenge that deter biopesticide companies from applying for registration (5) in some jurisdictions.

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

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, *Trichoderma* species are used as biopesticides against soil-borne plant pathogenic fungi (9) but they are known to enhance the absorption of micro and macro nutrients from the soil (10). They can also function as cell wall degrading enzymes, parasitise plant pathogenic fungi and can produce antibiotics (9) (11). Fluorescent Pseudomonas can also be used as both biocontrol agents as well as plant growth promoting agent (12). The Organization for Economic Co-operation and Development (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 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 and controlling 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 biopesticides. Despite the global interest and evolving regulatory frameworks around the globe to promote the technological advances in the development and commercialization of these 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 extensive field testing and screening procedures, inadequate risk assessment techniques, and low public awareness. The objective of this study was to review Nigeria's biopesticide regulatory system and develop a sustainable regulatory approach to enhance their development and commercialization in the country.

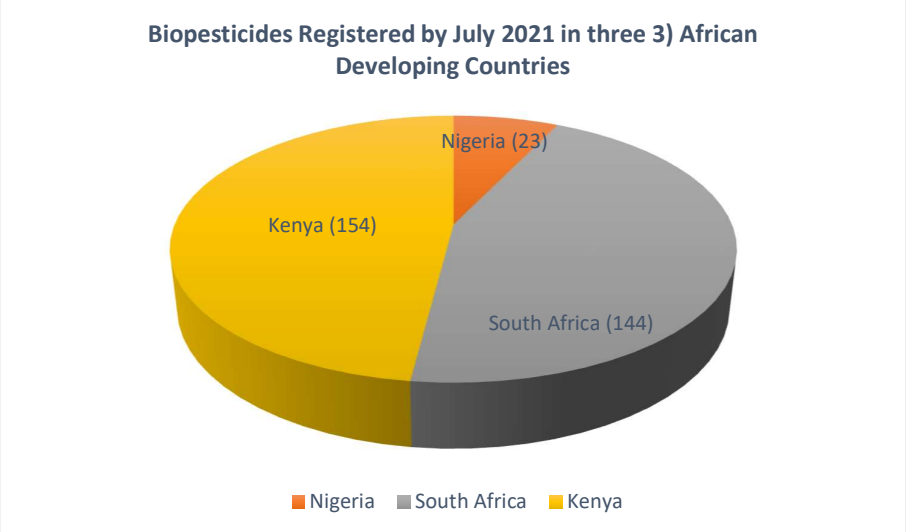


Fig. 1. Registered biopesticides by July, 2021 in Nigeria(14), South Africa(15) and Kenya(16).

### 1.1. Regulatory challenges to biopesticide registration

Most investors view regulatory oversight as an impediment to the timely development and commercialization of their products. The extended field trials and risk

 doi:10.20944/preprints202110.0270.v1

assessments conducted over two different growing seasons are seen as a key challenge for the development and marketing of biopesticide products. A further challenge is the multiplicity of modes of action of certain microorganisms. This often leads to more data requirements for regulators to better understand their biological properties and establish safety and efficacy criteria. The safety and efficacy of a biopesticide product is essential prior to authorization without which the registration and all regulatory processes become unfounded.

In addition, most applicants who intend to register Plant Incorporated Protectants (PIPs) as biopesticides do not often return to finalize their registration process. This is probably due to their inability to comply with the GMO safety assessments at the relevant Biosafety Agency (i.e., National Biosafety Management Agency). The successful commercialization 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. Conventional pesticides have been on the market for decades, well known to the public, less expensive and faster in mode of action when compared to biopesticides. Although issues of political, social and societal pressures cannot be completely overlooked as a challenge to the effective marketing of licensed biopesticide products in Nigeria.

## 2. Methodology

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

**i. Comparative assessment of biopesticide regulations:**
A comparative assessment of the Nigeria biopesticide regulations with other African developing countries (South Africa & Kenya) and developed regions (European Union (EU) & United States of America (USA)) were carried out. This was done to identify regulatory gaps and propose a way forward for the Nigerian regulatory system. The available online biopesticide related regulations with summary of the assessments for each of the countries and regions are tabulated in Table 1.

**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, Bio-pesticides and Bio-fertilisers Marketers (Doc. Ref. No: VMAP-GDL-016-05)-Table 2.

**iii. Review of Food and Agriculture Organisation (FAO) pesticide risk assessment guidelines:**
Risk Assessment is a valuable tool in evaluating the potentials for possible health and environmental effects of both new and existing biological pesticides. The potential toxicity (hazard) and exposure scenarios often helps to synthesize the overall conclusion of a risk either in a qualitative or quantitative manner.
The bridging risk assessment matrices in tables 4 and 5 were developed following the review of pesticide risk assessment techniques of the FAO. This is to help speed up the evaluation and authorization process of the biological pesticides.

**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.

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The overview of the regulatory framework comparison between EU, USA, South Africa, Kenya and Nigeria is summarised 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) Biopesticide Advertisement Regulations 2019 (22) |
| **Authorities** | EC, EFSA RMS | USEPA | DALRRD | PCPB | NAFDAC |
| **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 micro-organisms. |
| **Major Classification** | Pesticides: (Insecticides, Fungicides, Rodenticides, etc) | Biochemical, Microbia,l 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).

### 3.2. Review of the Nigeria biopesticide regulations and guidelines

The highlight of the observations made on the corresponding Nigeria biopesticide regulations and guidelines is tabulated in Table 2

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**Table 2.** Observation/Outcome of the critique 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 bio-pesticides on the Agency's official website, notifying the registration of a bio-pesticide. | Technically, specificity is important, the word "time to time" can be replaced with more specific words like: Quarterly, biannually, etc |
| | 5(i) | Efficacy assessment of a bio-pesticide to be introduced into the market shall be carried out to ensure that bio-pesticide approved would be efficacious for its intended use. | It will also be necessary to state other conditions in which efficacy trials can be accepted in lieu of local efficacy trials. Especially when importing from countries with similar environmental and climatic conditions. |
| | 5 (iv) | The assessment shall be monitored by the Agency at 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 template for upcoming institutes |
| | 11 (2) | A manufacturer or importer engaged in the manufacture, importation, distribution, sale or storage of bio-pesticide shall submit preliminary and final reports to the Agency of any adverse effect on non-target organism and environment; and loss of effectiveness associated with bio-pesticide occurring in Nigeria or elsewhere. | It will be more appropriate to immediately notify the agency of any adverse effects on Non-Target Organisms (NTO) and the environment. Submission of reports may come later. This is to ensure maximum safety protocols as quickly as possible |
| **Guidelines for Issuance of Permit to Import Field Trials Samples (Doc. Ref. No: VMAP-GDL-016-06)**(23) | 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, Bio-pesticides, and Bio-fertilisers Marketers. (**Doc. Ref. No: VMAP-GDL-016-05) (23) | 2.2.6 | Appointment and acceptance letters, 2 passport photographs of the technical officer including all credentials (Degree, NYSC certificates, etc.). The technical officer should have scientific background with minimum of Ordinary National Diploma; OND or its equivalent. | Technical officer with relevant trainings in biotechnology, or biopesticide research and development may also be considered in lieu of academic degree qualifications.<br><br>It is important to have a separate guideline for listing of biopesticide, different from other agrochemicals like: fertilisers, pesticides, etc. |
| | 2.2.11 | Evidence of fumigation / Pest control | Evidence of fumigation may not be necessary for a biopesticide warehouse |

## 4. Discussion

### Definition and classification of biopesticides

The biopesticide definition adopted by the USEPA is quite similar to that of Nigeria (21) (24). This identical definitions between the two might be responsible for the similarity in their classification (Table 1). Kenya defines biological pesticides as biological pest control agents that are naturally occurring or genetically modified (25) while, South Africa recognizes biopesticides as any biological remedy or any mixture or combination of any substance or remedy (19). Unlike Nigeria and the US, South Africa and Kenya do not recognize Genetically Modified Organisms (GMOs) as a biopesticide category and not included in their classification. Rather, they adopted the Microbial, Macrobial and Biochemicals classifications. However, South Africa included Semiochemicals in its biochemicals class,

 doi:10.20944/preprints202110.0270.v1

and have separate class for Enzymes, Hormones and Plant Extracts. The EU does not recognize biological pesticide as a separate regulatory category from conventional chemical pesticides. It considers biological pesticides as Plant Protection Products (PPPs) of biological nature (26) whose classification is mostly based on target organisms. The EU´s definition for biopesticides is the same for pesticides (27). Definition of biopesticides varies between countries and it seems to influence their classification and regulatory mechanisms. This different biopesticide classification might be responsible for some of the challenges faced by companies when moving their products across jurisdictions.

**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 obtained in other reviewed countries. Generally, the basic and common data required by most authorities are product chemistry, health and environmental risk assessments, efficacy, quality control and residue data (Table 1). In as much as product performance data must be developed for all biological pesticides, the USEPA does not typically require applicants to submit efficacy data unless the product bears a claim to control public health (28). It also require residue data for microbial pesticides only if, it has 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 (28). Contrary to the USEPA position, efficacy and residue data are considered vital components for the registration of biological pesticides in Nigeria, South Africa, Kenya and in the EU. However, the South African regulatory authority may issue provisional registration for applicants with toxicological assessment reports containing new active ingredients which is already registered in developed countries (like the USA, UK, EU, Australia or Japan) alongside a toxicological assessment from an independent accredited toxicologist in South Africa (19). Nigeria on the other hand may consider 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. The variation in data requirements between authorities may discourage applicants from submitting applications for registration in certain jurisdiction.

**Overview of regulatory framework for biopesticides**

The main aim of regulation is to ensure safety of human health and the environment. Regulation should not in any way be seen as a barrier to the development and commercialization of biological pesticides but rather, as a scientific process, tool, or path in ensuring that all biological pesticides placed on the market are safe and efficacious and will not pose unacceptable risk to human health, animal, and the environment. Different regulatory frameworks exist for the regulation of biological pesticides. The EU has three main regulatory authorities while USA, South Africa, Kenya, and Nigeria have one each (Table 1). The EU adopted the conventional pesticide regulatory model for the regulation of its biological pesticides while Nigeria and the USA have customized its regulations. Biological pesticides that fulfil the EU low-risk criteria will however, be considered as low-risk pesticides and benefits from the low-risk incentives which include faster authorization process and a longer license validity period compared to chemical pesticides (29). Applicants seeking approval or registration for PIPs as biological pesticides in South Africa, Kenya and Nigeria must first comply with the national GMO Act before applying to the biopesticide regulatory authorities for registration. However, USEPA self regulates PIPs and ensure it meets Federal safety standards before approval (30). Plant Protection Products containing GMOs in the EU are regulated in accordance with Directive 2001/18/EC in addition to the assessment of regulations governing placement of PPPs on the market (17).

 doi:10.20944/preprints202110.0270.v1

The license validity for biological pesticides varies across the examined countries: EU-15years USA-15years. South Africa-3years, Kenya-3years and Nigeria-5years. The shorter license validity period in the developing countries may be because constant monitoring and re-evaluation of the biopesticide products are needed to ensure consistency, efficacy, and safety. Moreover, the regulatory mechanism in developing countries may not be as sophisticated as that of the developed countries hence, the need for frequent product assessment.

**Overview of Risk Assessment**

Complete local Risk Assessments (RA) are sometimes time consuming and expensive, hence, regulators may 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 its toxicological profiles, impurities, and physicochemical properties (31). 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 (32). Bridging assumes that since the reference product is a registered biological pesticide, 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 same risk will be acceptable in their own local situation. The product use pattern, application rate, timing, withdrawal periods, restrictions (from reference if any), potential adverse effects, personal protective equipment and environmental conditions are important factors when considering the bridging approach before drawing overall conclusion on risks (31). 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 biological pesticide products deviates 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 (33). If risk assessments indicates a high likelihood of hazard, additional testing maybe required and approval for use may then be restricted or completely rejected. Risk reduction decisions are often based on the considerations of both pesticide risks and benefits.

The tiered approach assists regulatory agencies to make scientifically sound regulatory RA decisions in a timely and resourceful manner. Tiered testing approach entails structuring the assessments or evaluation methods in such a way that unnecessary or more complicated line of assessments are minimized or completely avoided. It is designed to first consider unrealistic ´worst case' scenario and if these scenarios are unrealistic or unlikely (does not pose any hazard), then further testing or RA is not necessary. But if Tier-1 screening indicates that unacceptable effects are possible or probable, (ie. Fail to prove adequate certainty of acceptable risks), then further testing must be carried out (34). For example, if a biological pesticide 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 ultimate goal of achieving adequate certainty of acceptable risk. It should be noted that uncertainty and variability are critical factors when conducting RA. Uncertainty cannot be eliminated but can be minimized characterized and managed via the use of more reliable data because it stems from lack of knowledge. Variability on the other hand cannot be minimized or reduced as it is an inherent characteristic of a population. People vary substantially in their

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susceptibility to potentially harmful effects and exposure scenarios, but with improved information, it can still be characterized.

**5. Recommendations for sustainable biopesticide regulations in Nigeria**

The following recommendations were developed and sectioned into four points to promote sustainable regulation of biopesticide products in Nigeria.

**I. 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 at any time and 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.

**II. Checklist for evaluation by equivalence.**

The checklist in Table 3 was developed using the template from the FAO pesticide tool kit (31) and the Kenya guidance on dossier for pest control products (33). This checklist will speed up the initial document evaluation and decision-making process by identifying potential areas of concern at the early stage of the application screening process.

Table3. 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* | | | |
| **Parameter** | **Describe/quantify the parameter for:** | | **Remarks** |
| | ***Local situation*** *(application)* | ***Reference country*** *(registration)* | |
| | **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 | | | |
| 7 | Formulation type | | | |

| | | | | |
|---|---|---|---|---|
| 8 | Active ingredient concentration in the product (cfu/g or mL, g a.i/L or g a.i/L | | | |
| 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 | | | |
| 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** | | | |

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| | | | | |
|---|---|---|---|---|
| 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 FAO pesticide registration tool kit (31) and Kenya guidance on dossier evaluation(33)

**Regional data sharing and harmonization of regulatory process.**

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

## III. Bridged risk assessment matrices for microbial and biochemical biopesticides

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

a) Bridged risk assessment matrix for a microbial biopesticide as shown in Table 4

b) Bridged risk assessment matrix for a biochemical biopesticide as shown in Table 5

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| Assume that toxicology is similar in two situations | | Reference Country Risk Assessment | |
|---|---|---|---|
| | | 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 Microbial Biopesticide

| Assume that toxicology is similar in two situations | | Reference Country Risk Assessment | |
|---|---|---|---|
| | | Risk Considered Acceptable | Risk Considered Unacceptable |
| | 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 |

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| | | | |
|---|---|---|---|
| Local Situation | 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 |

Table 5. Bridged Risk Assessment Matrix for a Biochemical Biopesticide

## IV. Capacity building, and public awareness

Capacity building of regulators, risk managers and increased public awareness on the benefits of biopesticides will help promote the sustainable approach initiative.

### 6. Summary

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

However, 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, multimode action of the microorganisms, and inability of applicants to fulfil the GMO requirements for registration of PIPs. Low public awareness and high market cost of biological pesticides also inhibits its commercialisation in the region.

Although, the biopesticide regulatory system in Nigeria is not significantly different from those in other countries, however, amendment of the current Nigeria biopesticide regulations, use of technical checklist and bridged risk assessment matrices will enhance the scientific decision-making process in a more timely and efficient manner. Data (Efficacy and Toxicity) sharing and harmonisation of regulatory processes between countries/regions with similar ecologic conditions will in no doubt, 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 biological pesticides, tiered RA approach 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 commercialization of biopesticides. Capacity building of regulators, developers, risk managers and public awareness will help smoothing the path of trans boundary trade and ease effective commercialization across regions and continents towards sustainable futures.

**Author Contributions:**

Study design: Dennis Ndolo, Christine Abey Ashaolu; Research and Analysis: Christine Abey Ashaolu; Supervision: Dennis Ndolo; Writing: Christine Abey Ashaolu with comments from Dennis Ndolo, Elizabeth Njuguna, and Chibuzor Okonkwo.

**Funding:** This research was funded by International Centre for Genetic Engineering and Biotechnology (ICGEB). Cape Town, South Africa. https://www.icgeb.org/activities/fellowship/.

**Data Availability Statement:**

Data on registered biopesticide

Kenya-The biopesticide registered data presented in this study are openly available at in https://www.pcpb.go.ke/biopesticides-on-crops/

South Africa-Data was available from third party at: https://sabo.org.za/

Nigeria-Data was available from third part available at www.nafdac.gov,ng.

**Acknowledgments:** ICGEB, Dr. Rufus Ebegba (National Biosafety Management Agency, Nigeria), Dr. Tunde Shigbeku (NAFDAC, Nigeria), Mrs. Grace Adetoye (NAFDAC, Nigeria), Mr. Tobi Okuwoga (NAFDAC, Nigeria) and Mrs. Karen Murihead (ICGEB, South Africa)

**Conflicts of Interest:** The authors declare no conflict of interest. The funders had no role in the design of the study; in the collection, analyses, or interpretation of information, data; in the writing of the manuscript, or in the decision to publish the results.

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