A Guide to the Development of Regulatory Frameworks for Microbial Biopesticides in Sub-Saharan Africa

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Foreword

Since its creation in 2003, the African Agricultural Technology Foundation (AATF) has been in the business of accessing, adapting and delivering appropriate agricultural technologies for use by smallholder farmers in Sub-Saharan Africa (SSA). This has been made possible by working through partnerships with both public and private actors drawn from academia, farmer organisations, civil society, national and international research systems and the seed industry.

One such effort is access to an aflatoxin bio-control technology that uses *Aflasafe*™, a natural, non-toxic technology that utilises the ability of native atoxigenic strains of *Aspergillus flavus* (the fungus that produces aflatoxin) to naturally out-compete their aflatoxin-producing cousins thereby reducing the frequency of aflatoxin producers and subsequent aflatoxin production in crop commodities. The technology, developed by the United States Department of Agriculture-Agricultural Research Services (USDA-ARS), the International Institute of Tropical Agriculture (IITA) and the National Agricultural Research Systems (NARS) in Africa has the potential to greatly reduce the presence of aflatoxins in maize, groundnuts, and other staple crops and throughout the environment. It is relatively inexpensive and highly effective, typically accounting for 80 to 95 percent reductions with a single application. Applications provide long-term and, thus, additive benefits across multiple years and provide the opportunity for area-wide prevention of aflatoxin contamination.

There are many such bio-based products increasingly gaining use among farmers in Africa. However, commercialisation of such products often requires rigorous processes for testing and registration. This poses a range of challenges since most countries have poorly developed regulatory frameworks. Even in countries where regulatory frameworks exist, similar challenges remain as existing regulations may only be geared for chemical rather than biological pesticides. AATF, in collaboration with the United States Department of Agriculture-Foreign Agriculture Service (USDA-FAS) has played a key liaison role of bringing together national governments in Africa, specifically, pesticide registration officials to explore requirements for registration of biological control agents in general and aflatoxin biocontrol products in particular. As more countries commence testing work, it is increasingly becoming clear that a range of country specific products will be developed resulting in diverse national regulations across Africa. Although such country-specific regulations are an inevitable indicator of national sovereignty, it is imperative to harmonise them so that country-to-country regulations have mutually comparable standards, norms and protocols for instance for sampling and testing and also facilitate trans-boundary trade in crop products.

Towards this end, AATF, with support from USDA-FAS has engaged key stakeholders including the National Regulatory Institutions (NRIs) from several African countries; regional authorities such as the Common Market for East and Southern Africa (COMESA) and IITA over the past one year to inform the process of analysing available information and drafting a harmonised framework for guidelines on registration of biopesticides in Africa.

I am delighted that this guidance document, a culmination of the hard work and patience of the Technical Working Group (TWG) whose membership is drawn from AATF, NRIs, NARs, IITA, ARS, USDA- FAS, and regional economic communities (RECs) is now ready for dissemination. The document targets a wide range of stakeholders involved in the

establishment of regulatory frameworks for biopesticides in respective African countries both at national and regional levels.

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Preface

This document was commissioned by AATF in an initiative involving the USDA-ARS, USDA-FAS, IITA, NARS and the NRIs from several African countries to put into use microbial biopesticides developed to mitigate against constrains facing farmers in the production of food and cash crops in SSA. An example is the reduction of the level of aflatoxin contamination in important crops such as groundnuts and maize.

Following experience with these biological control agents in Nigeria and Kenya, there is need to develop regulatory systems for their testing and registration across the region based on common data requirements, mutually equivalent standards and registration systems working towards a common goal. A consultation process began in Zanzibar, Tanzania in June 2012 to develop regulatory guidance for microbial biopesticides in general, and more specifically for products that could be used by national authorities through country-specific regulations or in a harmonised process on a sub-regional basis. A TWG was then convened to assist and guide the consultant in the development of the guidance. The culmination of this process involving USDA, IITA, NARs, NRIs, AATF and RECs in SSA is presented here with the guidance document on a *Registration Framework for Microbial Biopesticide Registration in Sub-Saharan Africa*. This document can also guide inter- and intra-regional harmonisation of registration in Africa**.**

This document presents a distillation of best practice in a form appropriate to the registration of this type of pesticide in SSA. It was reviewed and approved by the TWG and also peer reviewed independently. However, the author recognises that the regulatory processes recommended herein and the data requirements and other technical aspects of biopesticide registration needed to be 'road tested'. This should be done in real or simulated registration activities using worked examples or relevant case studies. There was an opportunity for such 'road testing' during the trilateral meeting on atoxigenic *Aspergillus flavus* products between Malawi, Mozambique and Zambia in August 2013. The final version of the document includes an addendum on models for harmonised registration of microbial biopesticides based on the lessons learned from this event.

As the consultant principally responsible for preparation of this document I am grateful for all the encouragement, advice and support received from the Technical Working Group and the stimulating dialogue held with many members of this group during its development. Special thanks go to Caitrin Martin (USDA-FAS) for proof reading of, and very helpful advice on, the manuscript. I am also grateful to all the participants of the above-mentioned trilateral registration meeting for the stimulating and fruitful discussion of the guidance presented.

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Acronyms and abbreviations

AATF	African Agricultural Technology Foundation
CILSS	Permanent Interstate Committee for Drought Control in the Sahel (Le Comité Inter Etats de Lutte contre la Sècheresse dans le Sahel)
EFSA	European Food Safety Authority
EPA	Environmental Protection Agency (Ghana)
EU	European Union
FAO	Food and Agricultural Organisation of the United Nations
GMO	Genetically Modified Organism
HSE	Health and Safety Executive (UK)
IITA	International Institute of Tropical Agriculture
IPM	Integrated Pest Management
IPPC	International Plant Protection Convention
ISO	International Standards Organisation
ISPM	International Standards for Phytosanitary Measures (IPPC)
LD_{50}	Lethal dose for fifty percent of test population
LC_{50}	Lethal concentration for fifty percent of test population
EC_{50}	Effective concentration for fifty percent of test population
LMO	Living modified organism (=GMO)
OECD	Organisation for Economic Cooperation and Development
NARS	National Agricultural Research System (organisation)
NOEL	No observable effect level (for toxicity or other undesired effects)
NRI	National regulatory institution
REC	Regional Economic Community
SEARCH	Southern and East African Regulatory Committee for Harmonisation of Pesticide Registration
SME	Small and Medium Enterprise
SPS Agreement	(Agreement on the Application of) Sanitary and Phytosanitary Measures
TWG	Technical Working Group
USDA-FAS	United States Department of Agriculture-Foreign Agricultural Service
VCG	Vegetative compatibility group
WHO	World Health Organisation
WTO	World Trade Organisation

Executive summary

This is the final version of the guidance document on *Regulatory Frameworks for Microbial Biopesticides in Sub-Saharan Africa* as commissioned by AATF through the assistance of USDA-FAS. The project to develop this guidance took its origins from an exploratory meeting of relevant stakeholders, in Zanzibar, Tanzania in June 2012 and was thereafter formerly initiated in November of that year, and continued with a meeting to review progress (completion of 'zero draft') in Nairobi early in 2013. Subsequent drafts were reviewed by a TWG convened for that purpose by teleconference and email exchanges.

The document begins (chapter one) with an introduction that includes background on regulatory principles involved in registration of microbial biopesticides. Chapter two completes the preliminary part of the guidance by considering how legal form and force could be given to the non-legal regulatory guidance provided.

Chapter 3 gives an account of the more practical part of the document including definitions of legal terms, followed by recommended registration procedures for registration authorities (chapter four) and guidance for registrants (chapter 5).

An Annotated Bibliography is followed by five annexes with further guidance (annex 1), data requirements, model forms/certificates and other technical details (annexes 2-4), and a checklist for primary law provisions on pesticides (annex 5).

The regulatory framework developed was used and 'road tested' in a trilateral meeting (Malawi, Mozambique and Zambia) for registration of a microbial biopesticide for aflatoxin control. These three countries are in tier one for adoption of the framework by national authorities but on a harmonised basis. As an outcome of the trilateral meeting an **addendum** was added on models for harmonised registration of microbial biopesticides. Next steps for wider adoption of the framework at national and REC level are under discussion.

Provision is made for the eventual demand for registration of microbial biopesticides that contain genetically modified organisms (GMOs), requiring their approval by the appropriate biosafety regulatory agency in the country of registration. This is the recommended approach towards such products. However, given the sensitivities towards GMOs in some countries, relevant passages are indicated for omission altogether if deemed necessary.

Table of contents

Chapter 1
Introduction – regulatory principles for microbial pesticides

1.1 What are microbial biopesticides and why is their registration important?

Microbial biopesticides are a type of biopesticide/biological pest control product in which the sole or principal component is a microorganism that can function as a pesticide. The microorganism could be a fungus, virus, bacterium, mycoplasma or rickettsia. The microbial active agent might be a pathogen of an invertebrate pest such as an insect or it could be active against another microorganism such as toxin-producing fungi that contaminate grain, pulses and other products.

Biopesticides in general are considered advantageous over conventional chemical pesticides because they are generally much less toxic to humans and other mammals than the latter and have less impact on wildlife and the environment. Biopesticides can be substituted for conventional pesticides and this is becoming increasingly necessary because many conventional pesticides are being withdrawn or banned because of their adverse side effects. They generally affect only the target pest and closely related organisms, in contrast to broad spectrum, conventional pesticides that may affect organisms as different as birds, insects, and mammals. Biopesticides often are effective in very small quantities and often decompose quickly, thereby resulting in lower exposures and largely avoiding the pollution problems caused by conventional pesticides. When used as a component of Integrated Pest Management (IPM) programmes, biopesticides can greatly decrease the use of conventional pesticides, while crop yields remain high. To use biopesticides effectively, however, users need to know a great deal about managing pests.

Microbial biopesticides are beneficial because, as well as being generally of very low toxicity (although they could cause allergies), they can be formulated and applied like conventional pesticides. Some microbial biopesticides show great promise for controlling pests and associated problems for which there is no conventional remedy.

Most African countries have or are developing regulatory systems for pesticides in order that pesticides may be used effectively and safely, especially as part of IPM programmes. Registration forms the core of such regulatory systems by ensuring that only approved pesticides can be used, that use is according to approved guidelines and that products considered to pose too great a risk are prohibited. Registration is also the key to ensure the satisfactory quality of approved products and that fraudulent pesticides are avoided. Quality aspects are particularly important for biological control products because farmers' and community groups are being encouraged to develop material for local use. Experience in some developing countries has shown that where registration of some biopesticides is waived because of their lower risk, farmers may be provided with poor quality material, either because of incompetent manufacturing or because of fraud.

The key to developing a successful microbial biopesticide **product** is identifying a strain of the microbial active agent that will be effective under conditions appropriate to the area in which it will be used. Usually, this will mean characterising and testing of locally isolated strains; therefore without doubt regulations for microbial biopesticides will have a degree of national specificity. Although such country-specific regulations are an inevitable indicator of national sovereignty, there is need to harmonise them so that country-to-country regulations

have mutually comparable standards, norms and protocols [for sampling and testing] that also facilitate trans-boundary trade in crop products. It should also be possible for the registration authority in one country or region to use efficacy and toxicity data provided in application for registration in another country or region, provided the originator of the data allows this and provided the new registering country or region wishes to do so. This is to avoid unnecessary duplicative testing and to encourage and facilitate registration of microbial biopesticides.

1.2 Purpose of the guidance document

The purpose of this guidance document is to provide the framework for a sound and rational system for microbial biopesticide registration in legal form or otherwise on a regionally harmonised basis, aiming for common data requirements and equivalent registration systems

A preliminary assumption is that there is already a regulatory framework in use or being drafted (presumed to be legislation but could be formal administrative provisions) for pesticides in general or conventional (chemical) pesticides. Whether this applies to the particular country or region where these guidelines are being adopted is discussed later (**chapter 2**) together with recommendations for legislative action in case there is no existing framework or the framework is deficient in some respects. For this reason, general regulatory principles are not covered in detail in this guidance but a normative legislative framework for pesticides control is presented in chapter 2. Instead the emphasis is on specific features relevant to microbial biopesticides.

Moreover, detailed methodology for compiling (**registrants**) and evaluating (**registration authorities**) data dossiers is not provided because a case-by-case approach is needed. Instead, the reader is referred to the following sources of guidance among others, as given later in the detailed bibliography (**Annotated Bibliography** (p. 49):

Item No. in Annotated Bibliography	Source	Abbreviated title or general
1	FAO	International Code of Conduct
4	OECD	Guidance for registration requirements
5		Guidance of industry data submissions
6		Guidance for country data reviews
7		Working document on evaluation of microbials
17	US EPA	Data requirements for pesticides
18		Experimental use permit data requirements
19		Pesticide registration manual. Chapter 2.
24	UK HSE	Applicant Guide: Parallel Trade Permit Procedure

1.3 Objectives of registration framework for microbial biopesticides

The objectives of the registration framework are to ensure that:

- *Only registered microbial biopesticides are placed on the market and made available for use;*
- *Only microbial biopesticides that are demonstrated to be safe and effective for intended use may be registered;*
- *Registered microbial biopesticides are used correctly and safely;*
- *Registration of a microbial biopesticide may be re-evaluated if new data becomes available following registration;*
- *Registration procedures take account of the lower inherent toxicity of microbial biopesticides but recognise special risks like allergenicity and genotoxicity;*
- *Registration procedures adopted by a national authority for microbial biopesticides follow a harmonised regional approach so that evaluation of an application for registration might utilise data from equivalent pesticides in other countries in the region and reduce testing requirements ('fast tracking'); and*
- *To facilitate inter-national/inter-regional trade in microbial biopesticides.*

In the next section of the introduction the scope of the regulatory framework is described with an explanation of what is included and what is omitted. This is followed by a discussion of other relevant background issues and a list of the documentary sources referred to when compiling the guidance. The necessary steps for adoption of the framework into legislation are discussed (chapter 2) with legal definitions following in chapter 3.

The remainder of the document (chapters 4 and 5, annexes) is the actual regulatory framework proposed - registration procedures for the registration authority, guidance for applicants and data requirements.

Definitions of words or terms in bold are given in chapter 3 for the reader's reference.

1.4 Scope of registration system

1.4.1 Microbial biopesticides

Only biopesticides with **microbial active agents** will be registered through this framework. For these purposes 'microorganisms' include bacterium, alga, fungus, protozoan, virus, phytoplasma, rickettsia but **excludes nematodes**.

Provision is made for **products** that may contain a chemical **active ingredient** or another kind of biological control agent in addition to a **microbial active agent**.

1.4.2 What formulation is to be registered?

Pesticides of any kind may be in circulation for research or for commercial purposes in three states of formulation:

- **Active agent** or **active ingredient/substance**
- **Technical grade formulation**
- Formulated **product** on the market

In some regulatory systems, principally the European Union (EU), a list of approved active ingredients is drawn up and published by the authorities based on consideration of their intrinsic efficacy and especially the risks they pose to non-target effects. Then only products containing approved active ingredients may be submitted for registration for marketing purposes. This practice appears to be followed in some African countries. Mostly however in Africa, registration of active substances and products is made at the same time and the data on both active ingredients and formulated products are evaluated together.

The registration framework described here has built-in flexibility to allow sequential or simultaneous registration of these three states of formulation. However, for some types of microbial biopesticides, e.g. atoxigenic *Aspergillus flavus*, there is no technical grade formulation. The **microbial active agent** is formulated directly on to seeds; this is the **product**. With others, e.g. *Metarhizium*, technical grade material consists of spores preserved in oil.

1.4.3 Registration at national or (sub-) regional level

Common data requirements and **equivalent registration systems** pave the way for harmonisation of pesticide registration either within a region or across the entire continent. Flexibility is provided in this framework for registration on three platforms depending upon the extent if any of regional integration:

(a) *Registration by national registration authority* for approval of a microbial biopesticide in that specific country.

(b) Joint reviews by two or more countries of submitted data whereby *responsibilities for evaluating applications are shared*. For example, one country might lead on efficacy and another leads on mammalian toxicity.[1]

(c) *Regionally harmonised system* where there is one regional level committee making decisions on behalf of all the member countries. *But each country has the right to refuse to register a given pesticide, or modify the conditions of registration.*

Platform (c) depends on there being **equivalent registration** systems with common data requirements. However, each participating country has the right to refuse admission of regionally registered product into national lists if the intended uses are inappropriate or if there are special risk factors.

In (b) there must be common data requirements but not *necessarily* equivalent registration because each participating country could make independent decisions.

1.4.4 Origin of microbial active agents

The framework allows for **indigenous microorganisms** (occurring in the country or region of registration) or **non-indigenous microorganisms** (occurring in other countries or regions) as **microbial active agents** but different procedures are applied according to their origins. The aim is to ensure that firstly microbial active agents referred to as 'indigenous' were isolated from the area (country or region - see below) in which registration takes place, and

[1] Adopted from NAFTA. See item 9 Annotated Bibliography (p. 45).

secondly that the importation of 'non-indigenous' microorganisms' was approved under appropriate biosecurity regulations or procedures. Further information is available from **International Standards for Phytosanitary Measures** (**ISPM) No. 3** (item 3 in **Annotated Bibliography,** p. **49**) under the **International Plant Protection Convention (IPPC)**[2].

However, the definitions for **indigenous microorganism** and **non-indigenous microorganisms** reflect the flexibility provided for harmonised registration as above. *The definitions should be adopted appropriately, particularly by inserting the name(s) of the country, countries or regions in the definitions. The term 'regional' has for this reason not been defined, relying on an ordinary or dictionary definition for interpretation.*

It is possible that a so-called 'indigenous' microorganism has been brought into the country or region of registration without permission or without even notifying the authorities and is actually 'non-indigenous' as defined, even though it has been released into the environment. This eventuality will be partially taken care of by the requirement that a culture has been deposited in a nationally recognised culture collection or that specific criteria for *registration of locally produced biopesticides* are met. If isolated strains of a **microbial active agent** are identified and characterised in a laboratory or research institution outside the country of origin, care should be taken to keeps records of the transfer and repatriation as proof of origin required for registration. This is particularly important if final strain selection for the **product** has been done abroad.

1.4.5 Use categories for microbial biopesticides

This framework covers microbial biopesticides used in any of the following spheres:

- Plant health/crop protection, pre- and post-harvest
- Animal health/veterinary matters
- Public health

1.4.6 Genetically modified organisms

Although not a reality at the present time, it is possible that in the future a **microbial biopesticide** might be presented for registration in which the **microbial active agent** is a **genetically modified organism (GMO)**[3]. Although there is widespread public and official antipathy to **GMOs** in many countries across the world (not just in Africa), it is felt that the possibility of GM **microbial biopesticides** cannot be ignored entirely in the registration framework. Nor is it advised specifically to exclude **GMOs** from the nationally or regionally adopted framework with a blanket ban because this might be seen as erecting a trade barrier (non risk-based) under the **SPS Agreement** of the World Trade Organisation (WTO).

Instead, the default position adopted in this guidance document is that there is a regulatory mechanism for approving the importation and use ('release into the environment') of **GMOs** (e.g. a Biosafety Act or Law). An applicant wishing to register a GM **microbial biopesticide** would then be referred to the appropriate biosafety authority for permission to import and use the **GMO**. Relevant guidance on risk analysis of GMOs (for environmental impact) is

[2] https://www.ippc.int/index.php?id=ispms&no_cache=1&L=0
[3] Living modified organism (LMO) in FAO terminology.

provided by ISPM 11 from the IPPC.[4]

If permission or licence were to be granted, registration of the microbial biopesticide would then proceed as for any other product. This is made clear to **registrants** in the guidance notes provided for them (chapter 5). However, if the issue of GMOs were to be so sensitive, perhaps because of the threat of violent protest by anti-GMO activists, then passages in chapters 3-5 and annexes referring to GMOs could be deleted as indicated in the box below, although this approach is not recommended.

References to GMOs that could be deleted in this chapter and following chapters are highlighted in turquoise:

Definitions in chapter 3.
Chapter 4. Recommended registration procedures for registration authorities
Chapter 5. Guidance for registrants
Annex 2, Part 1. Summary data requirements for pre-submission consultation
Annex 2, Part 2. Requirements for full data dossiers

Note on terminology – 'biosecurity' and 'biosafety'

In the British Commonwealth the term 'biosecurity' is taken to mean all regulatory activities aimed at preventing harmful organisms and harmful food products entering the country. This encompasses activities traditionally referred to as 'plant and animal quarantine'. In these jurisdictions, 'biosafety' is the part of biosecurity devoted to GMOs. However, misplaced concern about microbial active agents as GMOs when they are certainly not so may arise from anomalies in use of these terms.

In French, Portuguese and Spanish 'biosafety' is translated as 'biosecurité, 'biossegurança' and 'biosecuridad' respectively but these terms are also used for 'biosecurity'. Even in English language registration guidance or rules, microbial active agents may be subject to 'biosafety' provisions even if clearly they are not GMOs.

1.5 Identity and ownership of microbial biopesticides

1.5.1 Identity

The key to the several contentious issues around registration of any type of pesticide but also the key to safeguards for small, resource-poor farmers and consumers in Africa is the legal concept of **identity** of the registered product.

There may be different requirements for technical grade material and the marketed product, but it is clear from processes and procedures adopted in various jurisdictions (including African countries) that identity of any pesticide is determined by its composition:

- Details and concentration of active ingredients/active agents
- Details and concentration of formulants
- Details and concentration of impurities

In addition, in the case of certain types of **microbial active agents** it may be necessary to complete the **identity check** of a **microbial biopesticide** by providing:

[4] Pest risk analysis for quarantine pests including analysis for environmental risks and living modified organisms (2004). FAO. https://www.ippc.int/file_uploaded/1146657660135_ISPM3.pdf

- Details and concentration of microbiologically-derived contaminants such as specific metabolites

However, this is not necessary with the majority of **microbial biopesticides.** Additionally, the evaluation of data (and consequently the data requirements) should concentrate on impurities that are *toxicologically significant*.

*Overall, the detailed requirements for identity should be determined on a case-by case basis according to the nature of the **microbial biopesticide** proposed for registration.*

1.5.2 Ownership of a microbial biopesticide being registered

Microbial biopesticides being considered for registration may be either *public goods*, having been developed in publicly funded institutions for the benefit of farmers and other users at low cost or on a cost recovery basis; or they may be *private goods* owned by a company in a commercially oriented enterprise. In developed countries, many public bodies that have developed technology with government support have then formed commercial offshoots to market the developments, both to protect the inventions but also to ensure that these products are available on a cost-recovery basis to users. It is important to note that even if a **microbial biopesticide** is a public good, it is still likely to have a *trade name* as a form of intellectual property protection. Conversely, *generic pesticides* (see later) marketed for commercial purposes do not have a trade name.

Irrespective of whether a particular product is a public or private good, it should be recognised that the **registration** is effected because the **microbial biopesticide** is to be used and generally there will be some economic or commercial activities attached to its use. The legal or natural person in whose name the **microbial biopesticide** is registered (**registrant**) must be prepared to take on responsibility for the registered **product** post registration as part of **product stewardship** (see **1.6.3**) and normally will be required to make some sort of investment in the process.

The regulatory framework provided here is considered sufficiently robust to cover any type of endeavour whether public, community based or commercial and should be able to cope with the following developments:

- Commercial organisations offering alternative products for the same active agent.
- Generics marketed without a trade name.
- Small and medium enterprises (SMEs) and local communities developing microbial biopesticides for local use, as for some biopesticides in Africa and Asia. The need for registration here is to give users assurances of genuine, good quality products.

The regulatory scheme provided has been developed to allow users access to microbial biopesticides at acceptable price, while preventing fraud and preventing exploitation by unscrupulous commercial interests.

1.5.3 Confidential data

It is important to remember that even if a given **microbial biopesticide** to be registered is considered as 'public goods', the **registrant** should still either be the originator of the data

required or have a right to use that data. In some cases the data may be in the public domain so the second criterion will be satisfied. Additionally, even with public goods, the **microbial biopesticide** product will have a trade name.

There may however, be data that are 'commercial in confidence'. Confidential data could include data on identity but also accompanying manufacturing data that provide an explanation of the composition and the origin of impurities. Analytical data from an independent accredited laboratory to back up the assertions on identity and the required certificate of composition limits are not confidential, nor are data on efficacy and toxicology/other adverse effects.

However, the separate submission of confidential data (by secure means electronically or in sealed envelope) should be accompanied by a *disclosure declaration* detailing the extent to which the confidential data may be shared with other official regulatory bodies.

It is noted however that in some African registration systems, all data are regarded as confidential. This does not accord with international practice but the guidance issued herein should be modified in an appropriate manner.

1.5.4 Equivalent pesticides, generic pesticides and parallel registration

The concept of '**equivalent pesticides**' **('equivalence** of pesticides') arises with the registration (or attempted registration) of *generics* in cases where the active agent/ingredient is off-patent or the patent has expired. Equivalence of pesticides is about determining whether two or more pesticides are 'identical' to the extent that data dossiers may be shared. This is a complex issue involving not only the nature of the pesticide itself but issues of origin and ownership of data and legal identity of active ingredients. It is noteworthy that '**identity**' as defined for pesticide registration purposes (**1.5.1, 3.1**) includes composition of impurities. Controversy has arisen over commercial pesticide manufacturers attempting to protect their products first by blocking use of 'originator data' for registering generics and patent-expired pesticides, and secondly by interpreting identity in a certain way.[5]

A way round this is to conclude that two different pesticides are '*substantially similar*' but this may still meet legal objections from the holder of the originator data. The regulatory framework developed does not deal with generics in detail but reference is provided in chapter 4 to international guidance that will enable the registration authority to identify a **microbial biopesticide** present for registration as a generic and then proceed accordingly.

Parallel registration is a process for identical products permitted in some countries. In this case the **registrant** does not have to prove that a product is safe and efficacious if an identical product has already been registered. Parallel registration can take place in two ways:

- Parallel trade permit where under a regional scheme (e.g. EU), there is already a

[5] The controversy is objectively discussed at http://www.farmchemicalsinternational.com/article/18731/making-registration-systems-work-for-generics http://www.farmchemicalsinternational.com/article/18731/making-registration-systems-work-for-generics http://www.farmchemicalsinternational.com/article/18731/making-registration-systems-work-for-generics

product registered with an approved active ingredient/active agent in the country (the **reference product**) and an **identical** product is available from registration in another country participating in the regional scheme. However, a national registration authority is not obliged to register a product under this scheme if the pesticide is considered not safe or not suitable under prevailing conditions.

- 'Own use' permit where a single user is allowed to use a product for which there is no general registration but a reference product has been registered.

Parallel registration relies on strictly observing **identity** as discussed above. It should not be confused with registration of generics that are not necessarily **identical** with a reference product. In some African countries, 'parallel registration' appears to be used in connection with registration of generics.

Further guidance is available from national registration authorities, for example the Health and Safety Executive (HSE) in UK (items 24, 25 in **Annotated Bibliography**, p. 49).

1.6 Other background issues

1.6.1 Modes of registration

A general principle of pesticide registration (or any registration/licensing system) is that the registration authority has the power to respond to applications in a number of ways following the outcome of the evaluation of data dossiers. Thus the default position would be **full registration** valid for a specified period, but the registration might only be **provisional** if the pesticide is the subject of trials or if the **registrant** is required to provide more data. Alternatively, the registrant may be applying for **renewal of registration** or for a **modification** of an existing registration, perhaps because the **formulation** has changed, because additional uses are proposed or some uses have been discontinued. Of course, registration may be refused and existing registration may be revoked or modified at the insistence of the registration authority (see later). The registration fee required should vary according to the applicant's intentions.

These principles are included in the registration framework for microbial biopesticides.

1.6.2 Encouraging and facilitating microbial pesticide registration

It is generally recognised that registration of **microbial biopesticides** should be facilitated and encouraged in order to reap the benefits of this type of pesticide but also to put their use on a sound and safe footing (**Section 1.1**). The manner in which this is done in the registration framework proposed here is to offer a *Pre-Submission Consultation* to potential **registrants** with defined timelines for the consultation.

The *Pre-Submission Consultation*[6] is based on the following principles:

- Minimising data requirements to take account of lower inherent toxicity but

[6] Adopted from practice for microbial biopesticides in UK (http://www.pesticides.gov.uk/OneStopCMS/Core/TemplateHandler.aspx?NRMODE=Published&NRNODEGUID=%7bC9D1141A-E308-4B7C-84E5-60D55CD0D41C%7d&NRORIGINALURL=%2fguidance%2findustries%2fpesticides%2fuser-areas%2fbiopesticides-home&NRCACHEHINT=NoModifyGuest).

recognising the potential for **allergenicity** or **genotoxicity**

- Allowing the **registrant** to apply for data waivers in recognition of the lower intrinsic risk associated with **microbial biopesticides**. However, it is the **registration authority's** responsibility to accept or reject the waivers.
- Tiered data requirements (**chapter 4**)
- The registration fee for microbial biopesticides might also be lower than for conventional pesticides.

See also **Table 1**. Full details of the Pre-Submission Consultation for the purposes of the **registration authority** and the **registrant** are provided in the registration framework together with a draft text (**Annex 1**) for publicity purposes.

Table 1. Comparison of data requirements for chemical and microbial biopesticides.

Test area	Requirements for microorganisms	Requirements for chemicals
Identity/biological properties/physical chemical properties	Focus on identity and biological properties	Focus on physical-chemical properties
Toxicology	Focus on hypersensitivity, allergenicity and genetic toxicity	Greater focus on chronic, developmental and reproductive effects
Ecotoxicology	Fewer tests required overall than for chemicals, but some countries emphasize testing of effects on non-target organisms	
Efficacy	All countries required data in this area; some countries required extra tests not required for chemicals	Not all countries required efficacy testing

Adapted from OECD, item 4, **Annotated Bibliography** (p. 49).

An example of how the registration framework takes into account the complex issues discussed above is given in the box below and in **Figure 1**.

Consider the following case:

- Three countries, A, B and C, participating in a regional registration scheme or joint review of data
- Three different isolates of *Aspergillus flavus* as a non-toxigenic **microbial active agent** belonging to same vegetative compatibility group (VCG) distributed as follows:
    - Strain I: Countries A, B, C
    - Strain II: Countries B, C
    - Strain III, Countries A, B
- Three **products** are proposed for registration:
    - Mixture of I and II
    - Mixture of II and III
    - Mixture of I, I, III

It is assumed that these are public goods (1.5.2)

All three strains occur in all three countries (Figure 1) and therefore all are **indigenous** to this regional grouping.
Registration could proceed as follows:

- All three **microbial active agents** could be considered as **indigenous** (**1.4.4**)
- None of the three **microbial active agents** share **identity**
- None of the **products** share **identity**
- However, *data waivers* (**1.6.2**) could be applied for and likely to be granted for efficacy and toxicity/ecotoxicity data for two of the three **microbial active agents** and two of the three **products** because of considerable similarity
- *Tiered risk assessments* (**1.6.2**) would proceed as normal

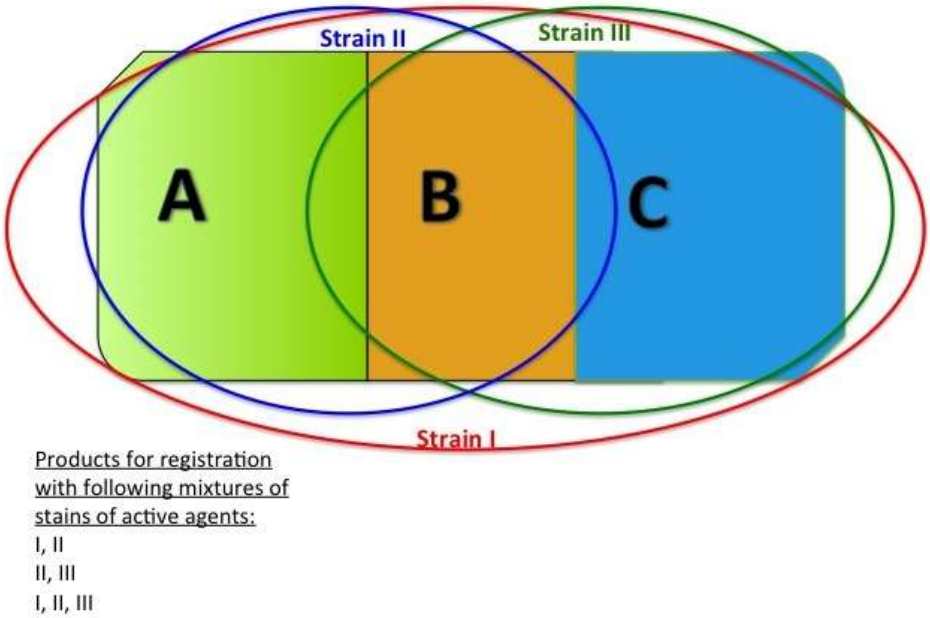

Figure 1. Registration of microbial biopesticides with mixtures of strains isolated in regional grouping of three countries, A, B, C

1.6.3 Post-registration controls – **product stewardship** by the **registrant**

(i) Farmer and applicator training and extension programmes
Any necessary training programmes of pesticide handlers in the broad sense should be developed for microbial biopesticides in general and augmented as necessary for each specific pesticide registered. Training should be developed and implemented in collaboration with the pesticide industry and with registrants.

(ii) Provision for follow-up data that may affect registration status
Provision for amending the registration conditions or suspending/revoking registration if adverse data emerges should be incorporated into the registration framework. Failing provision in the primary law (**section 2**), specific regulations or administrative rules should provide for the acquisition of data from (a) manufacturer/registrant, (b) from field use (including data on adverse occupational exposure) and (c) from health authorities (pesticide poisoning, residues in food).

(iii) Inspection of manufacturing, storage and selling premises and advertising and promotional activities, inspection of farms
The legal duties of pesticide inspectors should include monitoring all premises where pesticides of any sort are handled or used. This includes scrutiny for misuse, and for poor-quality, expired or fraudulent products in conjunction with appropriate sampling and testing.

1.6.4 Due process in registration

The registration authority has a duty to provide a good service to registrants and all others involved in the pesticide industry, ensuring that registration applications are treated fairly, without prejudice and bias and in a timely manner. Presumed to be in the primary are provisions for:

- Transparency in application process, data requirements and evaluation
- Time limit for evaluation and decision-making
- Giving reasons for refusal
- Complaints and appeals procedures

Provisions for these matters should be in fundamental pesticide law or general regulations for registration. They might also be found in administrative law/judicial review provisions (administrative code or common law).

1.7 Documentary sources for the regulatory framework

Reference was made to a great many sources of principles and practical guidance on the registration of pesticides in general and **microbial biopesticides** in particular. (References to other documents not specifically references in the development of this version of the guidance document are given in earlier drafts.) National and regional registration authorities and international organisations such as Food and Agriculture Organisation (FAO) and Organisation for Economic Cooperation and Development **(**OECD) produced these documents, listed in the **annotated bibliography** (p. 49). References on some other subjects such as pest risk assessment are given in footnotes.

Chapter 2
Giving the registration framework legal form and force

2.1 The form of the registration framework - legislation or guidelines?

There is no intention to provide a 'model law or 'model regulations' for biopesticide regulations because legal systems and legal drafting cultures vary too much across Africa without even considering the linguistic diversity. The approach taken is to provide the technical and regulatory content in a consistent form that could be adopted with relative ease. In any case it is recognised that in some countries appropriate regulatory frameworks and rules for registration may be in the form of an administrative document rather than legislation, either because this is the norm or because such provisions are necessary in the absence of a legal framework. Explanation of key issues provided in the previous section is designed to smooth the process of eventual adoption of the practical guidance that follows in **chapters 3-5** whether in legislative or administrative form.

However, the default position/assumption is that there is an existing legal framework for pesticides control including a basic registration framework. In this case it is likely that detailed rules for registration (such as guidelines or regulations) for conventional pesticides and biopesticides would work in parallel and subsidiary to the general law. However, it is apparent from a survey of relevant legislation among countries participating in the consultation over this Guidance Document that the existing primary legal framework in several countries is out of date and requiring amendment before a biopesticides registration framework could be adopted into law. Further information is provided in the next section. Here, the main issue is that amendments to primary laws or drafting and promulgating regulations do seem to take many years in SSA. Another situation is where there is no legal framework at all and the process of adopting a new law would take even longer. However, under the fundamental legal provisions of many countries registration frameworks including detailed rules may be adopted as guidelines or code of practice that still have legal weight provided they are subject to administrative supervision.

The emphasis of this Guidance Document is therefore to have registration frameworks working under whatever legal or administrative framework is available or appropriate rather than waiting for legislative reform. Nevertheless, it is important to ensure that there is ultimately legal authority for such measures. Therefore a normative framework for pesticide control and registration is provided below.

2.2 Normative legislative pesticide framework

2.2.1 Prerequisites for incorporating microbial biopesticides registration system into law

The following prerequisites for a microbial biopesticide registration system are assumed to be in place:

- Primary legal instrument governing pesticide or agrochemical control (Act of parliament/law, etc.)
    - Organisation responsible for pesticide registration and control

        - Governing body or board making decisions
        - Mandate to form specialist committee to register pesticides; to recommend registration (or refusal) to the governing body
        - Mandate to co-opt experts to advise on registration and evaluate
    - Basic definitions
        - Pesticide/pest control product/agricultural remedy
        - Classification of pesticides according to use and hazard (see below)
        - Key definitions for registration system (see below)
    - Power to make regulations or other secondary legislation
    - Registration system
        - Registrar or equivalent
        - Register of pesticides and certificate of registration
        - 'Registration 'committee' – see above
        - Defined categories of registration* (or power to create these categories); mandate to revoke or modify registration status Data and documentary requirements:
            - Full
            - Provisional (pending supply of further data)
            - Experimental use**
        - Provisions governing labelling, packaging, advertising
        - Due process in registration (transparency, timelines, etc.)
        - Pesticide use categories based on risk of adverse effects, e.g.:
            - General use
            - Restricted use*
            - Severely restricted use
            - Prohibited

          Microbial biopesticides are likely to be registered in the general use category but if for example there is potential allergenicity, they might be categorised as restricted use (requiring special precautions).

          *Some variations on these themes are evident from returned data in the survey of legislation. In Tanzania, for example, there is a special mode of registration for restricted pesticides. In Kenya there is '**Parallel Registration**' (**1.5.4**) for multiple trade names for the same active ingredient.
          ** In some countries, under experimental use registration, trials are confined to controlled conditions (laboratory or greenhouse), not allowed in farmers' fields.

    - Inspection and monitoring
        - Appointment of inspectors
        - Duties of inspectors
        - Powers of inspectors to enter premises, take samples, etc.
    - Provision for monitoring post-registration use

The definitions provided in **section 3.1** include definitions that are expected to be in the basic pesticide framework but might have to be included in the **microbial biopesticide** registration package.

2.2.2 Additional notes

The registration authority will normally have a permanent registration committee or panel whose job it is to consider applications for registration and recommend registration or otherwise to the registrar/governing body. However, evaluation of all the aspects of efficacy and adverse effects requires a wide range of expertise. It is therefore unlikely that the appointed members of the 'registration committee' will cover all the necessary expertise and so there should be provision for co-opting necessary expertise on a case-by-case basis.

The common law system provides for schedules attached to the act that contain detailed rules (e.g. labelling models), fees, lists of registered pesticides etc. These are effectively secondary legislation that may be changed by ministerial order in the same way as regulations and other secondary (subsidiary) legislation (subject to retrospective parliamentary approval). The equivalent in Napoleonic/civil jurisdictions is an annex but there may be constitutional restrictions on the authority to change without reference to parliament. On the other hand, civil law systems provide for ministerial or presidential decrees that may not necessarily need authority from parliament in the form of a primary law. This is a way around the cumbersome process of amending laws but is also a potential avenue for abuse of authority.

National or regional bodies that wish to assess the state of legislation in their country or region may wish to use the 'primary law checklist' provided in **Annex 6**.

From the responses received from four of the countries and one regional body participating in the consultations for this guidance document, the following issues *may require attention:*

- Not all frameworks recognise biopesticides as an alternative to conventional chemical pesticides.
- Active ingredient and formulated product may not be distinguished.
- Registration modes/categories recognised differ greatly.
- Fees may be fixed by statute and so may become out of date with inflation. It is preferable to set fees in secondary legislation or have a schedule (common law) or annex that may be amended without primary recourse to parliament.
- Confidential data - some countries regard all data as classified/confidential.

Chapter 3
Definitions

There is a need to accommodate alternative terminology for the same concept according to custom in different jurisdictions.

3.1 Definitions of technical terms

- **Pesticide/plant protection product/agricultural remedy** means any substance or mixture of substances intended for preventing, destroying or controlling any pest, including vectors of human or animal disease, unwanted species of plants or animals causing harm during or otherwise interfering with the production, processing, storage, transport or marketing of food, agricultural commodities, wood and wood products or animal feedstuffs, or substances which may be administered to animals for the control of insects, arachnids or other pests in or on their bodies. The term includes substances intended for use as a plant growth regulator, defoliant, desiccant or agent for thinning fruit or preventing the premature fall of fruit, and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport.
- **Active ingredient** means a chemical ingredient in a pesticide to which pest control activity is attributed.
- **Active agent** means a living component in a biopesticide to which pest control activity is attributed.
- **Biopesticide/biological pesticide** means a pesticide of biological origin including pheromones and other semiochemicals, or microorganisms such as bacteria, fungi, protozoa, viruses and viroids.
- **Biocontrol agent/biological control agent** means the active agent in a biopesticide to which the effects of biological pest control are attributed.
- **Microbial biopesticide** means a biopesticide in which the sole or main active agent is a microorganism.
- **Microbial active agent/microbial pest control agent** means a microorganism (bacterium, alga, fungus, protozoan, virus, mycoplasma, rickettsia) and any associated metabolites, to which the effects of pest control are attributed, but excluding nematodes.
- **Indigenous microorganism** means a microorganism originating naturally in the country or region in which the microbial biopesticide is being registered.
- **Non-indigenous microorganism** means a microorganism originating outside the country or region in which the microbial biopesticide is being registered.
- **Genetically-modified organism/living modified organism (FAO)** means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.
- **Modern biotechnology** means the application of:

  a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles; or

  b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

- **Identity** means the characteristics of a pesticide that confer uniqueness unambiguously as determined by its biological, chemical physical properties of its active ingredient(s) and the impurities consequent on its manufacture including microbial metabolites.
- **Manufacture** means the processes to produce a pesticide including synthesis of active agents and active ingredients, compounding, formulation and packaging.
- **(Formulated) product** means the pesticide active ingredient(s) and other components, in the form in which it is packaged and sold.
- **Technical (grade) material** means the commercial grade of the pesticide as it comes from the manufacturing plant, consisting of the active ingredient and any associated impurities, together with small quantities of additives necessary for stability.
- **Infectivity** means the ability of a microorganism to invade and persist in a viable state or to multiply within or on an organism, with or without disease manifestation.
- **Pathogenicity** means the ability of a microorganism to inflict injury and damage in the host after infection, to an extent depending on host resistance or susceptibility.
- **Toxicity** means the injury or damage in a host caused by a poison or toxin; infection, replication or viability of the microorganism is not necessarily required.
- **Allergenicity** means having the capacity to induce allergy.
- **LD_{50}** means the dose to kill 50 percent of the test population.
- **LC_{50}** means the concentration to kill 50 percent of the test population
- **EC_{50}** means the effective concentration to kill 50 percent of the test population.
- **NOEL** means the 'no observable effect level' in testing toxicity and other undesired effects of a pesticide.

3.2 Procedural definitions

- **Equivalent registration** means registration according to equivalent principles and practices.
- OR
- **Equivalence in registration** means the capability of registration systems in different countries to meet the same standards and objectives;
- **Equivalence** means, in the case of a pesticide, the determination of the similarity of the impurity and toxicological profile, as well as of the physical and chemical properties, presented by supposedly similar technical material originating from different manufacturers, in order to assess whether they present similar levels of risk.
- **Risk** means a function of the probability of an adverse health or environmental effect, and the severity of that effect, following exposure to a pesticide.
- **Hazard** means the inherent property of a substance, agent or situation having the potential to cause undesirable consequences (e.g. properties that can cause adverse effects or damage to health, the environment or property).
- **Product stewardship** means the responsible and ethical management of a pesticide product from its discovery through to its ultimate use and beyond.
- **Registration authority** means the official body responsible for registering pesticides as part of regulatory activity concerned with pesticides.
- **Registrar** means the official in the registration authority primarily responsible for registration of pesticides.

- **Registrant** means the legal or natural person applying to register a microbial pesticide and who will be the holder of the certificate of registration if granted.
- **Temporary registration** means registration status granted to a microbial biopesticide (with temporary registration number) after pre-submission consultation and approval has been given for full submission, but not allowing the microbial biopesticide to be used.
- **Provisional registration** means registration status granted to a microbial pesticide (bearing provisional registration number) pending supply of further data required by the registration authority.
- **Experimental use registration** means registration status granted (bearing experimental registration number) allowing experimental use prior to submitting application for full registration.
- **Full registration means** full registration status granted when all registration requirements have been met and the registration authority has granted approval for a microbial pesticide according to the conditions laid down in the certificate of registration.
- **Certificate of registration** means document certifying registration status of a particular microbial pesticide and including registration number according to the type of registration and any conditions applying to the registration such as use restrictions and categorisation.
- **General use pesticide** means a registered pesticide which has no restrictions for use.
- **Restricted use pesticide** means a registered pesticide which must only be used as indicated and by those authorised users because of potential adverse impact.
- **Severely restricted pesticide** means a pesticide whose use has been prohibited by the responsible authorities but which may be used under very specific conditions.
- **Prohibited pesticide** means a pesticide for which all registered use has been prohibited by regulatory action, or for which request for registration has not been granted or for which registration has been withdrawn or cancelled for health and environmental reasons.
- **Parallel registration** means the registration of a product without assessment of efficacy and toxicity when the parallel product is identical to a reference product already registered in the same country or region.
- **Reference product** means a product already registered in a country or region for comparison with a product being considered for parallel registration.

3.3 International organisations

- **FAO** means the Food and Agricultural Organisation of the United Nations.
- **International Plant Protection Convention (IPPC)** means the International Plant Protection Convention as adopted at the Conference of the United Nations Food and Agricultural Organisation at its Twenty-ninth Session (November 1997) and which came into force on 2 October 2005 and includes any subsequent amendments which are in force.
- **International Standards for Phytosanitary Measures (ISPM)** means the standards for phytosanitary measures adopted under the International Plant Protection Convention.
- **Organisation for Economic Cooperation and Development (OECD)** means the so named international organisation as a source of international guidelines for registration of microbial biopesticides.

- **SEARCH** means Southern and Eastern African Regulatory Committee on Harmonization of Pesticide Registration.
- **ISO 17025** means the international standard of the International Standards Organisation on 'General requirements for the competence of testing and calibration laboratories' that is required for a laboratory to be considered accredited to international standards in its area of competency.

Chapter 4
Recommended registration procedures for registration authorities

Explanation of regulatory concepts is provided in chapter 1. A normative legislative framework and definitions are provided in chapters 2 and 3 respectively.

Key to coloured highlighting of text in following Notes (4.2) and in Annex 2

<Green> **Details to be inserted on adoption of guidance in a country or region (in some cases suggestions are made).**

Turquoise **Optional text on GMOs to be omitted if necessary.**

4.1 Pre-submission consultation

4.1.1 First contact

In order to facilitate the registration and adoption of microbial biopesticides in agricultural production in Africa, a **Pre-submission Consultation** between the registrant and the registration authority is recommended. A model announcement for this process is provided in **Annex 1**. This consultation should be a face-to-face meeting with the minimum of formality but the registrant should request a meeting with the registration authority by submitting the **Summary Data Form** (**Annex 2 Part 1**) so as to supply the following information:

- Details of the identity of the biopesticide
- Origins of microbial active agent
- Deposition of culture in a nationally recognised culture collection
- Any non-microbial active ingredients
- Proof of ownership of the microbial biopesticide to be registered
- Type of registration to be requested *when full application is made*:
    - Registration for experimental use
    - Full registration
    - Renewal of registration

  (Amended registration (e.g. modified use, emergence of adverse effects) is not likely to apply to this situation)

    - Confidential data
        - a list specifying contents of the proposed product, including active ingredient and formulants, impurities and microbial metabolites*
        - manufacturing methods, information regarding any potential health or environmental effect
        - analysis report with certification of limits*

      * Analytical reports should come from accredited laboratories (ISO 17025)

    - Proposed disclosure agreement (for evaluation by official collaborators)
    - Technical data
        - a draft label;
        - short **summaries** of available data regarding efficacy, safety to the environment and human health that the registrant would like to include in the formal submission; including data on residues in

targeted food and persistence in environment after application (See Annex 2 sections 15 onwards)

- Likely requests for data waivers including scientific rationales for them

The meeting should take place within <10 working days> of the first contact.

4.1.2 Providing feedback to registrant

After the meeting the registration authority should respond within <15 working days> either with *a request for clarification of any outstanding issues* OR *with a letter with the following information*:

- Confirmation that the applicant is a suitable **registrant** as being the owner of the microbial biopesticide or in a suitable relationship with the owner. *The registration authority may also wish to verify that the applicant has the capacity for* ***product stewardship*** *and is not just a 'post office box' for a 'real'* ***registrant*** *outside the country that might be difficult to contact in case of problems.*
- Confirmation that full submission may proceed with objective of the specified mode of registration OR request further information.
- Any biosecurity issues to be satisfied – permission to import microbial active agent.
- Temporary registration number.
- Confirmation of data requirements including any data waivers.
- Directions for sample submission if local efficacy testing is required (**Annex 3**).
- Issues regarding confidentiality or ownership of data.
- Confirmation of disclosure agreement.
- Confirmation of the fee to be paid along with submission.

4.1.3 Multiple registration authorities

If multiple registration authorities are involved, e.g. for joint reviews of data, the above text and the model announcement in **Annex 1** should be modified appropriately.

4.2 Processing an application for registration of a microbial biopesticide

Full data requirements are given in **Annex 2 Part 2**, to be studied in detail.

Section of application form	**Data requirements**	**Key steps in registration process**
Preliminary		**I. Is there a Temporary Registration** (from Pre-Submission Consultation)? *Yes.* Check consistency of data with Summary Data Form ***GO TO III.*** *No.* Treat as new application ***GO TO II.***
	Type of registration applied for ☐**Full** ☐**Experimental use** ☐**Renewal** ☐**Modification of use**	**II. Checklist of data dossiers (Annex 2 Part 3)** **Sample Submission Form (Annex 3)** ***GO TO III***

	☐**Modification of composition**	
1	***Type of pesticide being registered*** There should be flexibility in the application procedures to allow registration of active ingredient and the formulated product sequentially or simultaneously. There may also be occasions when separate registration of technical grade material is necessary, for example to determine equivalence. The application form should therefore record which of the following pesticide types are being registered: • Active ingredient • Technical grade formulation • Product to be placed on market The sphere of uses includes: • Plant health/crop protection • Animal health/veterinary • Public health	**III. Basic data validated?** *Yes.* ***GO TO IV*** *No.* ***REVERT TO REGISTRANT***
	Details of registration of active agent/technical grade formulation/product in other countries It is important to know details of previous relevant registrations in this country or region or elsewhere	
2	**Details of registrant and owner of any commercial rights**	
	Under typical pesticide control legislation, a permit or licence is needed to conduct any form of business with pesticides, including importation, storage and transport for commercial purposes, manufacture and formulation, sale and disposal. Details required of the registrant should therefore include the licence/permit number of business registration number as appropriate along with name, (business) address and other contact details. The registration authority may not wish to register a pesticide on behalf of an applicant who appears to be only a distributor of an imported product without any apparent capacity for product stewardship.	
3	An emergency contact should be provided on the application form.	
4	**Identity of microbial active agent**	
	The following details should be required to identity biological and chemical active ingredients • Biological identity • Scientific name with genus, species, subspecies, strain, vegetative compatibility group (VCG) as appropriate	**IV. Identity of microbial active agent and right to register validated?** *Yes.* ***GO TO V.*** *No.* ***REVERT TO REGISTRANT***
	If there are any chemical active ingredients in a product being registered, the registrant should also complete **Section 11.**	**V. Any chemical active ingredients?** *Yes.* ***GO TO X.*** *No.* ***GO TO VI.***
5	**Origin of microbial active agent**	
	Registration authority must be satisfied that the microbial active agent is **indigenous** as defined.	**VI. Indigenous microbial active agent?** *Yes.*

	If a non-indigenous microbial active agent is involved, see section **10**. N.B. It is possible that a so-called 'indigenous' microorganism has been brought into the country of registration without permission or without even notifying the authorities and is actually 'non-indigenous' as defined, even though it has been released into the environment. This eventuality will be partially taken care of by the requirement that a culture has been deposited in a nationally recognised culture collection or that specific criteria for *registration of locally produced bio-pesticides* are met.	***GO TO VII.*** *No.* ***GO TO IX.***
	GMOs	
	Prospective importers of genetically modified microorganisms should be referred to the relevant legislation governing GMOs (e.g. 'Biosafety Act') and the authority responsible for administering it. This body may require a risk assessment before making a decision on importation. The International Standard for Phytosanitary Measures (ISPM) No. 11 from the Secretariat of the International Plant Protection Convention (IPPC) provides a risk assessment framework for GMOs (living modified organisms in FAO terminology) that might pose a risk to the environment. If the GMO in question is approved under biosafety provisions, registration should proceed as for any other pesticide. However, it is also recognised that some countries may ban GMOs altogether under national legislation or that GMOs are so controversial that any reference to them lead to protest and possible disruption.	**VI a. GMO approved?** *Yes* ***GO TO VII.*** *No.* ***STOP***
6	**Identity of technical grade material and/or product** Composition of technical grade material and product must generally be treated as confidential. This will have been dealt with during Pre-Submission Consultation and any disclosure agreements concluded (**see 4.1.1).** **The exact requirements for determining identity, especially impurities and microbial metabolites (if any) will depend on the nature of the microbial active agent.**	**VII. Confidential data discussed in Pre-Submission Consultation?** *Yes.* ***GO TO VIII.*** *No.* ***DISCUSS WITH REGISTRANT BEFORE PROCEEDING (VIII)***
Confidential (separate)	**Identity of technical grade material** (as necessary) **Composition (% and tolerance)** **Microbial active agent(s)** **Chemical active ingredient(s) if any – Section 11.** **Chemical impurities** **Impurities that are toxicologically significant** **Other impurities** **Microbial metabolites** **Formulants (additives, inert ingredients)**	**VIII. Identity of technical grade material and/or product validated?** *Yes.* ***GO TO XI.*** *No.* ***REVERT TO REGISTRANT*** *Chemical active ingredient.* ***GO TO X.***
Confidential (separate)	**Identity of product** **Composition (% and tolerance)** **Microbial active agent(s)** **Including mutant strains**	

	Chemical active ingredient(s) if any – Section 11. **Chemical impurities ('inert ingredients')** **Metabolic by-products** **Microbial contaminants (especially mammalian pathogens or antagonistic microbes)** **Formulants (additives, inert ingredients)** **Identifier of technical formulation** **Trade name of product**	
7 Confidential (separate)	**Manufacturing details including formation of any unintentional ingredients (impurities, contaminants)** **Quality control/quality assurance must be included, especially measures to mitigate any potential hazards** **Steps must include appropriate maintenance of seed cultures, quality controls for sterility, lack of microbial contamination and preferably some appropriate bioactivity measure related to acceptable field performance.**	
8, 9	**Analysis** **(From laboratories accredited to ISO 17025)** Also part of this data set are non-confidential analytical details **The certified limits are applicable to quality control. For microbial biopesticides, the lower limit is of most importance. A product with a concentration of microbial agent lower than the certified limit might be removed from circulation by the authorities.**	
10	**Importation of non-indigenous microbial active agent** Has permission to import been granted as part of pre-submission consultation? ☐Yes ☐No If **Yes**, provide certified copy of import permit from relevant authority If **No**, the registrant must seek approval to import from <name of biosecurity authority> before proceeding with application.	**IX. Permission to import non-indigenous microbial active agent?** *Yes* ***GO TO VII.*** *No.* ***STOP.***
11	**Identity of any non-microbial active ingredients** ***The presumption is that any non-microbial/chemical active ingredients are already registered. If this is not the case, appropriate registration procedures should be followed for these ingredients before submission of this application.***	**X. Chemical active ingredient permitted in country/region of registration?** *Yes.* ***GO TO VII.*** *No.* ***STOP.***
	Technical data for evaluation of application The Checklist of Data Dossiers Annex 2 Part 3 should be consulted for appropriate completion of data requirements for the following technical aspects	**XI. Begin evaluation of technical data.**

	of the microbial biopesticide: • *Formulation to be registered in relation to uses* • *Proposed uses and precautions* • *Efficacy in relation to proposed uses* • *Toxicity and other non-target/adverse effects* • *Packaging, labelling ad advertising* • *Post-registration control* For the methodology for evaluation of efficacy, general guidance is provided by OECD (Item 6 and Appendices, **Annotated Bibliography** p. **49**). **It is not considered appropriate to provide detailed methodology because evaluation of data will normally need to proceed on a case-by-case basis. Training of personnel responsible for evaluation may be necessary using worked examples or case studies.** **Where no units of measurement are given, the magnitude of effects are recorded on arbitrary scales according to the type of test**.	
12	**Details of formulation**	
	Formulation details should be accurate and appropriate	
13	**Uses**	
	The intended use(s) of the product should be clearly indicated with major uses indicated on the label. The ecological zones where it will be used are particularly significant (see below) and therefore details of previous registrations in other countries/regions are necessary.	
14	**Biology/ecology of active agent(s)** The biology and ecology of the microbial active agent(s) are important in relation to the intended uses and the evaluation of efficacy. It is particularly important to be able to predict the behaviour in the designated ecological zones for use of the pesticide.	
15	**Efficacy**	
	Field trials and/or test data files relevant to each intended use and each ecological zone declared in Section 13. *The biology and ecology of the microbial active agent(s) are important in relation to the intended uses and the evaluation of efficacy. It is particularly important to be able to predict the behaviour in the designated ecological zones for use of the pesticide.*	
16-	**Risk assessment for adverse effects** The data to be evaluated in risk assessment are very complex and diverse because of the different modes of potential toxicity and other non-target effects and the means of exposure on humans (operators, bystanders, food consumers), wildlife and environment. Each type of data requires specific techniques of risk assessment but an extra dimension is the provision for tiered risk assessment as part of fast-tracking given the inherently lower toxicity of microbial active ingredients. There is no consistent	

	global approach to the number of tiers and the level of tiers may vary for each aspect of toxicity. Primarily evaluation procedures should be developed for first registration of microbial biopesticides, but secondarily, streamlined procedures for renewal of registration and for addition of new or minor uses should be developed. The registration authority should be able to respond to the emergence of new data post-registration in order to modify the registration or if necessary revoke it. . ***Annex 2 Part 2*** *gives indications of variation of data requirements according to the mode of registration.* Administratively, legal authority should be given to a registration committee who consider applications and make a recommendation on registration to the full board of the registration authority. It is presumed that these legal provisions are in the primary law on pesticides. However, although the registration committee should be composed of people with technical experience and experience on various aspects of pesticide, the bulk of risk assessments should be done by seconded specialists appropriate to each type of pesticide. The composition of these specialist panels will consequently vary whereas the members of the registration committee will have formal appointments for a specified term and to whom the technical panels will report.	
16	**Primary toxicological data – mammals** <u>Data waivers</u> Waiving certain data requirements for microbial biopesticides is a means of encouraging and facilitating registration for this type of pesticide. Data waivers should be considered as a procedural measure to be distinguished from risk assessments by a tiered approach. Reference to **Table 1** in Chapter 1 indicates that data waivers could be applied for: • Physical/chemical properties of microbial active ingredients • Standard toxicity with instead emphasis on hypersensitivity, allergenicity and genetic toxicity • Some aspects of ecotoxicology with emphasis on other aspects Similarly, data from pesticides with similar active agents being allowed to substitute for novel data is a means of facilitating registration and avoiding unnecessary testing, not avoiding or reducing risk assessment. See example in **1.6.2** of introductory guidance.	
16.1	**Tier I**	
	Occupational health surveillance report on workers and bystanders during production and testing including information on: sensitisation and allergenic response of	

	fermentation; workers related to exposure with special attention to those who might be especially susceptible (e.g. children, the elderly and pregnant women).	
	Acute oral toxicity (mg/kg) Acute oral infectivity	
	Acute intra tracheal/inhalation toxicity and infectivity (mg/4h)	
	Acute intravenous/ intra peritoneal infectivity by injection	
	Acute dermal toxicity/infectivity (g/kg)	
	Acute eye irritation	
	Primary dermal irritation	
	Cell culture for viruses and other non-cultivable or fastidious microorganisms	
	Genotoxic potential, especially for fungi and actinomycetes	
	Toxicity studies on metabolites (especially toxins)	
	Proposed first aid measures and medical Treatment	
16.2	**Tier II**	
	Acute toxicology NOEL (mg/kg/day)	
	Subchronic toxicity/pathogenicity NOEL (mg/kg/day)	
16.3	**Tier III**	
	Reproductive/fertility effects (lifetime exposure) NOEL (mg/kg/day)	
	Carcinogenicity NOEL (mg/kg/day)	
	Immunotoxicity NOEL (mg/kg/day)	
	Infectivity/pathogenicity analysis	
	Teratogenicity NOEL (mg/kg/day)	
	Neurotoxicity NOEL (mg/kg/day)	
17	**Effects on wildlife and non-target organisms**	
17.1	**Tier I** **The tier 1 tests are usually done at some higher than expected level (10 or 100x) from that proposed**	

	for use in the field.	
	Birds (2 species) LD_{50} (mg/kg)	
	Fish or other aquatic vertebrates (2 species) LC_{50} (mg/ml)	
	Aquatic invertebrates LC_{50} (mg/ml)	
	Effects on algal growth EC_{50} (mg/l)	
	Bees (mg/bee)	
	Earthworms or other relevant soil invertebrates The registrant should propose long-term testing when the comparison of the (predicted) environmental exposure with the results from the short-term toxicity test(s) indicates the need to investigate further the effects on terrestrial organisms. The choice of the appropriate test(s) depends on the outcome of this comparison. These studies do not need to be conducted if direct or indirect exposure of the soil compartment is unlikely.	
	Non-target soil microorganisms	
	Effects on aquatic or terrestrial plants Units: mg/l for EC_{50} and NOEC EC50: in this method, that concentration of test substance which results in a 50% reduction in either growth (E_bC_{50}) or growth rate (E_rC_{50}) relative to the control.	
	Wild mammals	
	Non-target terrestrial invertebrates	
	Other terrestrial inverts	
	Tier II	
	Data from expression tests if indications of toxicity in tier I	
	Tier III	
	Dose response tests if necessary indications from tier I and tier II	
17.4	**Tier IV**	
	Field or simulated testing if necessary indications from lower tiers	
18	**Residues**	
18.1	**Residues in food or other materials to which applied** Nature of residues Taint (odour, taste, colour) in food Analytical methods **Acceptable daily intake (ADI)** **Data waivers** ***Rationale required for waiver based on a substantiated estimation that microbial active***	

	agent is unlikely to occur on treated food/feed stuffs in concentrations considerably higher than under natural conditions	
18.2	Nature of residues in plants and/or animals Residues in rotational crops	
18.3	Analytical methods for residues in plants and/or animals	
18.4	Storage stability **Shelf life is a critical factor for biopesticides in general because it is a key factor in farmers' acceptance (see also 8,9)**	
	Level of residue in plants	
18.5	Level of residues in milk, meat, poultry and eggs	
18.5	Magnitude of residues in potable water, fish, and irrigated crops	
19	**Residue and fate of metabolic products in the environment**	
	Sufficient information on the origin, properties, survival and residual metabolites of the microorganism to assess its fate and behaviour in the environment. *Information provided in earlier parts of the toxicology data dossier may suffice*	
20	**Safety data sheet**	
	Safe handling including formulation, transport, sale, use **Safe disposal** **Procedures for decontamination of water and terrestrial environment in case of spillage** **Emergency procedures in case of fire**	
21-24	**Packaging, labelling, advertising plans, post-registration control** Correct labelling of pesticides for safe and efficient use is essential. The plans for labelling (e.g. sample labels) submitted with the registration form should be scrutinised for conformity for accepted standards, e.g. FAO, if these are not already established in national legislation. Whereas primary use of a microbial pesticide would be recorded on the label, there may be provision of minor or off-label use provided there is appropriate justification through efficacy data and the registration authority approves such uses. Similarly, advertising plans should be scrutinised to ensure that unwarranted or misleading claims are not used and inappropriate methods such as sexual innuendo are not employed. If this topic is not prescribed in national legislation, there are international guidelines to follow (e.g. WHO). Finally, plans for post registration controls to be	

	adopted by the registrant should be scrutinised and either approved or modified through the medium of the certificate of registration.	
	Type **Materials** **Size** ***Include sample***	
22	**Labelling**	
	Specimen label in accordance with prescribed standards **Specimen of technical leaflet**	
23	**Advertising plans**	
	Type of media (billboards, promotional leaflets, TV, radio, etc.) **Indicative content**	
24	**Post-registration controls and other activities**	
	Provision to acquire emerging data and to notify authorities of the following incidents: • Non-target effects • Injury from occupational exposure • Injury to bystanders • Loss of efficacy • Unforeseen problems arising from use	
	Training plans for distributors, extension workers and users	
		XII. Evaluation completed? *Yes* ***MAKE DECISION ON REGISTRATION (See 4.3)*** *Incomplete data* ***REVERT TO REGISTRANT***

4.3 Making a decision on registration

4.3.1 Modes of registration

The application will include the mode of registration applied for

- Provisional/full
- Experimental use
- Renewal
- Modification of use
- Modification of composition

A decision must be based 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 full registration, the registration authority may decide to grant provisional approval if further

data are required. This situation may arise with a new product where there is insufficient experience of field use.

The next step is to record a registration number and details of registration in the official register and issue a corresponding certificate of registration (**Annex 4**). The register and the certificate will record the *Conditions of Registration* such as post-registration controls, major use categories, restrictions or cautions on use permitted off-label and minor uses, and any observations or directions on submitted plans for labelling and advertising.

The registration authority should reserve the right to revoke, suspend or modify registration on its own initiative subject to emergence of data post-registration (see later).

If an unfavourable decision is made, either on first application or post-registration, the registrant would normally have the right of appeal, to a higher authority in the first instance, and ultimately to the courts. There may be provision for this in general pesticide law or in administrative law (judicial review).

4.3.2 Certificate of registration (Annex 4)

A form should be produced for the certificate of registration to bear all the important details of registration including:

- Registration number/previous registration status and No.
- Type of registration
- Period of validity
- Registrant's details
- Emergency contact
- Details of pesticide
- Conditions of registration:
  - Permitted on-label uses
  - Permitted off label/minor uses
  - Post-registration controls imposed on registrant
- Type of pesticide: insecticide, fungicide, herbicide, etc.
- Restrictions and cautions, e.g.
  - Pathogenic to plants – restrict use in some rotations, e.g. do not use if rice is followed by vegetables
  - Wear protective clothing
  - Toxic to bees
  - Toxic to fish
  - Etc.

4.3.3 Register of microbial biopesticides

The register of pesticides may be provided in paper and/or electronic form.

If a national registration system is being considered but there is a relevant regional body looking towards harmonisation of (bio-)pesticide registration (e.g. REC), then it is recommended that the Register be shared with the regional body with a view to making the register available to other countries in the region.

4.3.4 Schedule of fees

The fees for different categories of registration should be transparent. It is preferable if fees are announced in secondary legislation rather than in primary law so that fees established previously do not become outdated through inflation. It is recommended that fee levels should be subject to stakeholder consultation. If there is a regional dimension to registration, there should be coordination between the regulators in order to avoid 'forum shopping' by registrants.

4.3.5 Due process in registration

The registration authority has a duty to provide a good service to registrants and all others involved in the pesticide industry, ensuring that registration applications are treated fairly, without prejudice and bias and in a timely manner. Presumed to be in the primary are provisions for:

- Transparency in application process, data requirements and evaluation.
- Time limit for evaluation and decision-making.
- Giving reasons for refusal.
- Complaints and appeals procedures.

Most importantly, it is reasonable that an indicative time limit should be given for a decision on registration. If the evaluation cannot be completed within the allotted time, the registrant should be informed as to the reasons.

If these provisions are lacking (or there is no applicable pesticide legislation), the registration authority should become familiar with national provisions in administrative law such as judicial review (administrative law code or common law depending on the jurisdiction).

4.3.6 Post-registration controls – product stewardship

Even while recognising the lower inherent risks in the use of microbial biopesticides compared with conventional chemical pesticides, post-registration controls are necessary for a number of reasons:

- Emergence of new data on non-target effects and toxicity that might require a revision of registration.
- Emergence of new data on efficacy, e.g. data indicating resistance in target pest.
- Poor-quality, expired and fraudulent products appearing on the market.
- Evidence of poor handling of pesticides such as improper storage, application methods exposing operator or community to risk, use in contravention of label instructions.
- Emergence of residue levels in food or environmental contamination in excess of maximum permitted levels.

  The governing primary law on pesticides should have provision for post-registration controls effected through the work of inspectors who monitor commercial activities on pesticides on- and off-farm and also take samples of pesticides suspected to be illegal and samples of food and water suspected to be contaminated (Chapter 2).

  However, the manufacturer or registrant of a microbial biopesticide should also declare a plan for post-registration controls and be under an obligation to carry out these controls. In particular, the registrant should be under an obligation to provide any

emerging data concerning the pesticide's efficacy and toxicity.

The registrant should also be under an obligation to prepare a plan for delivering any training necessary to all those handling the pesticide (sellers and users) to ensure safe and efficient use. In the context of developing countries, there may be a requirement for the registrant to provide the training or subsidise the training done by public bodies and also help with the cost of necessary personal protective equipment.

Chapter 5
Guidance for registrants

5.1 Introduction

This guide explains the requirements and procedures for making an application for registering **microbial biopesticides** that supplement or override the corresponding procedures for conventional chemical pesticides or biopesticides in general. The guide also explains what the registration authority will do to process an application and what kind of response the applicant could expect from the authority.

What **microbial biopesticides** are and what they do are explained in the accompanying guidance on **Pre-Submission Consultation** (**Section 2/Annex 1**) that **registrants** are encouraged to seek prior to submitting full registration application. Precise legal definitions of various technical and procedural terms needed for full understanding of the registration are given below before the full application process and data requirements are described. Finally, the possible outcomes from the application are described.

5.2 Definitions

Refer to Chapter 3.

5.3 Pre-submission consultation

In order to encourage and facilitate the registration of microbial biopesticides, intending registrants should hold/request a **Pre-Submission Consultation** with the registration authority prior to making a full/formal application.

Details of this process and a guide to the outcome and next steps are given in **Annex 1.** *However, registrants should familiarise themselves with the requirements for a full application and with the full data requirements as below before seeking a Pre-Submission Consultation.*

The request for Pre-Submission Consultation should be accompanied by the **Summary Data Form (Annex 2 Part 1)**.

The various forms are available or will be supplied as editable documents so that blocks may be expanded or duplicated as necessary.

5.4 Making an application to register a microbial biopesticide

Requirements:

- Application form **Annex 2 Part 2.**
- Full data dossiers with checklist **Annex 2 Part 3.**
- Sample form **Annex 3.**
- Appropriate fee

Guidance on making an application and data requirements is available as follows:

- OECD Guidance for Industry Data Submissions (Item 5 and Appendices, **Annotated Bibliography** (p. 49).

- US EPA (Item 19, **Annotated Bibliography** with more detailed technical guidance in items 17, 18 and 20-22).

Consulting the FAO *Code of Conduct on the Distribution and Use of Pesticides* (Item 1) and Crop Life International's Guide to this Code (Item 9) might also be advantageous.

Notes on making application – refer to appropriate sections of Application Form

Section	Notes
Preliminary	(i) It will be to the advantage of the registrant to seek a Pre-Submission Consultation before making a full application. (ii) If this procedure has been followed, a Temporary Registration will have been provided. (iii) The following modes of registration may be applied for and are described in the definitions given above: • Full • Experimental use • Renewal • Modification of use • Modification of composition The application form indicates the data requirements for each category as compulsory (R) or conditionally required (CR) subject to confirmation by registration authority, normally in the response to the Pre-Submission Consultation. (iv) If the registration authority requires additional data or clarification of some parts of the submission, they may at their discretion grant *Provisional Registration*
1	(i) Normally, for a new microbial product, neither the active agent nor technical grade material will have been previously registered but if this has been done, the appropriate boxes should be ticked. (ii) As proof of previous registration with the **same authority**, copies of any registration certificate should be supplied.
	Details of product registration in other countries should also be supplied if applicable.
2	Full details of the registrant, manufacturer and/or the owner of trade name or patent if different must be supplied as proof that the registrant has the right to register the product in question. The registration authority may require details of the registrant's capacity for product stewardship and ability to respond to emergencies and other events post-registration.
3	(i) Supply emergency contact details in case of accidents or other emergencies post-registration. (ii) **Changes post-registration must be notified.**
4	(i) Providing full details of the **identity** of the microbial biopesticide as legally defined is essential for successful registration and to confirm that the registrant is entitled to register it. Identity in this case includes biological aspects (taxonomic identity) and compositional details. This section requires the biological details. Compositional details (section 7.8) may be supplied confidentially if the registrant so desires. (ii) If there is more than one microbial active agent in any biopesticide being registered, this section must be duplicated for each agent by copying appropriate rows of the form and inserting data.

	(iii) If there are any non-microbial active ingredients, even if they are of 'biopesticide' nature, details must be supplied in Section 11.
5	(i) It is important to establish the precise origin of the microbial active agent and particularly whether it is indigenous (native) to the country/region of registration or if originated outside. If the microbial active agent has been sent abroad for identification and testing and then repatriated, keep records of the transfer as proof of local origin. This is particularly important if final strain selection for the product has been done abroad. In the case of non-indigenous organism, the application will not be processed without proof that the organism has been imported with the approval of the appropriate agency responsible for biosecurity (see section 10). (ii) Locality from which sample obtained, not laboratory where isolated. Provide geographical descriptor and/or latitude/longitude. (iii) Isolates must be deposited with an agreement to ensure that the sample will be maintained and will not be discarded for the duration of the associated registration(s). (iv) Registrants wishing to register a pesticide based on microbial active agent that is a genetically modified organism (GMO) should apply to the national agency responsible for approving importation and use of such organisms and related biotechnology. If the GMO is approved, registration will proceed as for any other pesticide.
6	(i) Confidential data should be supplied separately according to instructions from the registration authority: a. Paper form in sealed enveloped; or b. Passworded file by email; or c. Secure online submission (ii) Depending on what type of formulation is being registered (Section 1), there may be confidential data on technical grade and/or formulated product. (iii) For any non-microbial active ingredients, see Note (iii) in Section 4. (iv) The confidential data should be accompanied by a **Disclosure Declaration** allowing confidential data to be shared with other public bodies involved in evaluating data. This normally will have been discussed during the Pre-Submission Consultation **The exact requirements for determining identity, especially impurities and microbial metabolites (if any) will depend on the nature of the microbial active agent. The registration authority will advise during the Pre-Submission Consultation.**
7	(i) Manufacturing details are required and may be submitted confidentially as above. (ii) For any non-microbial active ingredients, see Note (iii) in Section 4.
8	(i) Reports of analysis of microbial biopesticides from accredited laboratories (ISO17025 or equivalent) are required. These reports are not considered confidential. (ii) Any non-microbial active ingredients must be included.
9	(i) Certification of limits of composition (from an accredited laboratory) forms part of the identity of the microbial biopesticide being registered. Certified limits are legally binding. (ii) Any non-microbial active ingredients must be included. The certified limits are applicable to quality control. For microbial biopesticides, the lower limit is of most importance. A product with a concentration of microbial agent lower than the certified limit might be removed from circulation by the authorities.
10	As mentioned above, the application will not be processed in case any non-indigenous microbial active agents have not been approved for importation.

11	Any non-microbial active ingredients are required to be separately registered under appropriate procedures and proof of registration supplied.
12	(i) Details of the formulation should be provided using standard codes where available. For example microbial biopesticides might be formulated as coated seed. The code in this case is PS. See list of formulation codes in OECD guidance (item 5b in **Annotated Bibliography**, p. 49). (ii) The concentration of active agents/active ingredients in the supplied formulation should be given in units appropriate to the formulation (i.e. whether liquid or solid). (ii) Other publicly available data as available should be provided according to the application form.
13	(i) The product should first be categorised according to the sector in which it is intended to be used. (ii) Summary data should be accompanied by the full technical leaflet(s) that will be made available to users (see **Annex 2 Part 3).**
14	Sufficient data on the biology of the active agent(s) must be supplied. It should not be necessary to supply a separate file but references to scientific publications should be included.
15	Application form should be completed with indicative data but accompanying full data dossiers should be appended (see **Annex 2 Part 3).**
16, 17, 18, 19	Toxicology and data on potential adverse impact (i) Application form should be completed with indicative data but accompanying full data dossiers should be appended (see **Annex 2 Part 3).** International guidelines (e.g. OECD) should be consulted for detailed guidance on compiling data dossiers. (ii) Any data waivers applied for must be accompanied by scientific justification. (iii) During the Pre-Submission Consultation, the registration authority will have indicated specific data requirements and taken into account any data waivers applied for and subsequently accepted or rejected. (iv) The registration authority will indicate what data are required for tier assessments higher than tier I.
20	Safety data Indicative data should be supplied on application form and supplemented by Full Safety Data Sheet (see **Annex 2 Part 3)**.
21	Packaging Details of packaging should be accompanied by samples/specimens of packaging (see **Annex 4).**
22, 23	Labelling (i) Indications of how label and any projected advertising meets national or international standards (e.g. FAO International Code of Conduct on Distribution and Use of Pesticides) (ii) Specimen label to be attached. (iv) Technical leaflet to be supplied with sold product should be attached. (iii) Specimens of any promotional leaflets should be attached. See **Annex 2 Part 3.**
24	Post registration controls and other activities (i) Explain how the product's use, efficacy and any adverse impact will be

	monitored by the registrant and how the registrant will cooperate with the authorities to provide any emerging data that may affect registration and use. (ii) Training plans for distributors, extension workers, users and others should be explained together with any support provided for personal protective equipment (e.g. free issue or subsidised sale)
25	Declaration The application should be completed by supplying all the required details.

5.5 Next steps

5.5.1 Outcome of submission

The registration authority will have informed the registrant of the expected time required to process the application and evaluate the data. If this period of time elapses without any response, the registrant should contact the authority for the status of the submission. Normally, a response will come as follows:

(i) Registration granted with a certificate of registration and a registration number. The certificate will bear conditions of registration to be complied with, including any mandatory modifications to the intended use, label indications, etc. The certificate will bear the use category (general use, restricted, severely restricted) according to the definitions in **section 3**.
(ii) A request for more data or clarification of certain issues arising from the evaluation of the data submitted. In this case the registration authority may issue a provisional registration or alternately suspend the evaluation process until the required information has been submitted.
(iii) Registration refused, in which case the registration authority is obliged to provide reasons for refusal.

If the registrant is not satisfied with either the conditions of registration or with a refusal to register the product, the registrant may make a complaint to the authority. If the outcome is not satisfactory to the registrant, an appeal to higher authorities may be possible under prevailing general pesticide law or national administrative law; in the first instance to the government minister responsible, and perhaps ultimately to the courts.

5.5.2 Responsibilities of the registrant post-registration

Farmer and applicator training and extension programmes

Any necessary training programmes of pesticide handlers in the broad sense should be developed for microbial biopesticides in general and augmented as necessary for each specific pesticide registered. Training should be developed and implemented in collaboration with the pesticide industry and with the registration authority. Training plans submitted with the application for registration should be followed and any modifications post-registration notified to the registration authority.

Provision for follow-up data that may affect registration status

(i) Use of the registered microbial biopesticide should be monitored and any adverse impact on users, other handlers and bystanders notified to the registration authority without delay.

The registration authority will be working with pesticide inspectors and with health authorities to report any incident of health impact (pesticide poisoning in workers or from food) and with environmental protection authorities for emerging data on environmental impact. In case adverse impact is found, it may be necessary to modify the registration status of the microbial biopesticide in question **6.5.3**). If for example workers in the distribution trade are found to suffer toxicity or other adverse effects, it might be necessary to modify the **conditions of registration** on the registration certificate. In extreme cases, registration might be revoked.

(ii) Similarly considerations apply to any observed loss of efficacy. This might be due to improper storage, to resistance developing in the target pest or loss of virulence with the microbial active agent.

(iii) Changes in emergency contact details (Section 3 of application form) must be notified immediately to the registrar.

5.5.3 Modification of registration status

Renewal of registration

The registration for a given product will normally be valid for a specified period. If towards the expiry date of the registration <three months>, the registrant wishes to continue marketing the registered product, an application for renewal of registration must be made. If registration is not renewed, the product will cease to be registered and it would be illegal to engage in any regulated activities connected with it, including formulation, transport and distribution, sale and use. The data requirements for renewal of registration are indicated in the application form.

Modification of use and modification of composition

If after initial registration, there is cause to modify use or modify composition of the product, an application to modify the registration status must be made according to the data requirements in the application form. The need is likely to arise from data emerging from post-registration monitoring of the use, effectiveness and adverse effects of the microbial biopesticide or from information coming from other countries where the same or similar products are in use. A modification to the registration may be required by the registration authority when they become aware of emerging data or the need may arise from the registrant's own post-registration monitoring.

Modification of registration status will also apply when the registrant wishes full registration for an 'experimental use' microbial biopesticide.

Revocation of registration

A situation may arise where the registration authority considers that because of emerging data, a given microbial biopesticide presents too great a risk to continue its use. Alternatively, efficacy may be reduced to such an extent that its use is no longer beneficial. In these situations registration may be revoked but the registrant will be told the reasons for such action. In this case the microbial pesticide will effectively be classified as a prohibited pesticide.

Addendum
Models for harmonised registration of microbial biopesticides in Sub-Saharan Africa

Preliminary considerations

Following the completion of the final draft of the Guidance Document *Regulatory Frameworks for Microbial Biopesticides in Sub-Saharan Africa*, the framework was presented at a trilateral meeting (Malawi, Mozambique, Zambia) considering the registration of a microbial biopesticide (*Aflasafe*™, atoxigenic *Aspergillus flavus*) for aflatoxin control. The meeting was convened for the benefit of the registrars of pesticides for the three countries with several facilitators and resource persons in attendance. Furthermore the framework was used in a simulated registration exercise in which the pesticide registration authorities in each of the three countries were asked to consider an application for registration of a microbial biopesticide according to the appropriate existing legal frameworks. The departure point was the 'Regional Guidelines for the Regulation of Plant Protection Products in SADC Member States'[7] and especially the 'Unified Application Form' annexed therein. With respect to regional integration and harmonisation of pesticide registration, Malawi, Mozambique and Zambia are members of SADC but only Malawi and Zambia are members of COMESA.

The exercise simulated the Pre-Submission Consultation proposed in the Guidance Document. Key points in the summary application form 'submitted' was that:

1. The microbial biopesticide being registered was based on a mixture of **non-indigenous**, imported strains of atoxigenic *A. flavus*.
2. **Data waivers** were applied for the toxicity, ecotoxicity and efficacy data.

The following key observations are made on the outcome of the exercises:

1. None of three registration countries would consider **full registration** for the product because the microbial active agents were non-indigenous/imported.
2. Registration for **experimental use** could be permitted with trials required for 2-3 seasons but there was a question about who should conduct the trials ('commercial registrant' or national research organisation) and consequently who should be the registrant for experimental use registration.
3. Full registration could be applied for when indigenous strains had been identified, tested and formulated into the product.
4. Care should be taken to ensure that the registrant has the capacity for **product stewardship**.
5. Applications for **data waivers** were generally accepted.

[7] Item 15 in Annotated Bibliography.

Models for harmonised registration of microbial biopesticide registration

Models for harmonised registration are based on the three alternate national/sub-regional platforms considered in **Section 1.4.3** (p. 11) of the Guidance Document.

Pre-requisites

1. The 'region' defined as a group of countries that have **equivalent registration systems** (*by each adopting the regulatory processes set out in the Guidance Document*) and have an agreement to harmonise.
2. Only strains of **microbial active agents** that fit the definition of ***indigenous to the region*** should be considered for registration.
3. If strains have been sent outside the region for identification, characterisation and/or testing and particularly if final strain selection has been done abroad, there should be documentary proof of their isolation in the region, transfer abroad and repatriation.
4. Full registration should only be granted if the applicant has the characteristics of a genuine 'registrant', i.e. has the capacity and resources for product stewardship. The registration authority should be wary of an applicant who is merely a distributor for a product taking no responsibility for its use; particular attention to be paid where the 'applicant' cites a foreign 'registrant'.

Models for harmonised microbial biopesticide registration

Registration according to platform (a) Registration by national registration authority for approval of a microbial biopesticide in that specific country

1. An agreement to share data between the countries in the region.
2. First application for full registration granted in one country of the region; **conditions of registration** to be set in the **Certificate of Registration**.
3. The other countries could then register the identical product after application without further ado if they were satisfied that the data presented fitted the conditions in their areas. If for example proposed data waivers were accepted in the first country, they could be regarded as applicable in the subsequent countries of registration.
4. Alternatively, on receipt of the application, each country could refuse registration if the product was considered unsuitable (e.g. no suitable crop or use); or where indications from particular local issues (e.g. unfavourable conditions for storage leading to shorter shelf life) required that some particular national conditions of registration be set.
5. Account should be taken about linguistic differences between the countries in the region and differences in levels of literacy and education among farmers and other people handling the products.

Registration according to platform (b) Joint reviews by two or more countries of submitted data whereby responsibilities for evaluating applications are shared.

1. Simultaneous application for registration in all the countries.
2. The evaluation of data and the proposals for data waivers is shared, so that for example, one country looks at toxicity, another country looks at ecotoxicity and a third country evaluates efficacy data.

Registration according to platform (c) Regionally harmonised system where there is one regional level committee making decisions on behalf of all the member countries

(but each country has the right to refuse to register a given pesticide, or modify the conditions of registration.)

At present neither SADC nor COMESA has a sub-regional registration committee. The Permanent Interstate Committee for Drought Control in the Sahel (Le Comité Inter Etats de Lutte contre la Sècheresse dans le Sahel - CILSS) is the only sub-regional organisation to have fully harmonised pesticide registration on this basis.

Towards this end, next steps are being considered by consultation with all interested parties.

Annotated bibliography of documentary sources for the regulatory framework

Item	Source	Title	Year	URL	Comments
1	FAO	International Code of Conduct on the Distribution and Use of Pesticides. Guidelines for the Registration of Pesticides	2010	http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/Code/Registration_2010.pdf	Basics on confidential data, waivers, equivalence. To be revised and renamed as *International Code of Conduct on Pesticides Management*
2		Specifications for pesticides. A Training Manual. Trial Edition 1.	2008	http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/Particpant_Guide_pesticide_Specifications.pdf	
3	IPPC	ISPM 3. Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms	2005	https://www.ippc.int/file_uploaded/1146657660135_ISPM3.pdf	Biosecurity aspects of biological control agents.
4	OECD	Guidance for Registration Requirements for Microbial Pesticides	2003	http://www.oecd.org/env/ehs/pesticides-biocides/28888456.pdf	Compares data requirements in different jurisdictions
5		OECD Guidance for Industry Data Submissions for Microbial Pest Control Products and their Microbial Pest Control Agents (Dossier Guidance for Microbials)	2005	http://www.oecd.org/env/ehs/pesticides-biocides/43435253.pdf	Format of data requirements Content and quality of reports on efficacy, toxicology, etc. Explanation of tiers
5a		Appendix 1	2008	http://www.oecd.7org/env/ehs/pes8ticides-bio9cides/27764880.pdf	Standard terms and abbreviations
5b		Appendix 2	2003	http://www.oecd.org/env/ehs/pesticides-biocides/27765530.pdf	Formulation codes
5c		Appendix 3	2003	http://www.oecd.org/env/ehs/pesticides-biocides/27765578.pdf	Intended use
5d		Appendix 4	2006	http://www.oecd.org/env/ehs/pesticides-biocides/43464201.pdf	Format for compilation of Tier 1 checks Part 1 Summary
5e		Appendix 5	2003	http://www.oecd.org/env/ehs/pesticides-biocides/27766461.pdf	Form for crop residue data

5f		Appendix 6a	2006	http://www.oecd.org/env/ehs/pesticides-biocides/43435264.pdf	Format for listing study reports
5g		Appendix 6b	2006	http://www.oecd.org/env/ehs/pesticides-biocides/43435297.pdf	Numbering systems for data
5h		Appendix 6c	2006	http://www.oecd.org/env/ehs/pesticides-biocides/43435327.pdf	Numbering systems continued
5i		Appendix 7	2006	http://www.oecd.org/env/ehs/pesticides-biocides/43435364.pdf	Tier II Summaries Identity – biological properties
5j		Appendix 8		http://www.oecd.org/env/ehs/pesticides-biocides/43435364.pdf	Tier II Summaries Identity – physical properties
5k		Appendix 9	2006	http://www.oecd.org/env/ehs/pesticides-biocides/43435456.pdf	End point listing
5l		Appendix 10	2003	http://www.oecd.org/env/ehs/pesticides-biocides/27772036.pdf	Tier III Summaries
5m		Appendix 11	2006	http://www.oecd.org/env/ehs/pesticides-biocides/43435481.pdf	Forms for checking completeness of dossiers
6		OECD Guidance for country data reviews on microbial pest control products (Main Document)	2006	http://www.oecd.org/env/ehs/pesticides-biocides/43464397.pdf	Main document – explanation of Appendices
6a		Appendix 1		http://www.oecd.org/env/ehs/pesticides-biocides/27532950.pdf	Standard terms and abbreviations
6b		Appendix 2		http://www.oecd.org/env/ehs/pesticides-biocides/27532958.pdf	Formulation codes
6c		Appendix 3	2003	http://www.oecd.org/env/ehs/pesticides-biocides/27532966.pdf	Guidance on pagination, layout, etc.
6d		Appendix 4	2003	http://www.oecd.org/env/ehs/pesticides-biocides/27395958.pdf	Guidance on reports from registration authority
6f		Appendix 5	2003	http://www.oecd.org/env/ehs/pesticides-biocides/27395979.pdf	Form for reporting intended uses
6g		Appendix 6	2004	http://www.oecd.org/env/ehs/pesticides-biocides/43464550.pdf	Format for listing end points

6h		Appendix 7	2006	http://www.oecd.org/env/ehs/pesticides-biocides/43464583.pdf	Format for listing test and other and other study reports Annex A
6i		Appendix 8	2006	http://www.oecd.org/env/ehs/pesticides-biocides/43464593.pdf	Format for listing test and other and other study reports Annex B
7		Working document on the evaluation of microbials for pest control	2008	http://www.oecd.org/env/ehs/pesticides-biocides/41946259.pdf	Guidance on: Taxonomic identification (Ch. 1) Genotoxicity (Ch. 2) Occupational, bystander and consumer exposure and risk Assessments (Ch. 3) Microbial metabolite residues in food (Ch. 4) Efficacy evaluation (Ch. 5)
8	EFSA	Guidance for applicants on peer reviewed literature required by Article 8(5) of Re 1107/2009.	2009	http://www.pan-europe.info/News/PR/101020_EFSA.pdf	2. 2. Data requirements on microbial active substances
9	NAFTA	Updated procedures for the joint review of biopesticides	2010	http://www.epa.gov/oppfead1/international/naftatwg/guidance/jointreview-biope.pdf	Main source for Pre-Submission Consultation
10	Crop Life International	Guide for Industry on the Implementation of the FAO Code of Conduct on the Distribution and Use of Pesticides (revised version)	2004	www.croplife.org/view_document.aspx?docId=619	
11	Ghana	Guide to registration of biological control agents	2011	http://www.researchintouse.com/resources/ext/17-042012-BCA-guidelines.pdf	Important source of data requirements
12	Kenya	Annex 1 Application for the Registration of a Microbial Pest Control Agent Annex to Pest Control Products Act	2011	http://teca.fao.org/sites/default/files/technology_files/BiopestAnx1.pdf	Full Annexes
13		Form A1. Application form for the registration of a microbial pest control product An annex to Pest Control Products Act	2011	http://www.kenyalaw.org/klr/fileadmin/pdfdownloads/Acts/PestControlProductsAct__Cap346_.pdf	Important source of data requirements Clear statement of units of measurement.
14		Form B1. Summary of the data submitted to the PCPB for registration of a microbial pest control product	2011		Source of summary data

15	SADC	Regional Guidelines for the Regulation of Plant Protection Products in SADC Member States		http://www.sadc.int/fanr/crops/fscbrc/documents/Legislation%20Harmonisation%20Workshop%20%28October%202009%29/CROP%20PROTECTION%20PRODUCTS%20REGIONAL%20PESTICIDE%20FINAL%20GUIDELINES%20eng.pdf	Mentions 'microbial product' and defines 'biopesticide'
16	CILSS	Composition of the Registration Dossier for bio-pesticides in the Sahel region	2001	http://www.insah.org/doc/pdf/Biopesticide_Registration_Dossier.pdf	Clear indication of summary requirements and full dossiers
17	US EPA	Electronic code of Federal Regulations Title 40. Protection of the environment 158. Data requirements for pesticides Subpart V Microbial pesticides		http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=91cf172177d59f26ca08697bccbc2dab&n=40y25.0.1.1.9.16&r=SUBPART&ty=HTML	Main source for data requirements (Annex 2).
17a		§ 158.2100 Microbial pesticides definition and applicability.			
17b		§ 158.2110 Microbial pesticides data requirements.			
17c		§ 158.2120 Microbial pesticides product analysis data requirements table.			
17d		§ 158.2130 Microbial pesticides residue data requirements table.			
17e		§ 158.2140 Microbial pesticides toxicology data requirements table.			
17f		§ 158.2150 Microbial pesticides nontarget organisms and environmental fate data requirements table.			

17g		§ 158.2160 Microbial pesticides product performance data requirements.			
18		§ 158.2170 Experimental use permit data requirements—microbial pesticides.			
18a		§ 158.2171 Experimental use permit microbial pesticides product analysis data requirements table.			
18b		§ 158.2172 Experimental use permit microbial pesticides residue data requirements table.			
18c		§ 158.2173 Experimental use permit microbial pesticides toxicology data requirements table.			
18g		§ 158.2174 Experimental use permit microbial pesticides nontarget organisms and environmental fate data requirements table.			
19		Pesticide Registration Manual: Chapter 2 - Registering a Pesticide Product		http://www.epa.gov/pesticides/bluebook/chapter2.html	General up-to-date guidance on microbial pesticides may be found at this site
20		How to prepare a confidential statement of formula (CSF) for biochemical and microbial biopesticides	2010	http://www.epa.gov/pesticides/biopesticides/regtools/biopest_csf.pdf	Main source for confidential data requirements

21		Tips for Avoiding Confidential Statement of Formula or Product Chemistry Issues with Biopesticides	2010	http://www.epa.gov/pesticides/biopesticides/regtools/product_chem_csf.htm#statement	
22		OCSPP Harmonized Test Guidelines Series 885 - Microbial Pesticide Test Guidelines	2012	http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series885.htm	Downloadable guidelines provided for each part of data requirements.
23		OECD Data Evaluation Records (DER) Templates - Microbial Pesticides		http://www.epa.gov/opp00001/biopesticides/regtools/oecd-der-template.html	As used by EPA in collaboration with NAFTA partners Forms (Microsoft Word) with completion notes (not guidance) for each part of the evaluation are available for download.
24	UK Health and Safety Executive (HSE)	The Applicant Guide: Parallel Trade Permit Procedure	2013	http://www.pesticides.gov.uk/guidance/industries/pesticides/topics/pesticide-approvals/pesticides-registration/applicant-guide/the-applicant-guide-parallel-trade-permit-procedure	Guidance on parallel registration
25		Databases home page		http://www.pesticides.gov.uk/guidance/industries/pesticides/topics/databases/databases-home	Provides link to Excel file of expiry dates of registration

Annexes

Annex 1

Announcement and notification of procedures for Pre-Submission Consultation for proposed registration of microbial biopesticide

In order to encourage the adoption of microbial biopesticides into use and to facilitate their registration, the <registration authority> of <country/region> is providing access to advise on registration to intending registrants by means of a PRE-SUBMISSION CONSULTATION.

What are microbial biopesticides?

Microbial biopesticides are a type of biopesticide/biological pest control product in which the sole or principal component is a microorganism that can function as a pesticide. The microorganism could be a virus, bacterium, fungus or other type. The microbial active agent might be a pathogen of an invertebrate pest such as an insect or it could be active against another microorganism such as toxin-producing fungi that contaminate grain, pulses and other products.

Why are microbial biopesticides encouraged?

Biopesticides in general are considered advantageous over conventional chemical pesticides because they are generally much less toxic to humans and other mammals than the latter and cause less damage to the environment and to wildlife. Biopesticides can be substituted for conventional pesticides and this is becoming increasingly necessary because many conventional pesticides are being withdrawn or banned because of their adverse side effects.

Microbial biopesticides are beneficial because, as well as being generally of very low toxicity (although they could cause allergies), they can be formulated and applied like conventional pesticides. Some microbial biopesticides show great promise for controlling pests for which there is no conventional remedy.

How to initiate a Pre-Submission Consultation

1. Become familiar with the Guidance Document on making a (full) application to register a microbial pesticide, including the requirements for a full data submission.
2. Decide on the mode of registration to be requested (full/experimental use, etc.).
3. Complete a summary data/application form – **Annex 2 Part 1**.
   <provide URL for online submission>
4. Attach a request and justification for any data waivers requested.
5. Supply *Confidential Data* separately (passworded file by email or secure path for online application), including a *Disclosure Declaration*.
6. Send by email to <…….> or apply online <……..>

What will happen next?

Within <10 working days> the registration authority will respond to arrange a meeting to consult on the proposed submission and make a preliminary response to the data submitted including the request for data waivers. The authority may ask for further data at this stage.

Not more than <15 days> after the meeting there will be a full and formal response from the authority with:

- Confirmation that full submission may proceed with object of specified mode of registration OR request for further information.
- Any biosecurity issues to be satisfied – permission to import microbial active agent.
- Temporary registration number.
- Confirmation of data requirements including any data waivers.
- Directions for sample requirements for local efficacy testing, if necessary (**Annex 3**).
- Issues regarding confidentiality or ownership of data.
- Confirmation of disclosure agreement.
- Confirmation of the fee to be paid along with submission.

Annex 2

Data requirements for registration of microbial biopesticides/ application form

Provide as PDF as part of Guidance Document but also make available as editable document (rtf, .doc, .docx) so that text boxes may be expanded as required for electronic submission (email or online).

Similarly, confidential data could either be submitted in sealed envelope, in a pass worded document sent by email or on a secure site.

Part 1: Data summary for Pre-submission Consultation

Section	**Data requirements**
Preliminary	**Type of registration applied for** ☐**Full** ☐**Experimental use** ☐**Renewal** ☐**Modification of use** ☐**Modification of composition**
1	**Type of material registration applied for and type of use to be registered** (More than one box may be ticked) ☐Active agents)/active ingredients) ☐Technical grade formulation (not available for some microbial biopesticides) ☐Formulated product for use **Details of previous registration of active agent and/or technical grade formulation in this country** e.g. copies of registration certificate(s)
	Details of registration of active agent/technical grade formulation/product in other countries (SEARCH countries, OECD countries, other countries)
2	**Details of registrant and owner of any commercial rights**
	Registrant name
	Registrant address Telephone number Fax number Email address
	Owner of trade mark and/or patent if different from above ***If necessary, provide statement indicating relationship between registrant owner of trademark and/or patent***

	Manufacturer of active ingredient(s)/active agent(s) *Specify separately if more than one active agent/active ingredient*
	Manufacturer of formulated product
	Name of agent or distributor (if different from registrant) Contact details
3	**Emergency contacts** Name of emergency contact Best telephone no. for emergency contact (Landline or mobile) Fax number Email
4	**Identity of microbial active agent**
	Taxonomic name **Genus** **Species/subspecies** **Strain/pathotype/serotype** **Other taxonomic descriptors** **Vegetative compatibility group** **Spontaneous mutant ☐Yes ☐ No** **Induced mutant ☐Yes ☐ No** **If there are any chemical active ingredients in a product being registered, the registrant should also complete Section 11.**
5	**Origin of microbial active agent**
	Locality of origin **Country** **Accession number for deposition of culture in a nationally recognised culture collection**
	Status in country in which registration is being requested **☐Indigenous** **☐Non/indigenous/already imported under permit** **☐Non-indigenous/to be imported from outside country/region <specify>** **Please tick whichever boxes apply.** **If 'non-indigenous/to be imported' go to Section 10.**
	If the microbial active agent is a genetically modified organism (GMO), permission must first be sought to import and use from the biosafety authority of the country/region who will conduct a risk assessment according to international standards. If approval is given, registration will proceed as for any other pesticide.

6	**Identity of technical grade material and/or product**
Confidential (separate)	**Identity of technical grade material** (as applicable) **Composition (% and tolerance)** **Microbial active agent(s)** **Chemical active ingredient(s) if any – Section 11.** **Chemical impurities ('inert ingredients')** **Metabolic by-products** **Microbial metabolites** **Formulants (additives, inert ingredients)** **The exact requirements for determining identity, especially impurities and microbial metabolites (if any) will depend on the nature of the microbial active agent. The registration authority will advise during the Pre-Submission Consultation.**
Confidential (separate)	**Identity of product** **Composition (% and tolerance)** **Microbial active agent(s)** **Incl. mutant strains** **Chemical active ingredient(s) if any – Section 11.** **Chemical impurities ('inert ingredients')** **Metabolic by-products** **Microbial metabolites** **Formulants (additives, inert ingredients)** **Identifier of technical formulation (as applicable)** **Trade name of product**
7 **Confidential (Separate)**	**Manufacturing details including formation of any unintentional ingredients (impurities, contaminants)** **Quality control/quality assurance must be included, especially measures to mitigate any potential hazards**
8	**Analysis** **(From laboratories accredited to ISO 17025)**
9	**Certificate of limits** **(From laboratories accredited to ISO 17025)** **Legally binding and enforceable**
10	**Importation of non-indigenous microbial active agent** **Has permission to import been granted as part of pre-submission consultation?** **☐Yes** **☐No** **If Yes, provide certified copy of import permit from relevant authority** **If No, the registrant must seek approval to import from <name of biosecurity authority> before proceeding with application.**
11	**Identity of any non-microbial active ingredients** **The presumption is that any chemical active ingredients are already registered. If this is not the case, appropriate registration procedures should be followed for these ingredients before submission of this application.**
12	**Details of formulation**
	Type of formulation **Provide details of the formulation using appropriate codes as available** (see item 5b in **Annotated Bibliography** (p. 49.) **Concentration of active agents/ingredient(s).**
	Properties and characteristics of formulation

	WHO classification of the formulation if available **With corresponding publicly available basic toxicity data:** **LD50 oral and dermal (mg/kg)** **LC50 inhalation (mg/l)**
	Physical properties
	Colour **Physical state** **Smell** **Stability** **Miscibility/wettability** **Corrosion characteristics** **pH** **Viscosity**
13	**Uses**
	Plant health use: crops or plant products to which applied (summary for label) **Pest organism(s) as target(s) (Summary)** **Indications of resistance developing**
	Animal health use **Target animal pathogen or invertebrate pest** **Target livestock species** **Indications of resistance developing**
	Public health use **Target pest** **Environment in which to be used** **(Domestic, public spaces, industrial, storage, etc.)** **Indications of resistance developing**
	Ecological zones in which used: **<List of options to be specified relevant to the country/region in question>** **Application methods** **Dosage (summary for label)**
	Precautions in use (summary for label
	List of countries where product with the same or similar uses is registered

14	**Biology/ecology of active agent(s)**
	Lifecycle/Means of multiplication and dispersal
	Natural distribution of related species
	Mode of action **Include hosts if pathogen**
	Survival under natural conditions (in vivo)
	Genetic stability (likelihood to mutate)
	Metabolites produced (especially toxins)
	Antibiotics produced
	Infectivity **Pathogenicity** **Relationship to known human/animal pathogens**
15	**Efficacy**
	Summary reports of field trials and/or test data files relevant each intended use and each ecological zone declared in Section 13. **The purpose of the trials or laboratory test data is to determine:** **• the product's efficacy in stated use** **• how specific or selective the product is towards its targets** **•the presence of any residues in harvested or stored food, other products or environment**
16	**Primary toxicological data – mammals** **Data waivers** **Rationale required for waiver of toxicological data based on information from scientific literature, etc. showing that microbial active agent is not hazardous to mammals, i.e. lack of potential for a known mammalian toxin and negative result from the acute oral toxicity test.**
16.1	**Tier I**
	Occupational health surveillance report on workers during production and testing including information on: **sensitisation and allergenic response of workers and bystanders related to exposure with special attention to those whose may be more susceptible (e.g. children, the elderly, pregnant women)**
	Toxicology summary and full dossiers **Provide data for active agent(s) and/or formulated product as according to registration request (*Section 1*)** *Duplicate blocks as necessary*
	Acute oral infectivity and toxicity
	Acute intra tracheal/ inhalation infectivity and toxicity
	Acute intravenous/ intra peritoneal infectivity by injection
	Acute dermal toxicity/infectivity
	Acute eye irritation
	Primary dermal irritation
	Cell culture for viruses and other non-cultivable or fastidious microorganisms
	Genotoxic potential, especially for fungi **and actinomycetes**
	Toxicity studies on metabolites (especially **toxins)**

	Proposed first aid measures and medical Treatment
16.2	**Tier II**
	Acute toxicology
	Subchronic toxicity/pathogenicity
16.3	**Tier III**
	Reproductive/fertility effects (lifetime exposure)
	Carcinogenicity
	Immunotoxicity
	Infectivity/pathogenicity analysis
	Teratogenicity
	Neurotoxicity
17	**Effects on wildlife and non-target organisms**
17.1	**Tier I** **The tier 1 tests are usually done at some higher than expected level (10 or 100x) from that proposed for use in the field.**
	Birds
	Fish
	Aquatic invertebrates
	Effects on algal growth
	Bees
	Earthworms
	Non-target soil microorganisms
	Effects on aquatic or terrestrial plants
	Wild mammals
	Non-target terrestrial invertebrates
	Other terrestrial inverts
	Tier II
	Data from expression tests if indications of toxicity in Tier I
	Tier III
	Dose response tests if necessary indications from Tier I and Tier II
	Tier IV
	Field or simulated testing if necessary indications from lower Tiers
18	**Summary of residues in food or other materials to which applied** Nature of residues Taint (odour, taste, colour) in food Analytical methods Acceptable Daily Intake (ADI) **Data waivers** **Rationale required for waiver based on a substantiated estimation that microbial active agent is unlikely to occur on treated food/feed stuffs in concentrations considerably higher than under natural conditions**
18.1	**Nature and levels of residues in plants and/or animals** **Analytical methods** **Residues in rotational crops**
19	**Residue and fate of metabolic products in the environment**
	Sufficient information on the origin, properties, survival and residual metabolites of the microorganism to assess its fate and behaviour in the environment. **Information provided in earlier parts of the toxicology data dossier may suffice**

20	**Safety data sheet**	
	Safe handling including formulation, transport, sale, use **Safe disposal** **Procedures for decontamination of water and terrestrial environment in case of spillage** **Emergency procedures in case of fire**	
21	**Packaging**	
	Type **Materials** **Size** **Include sample**	
22	**Labelling**	
	Specimen label in accordance with prescribed standards **Specimen of technical leaflet**	
23	**Advertising plans**	
	Type of media (billboards, promotional leaflets, TV, radio, etc.) **Indicative content**	
24	**Post-registration controls and other activities**	
	Provision to acquire emerging data and to notify authorities • **Non-target effects** • **Injury from occupational exposure** • **Injury to bystanders** • **Loss of efficacy** • **Unforeseen problems arising from use**	
	Training plans for distributors, extension workers and users	
25	**Declaration**	
	Name	
	Signature	**Date**
	Position	
	Signed on behalf of **(Registrant)** **Overlay stamp of registrant**	
	Received by registration authority **Name** **Signature Date** **(Apply (date) stamp if applicable)**	

Part 2: Requirements for full data dossiers

THE APPLICATION BY MEANS OF THE FORM BELOW SHOULD BE ACCOMPANIED BY FULL DATA DOSSIERS (ANNEX 2 PART 3) AND SAMPLE SUBMISSION (IF REQUIRED, ANNEX 3).

R = required/obligatory
CR= conditional required subject to confirmation by registration authority

Section	Data requirements	Provisional/Full	Experimental use	Renewal	Modification of use	Modification of composition
Preliminary	**Has there been a pre-submission consultation?** **☐Yes ☐No** **If yes, give Temporary Registration No.**	**R**	**R**			
	Type of registration applied for **☐Full** **☐Experimental use** **☐Renewal** **☐Modification of use** **☐Modification of composition**					
1	**Type of material registration applied for and type of use to be registered** (More than one box may be ticked) ☐Active agents)/active ingredients) ☐ Technical grade formulation (not available for some microbial biopesticides) ☐Formulated product for use **Details of previous registration of active agent and/or technical grade formulation in this country** e.g. copies of registration certificate(s)	**R**	**R**	**R**	**R**	**R**
	Details of registration of active agent/technical grade formulation/product in other countries **SEARCH countries** **OECD countries** **Other countries**					
2	**Details of registrant and owner of any commercial rights**	**R**	**R**	**R**	**R**	**R**
	Registrant name					

	Registrant address Telephone number Fax number Email address					
	Owner of trade mark or patent holder *If necessary, provide statement indicating relationship between registrant owner of trade and/or patent*					
	Manufacturer of active ingredient(s)/active agent(s) *Specify separately if more than one active agent/active ingredient*					
	Manufacturer of formulated product					
	Name of agent or distributor (if different from registrant) Address Telephone number Fax number Email address					
3	**Emergency contacts** Name of emergency contact Best Telephone No. for emergency contact (Landline or mobile) Fax number Email	**R**	**R**	**R**	**R**	**R**
4	**Identity of microbial active agent**	**R**	**R**	**R**	**R**	**R**
	Taxonomic name Genus Species/subspecies Strain/pathotype/serotype Other taxonomic descriptors Vegetative compatibility group Nucleic acid sequence(s) (if any), e.g. GenBank Accession No(s). Spontaneous mutant ☐Yes ☐ No Induced mutant ☐Yes ☐ No ***If there are any chemical active ingredients in a product being registered, the registrant should also***					

	complete **Section 11.**					
5	**Origin of microbial active agent**	**R**	**R**	**R**	**R**	**R**
	Locality of origin: Country: Accession number for deposition of culture in a nationally recognised culture collection[1]					
	Status in country/region in which registration is being requested ☐ Indigenous ☐Non/Indigenous/already imported under permit ☐ Non-indigenous/to be imported from outside country/region <specify> **Please tick whichever boxes apply.** **If 'non-indigenous/to be imported' go to Section 10.**					
	If the microbial active agent is a genetically modified organism (GMO), permission must first be sought to import and use from the biosafety authority of the country/region who will conduct a risk assessment according to international standards. If approval is given, registration will proceed as for any other pesticide.					
6	**Identity of technical grade material and/or product**	**R**	**R**			**R**
Confidential (Separate)	**Identity of technical grade material** (as applicable) **Composition (% and tolerance)** **Microbial active agent(s)** **Chemical active ingredient(s) if any – Section 11.** **Chemical impurities ('Inert ingredients'** **Microbial contaminants** **Metabolic by-products** **Formulants (additives, inert ingredients)**					
Confidential (Separate)	**Identity of product** **Composition (% and tolerance)** **Microbial active agent(s)** **Incl. mutant strains** **Chemical active ingredient(s) if any – Section 11.** **Chemical impurities ('inert ingredients')** **Metabolic by-products** **Microbial contaminants (especially mammalian pathogens or antagonistic microbes)** **Formulants (additives, inert ingredients)** **Identifier of technical formulation (as applicable)** **Trade name of product**					
7 Confidential (Separate)	**Manufacturing details including formation of any unintentional ingredients (impurities, contaminants)** **Quality control/quality assurance must be included, especially measures to mitigate any**	**R**	**R**			**R**

	potential hazards **Steps must include appropriate maintenance of seed cultures, quality controls for sterility, lack of microbial contamination and preferably some appropriate bioactivity measure related to acceptable field performance.**					
8	**Analysis** **(From laboratories accredited to ISO 17025)**	**R**	**R**			**R**
9	**Certificate of limits** **(From laboratories accredited to ISO 17025)** **Legally binding and enforceable**	**R**	**R**			**R**
10	**Importation of non-indigenous microbial active agent** Has permission to import been granted as part of pre-submission consultation? ☐Yes ☐No If **Yes**, provide certified copy of Import Permit from relevant authority If **No**, the Registrant must seek approval to import from <name of biosecurity authority> before proceeding with application.	**R**	**R**	**R**		**R**
11	**Identity of any non-microbial active ingredients** ***The presumption is that any non-microbial/chemical active ingredients are already registered. If this is not the case, appropriate registration procedures should be followed for these ingredients before submission of this application.***	**R**	**R**	**R**		**R**
12	**Details of formulation**	**R**	**R**			**R**
	Type of formulation **Provide details of the formulation using appropriate codes where available**. (See item 5b of **Annotated Bibliography**, p. 49.) **Concentration of active agents/ingredient(s) appropriate to the formulation**					
	Properties and characteristics of formulation					
	WHO Toxicological classification of the formulation ***if available*** **With corresponding publicly available basic toxicity data** **LD_{50} oral (mg/kg)** **LD_{50} dermal (g/kg)** **LC_{50} inhalation mg/4h**					
	Physical properties					
	Colour **Physical state** **Smell** **Stability**					

	Inherent stability of active agent(s) **Storage stability (to indicate the shelf life of the product in its commercial packing)** **Thermal and chemical stability (normal and elevated temperatures, metals, and metal ions)** **Storage stability** **Miscibility/Wettability** **Corrosion characteristics** **pH** **Viscosity**					
13	**Uses**	**R**	**R**		**R**	**R**
	Plant health use: crops or plant products to which applied (summary for label) **Pest organism(s) as target(s) (Summary)** **Indications of resistance developing** *ATTACH FULL TECHNICAL LEAFLET THAT WILL BE MADE AVAILABLE TO USERS*					
	Animal health use **Target animal pathogen or invertebrate pest** **Target livestock species** **Indications of resistance developing** *ATTACH FULL TECHNICAL LEAFLET THAT WILL BE MADE AVAILABLE TO USERS*					
	Public health use **Target pest** **Environment in which to be used** **(Domestic, public spaces, industrial, storage, etc.)** **Indications of resistance developing** *ATTACH FULL TECHNICAL LEAFLET THAT WILL BE MADE AVAILABLE TO USERS*					
	Ecological zones in which used: **<List of options to be specified relevant to country/region>** **Application methods** **Dosage (summary for label)**					
	Precautions in use (summary for label					
	List of countries where product with the same or					

	similar uses is registered					
14	**Biology/ecology of active agent(s)**	**R**	**R**			**R**
	Lifecycle/Means of multiplication and dispersal					
	Natural distribution of related species					
	Mode of action *Include hosts if pathogen*					
	Survival under natural conditions (*in vivo*)					
	Genetic stability (likelihood to mutate)					
	Metabolites produced (especially toxins)					
	Antibiotics produced					
	Infectivity **Pathogenicity** **Relationship to known human/animal pathogens**					
15	**Efficacy**	**R**			**R**	**R**
	Field trials and/or test data files relevant each intended use and each ecological zone declared in Section 13. *The purpose of the trials or laboratory test data is to determine:* • *the product's efficacy in stated use* • *how specific or selective the product is towards its targets* • *the presence of any residues in harvested or stored food, other products or environment*					
	Trial/test descriptors					
	Organisation carrying out trials/tests **☐Field trial for crop/food use** **☐Laboratory test** **☐Test on livestock** **☐Public health trial** **Location** **Ecological zone for field trial** **Date(s)**					
	Trial or test protocol Layout or experimental design including replication dosage/treatment levels Application method					

	Timing/frequency of application Special conditions/observations					
	Trial or test reports					
16	**Primary toxicological data – mammals** **Provide summary data as required below and attach full dossiers from laboratory tests.** **Provide data for active agent(s) and/or formulated product as according to registration request (*Section 1*).** Where no units of measurement are given, the magnitude of effects are recorded on arbitrary scales according to the type of test. ***Duplicate blocks as necessary*** **Data waivers** ***Rationale required for waiver of toxicological data based on information from scientific literature, etc. showing that microbial active agent is not hazardous to mammals, i.e. lack of potential for a known mammalian toxin and negative result from the acute oral toxicity test.***	**R**	**R**			**R**
16.1	**Tier I**	**R**	**R**			**R**
	Occupational health surveillance report on workers during production and testing including information on: sensitization and allergenic response of fermentation workers related to exposure with special attention to those whose susceptibility may be affected					
	Acute oral toxicity (mg/kg) Acute oral infectivity					
	Acute intra tracheal/inhalation toxicity and infectivity (mg/4h)					
	Acute intravenous/ intra peritoneal infectivity by injection					
	Acute dermal toxicity/infectivity (g/kg)					
	Acute eye irritation					
	Primary dermal irritation					
	Cell culture for viruses and other non-cultivable or fastidious microorganisms					
	Genotoxic potential, especially for fungi					

	and actinomycetes					
	Toxicity studies on metabolites (especially toxins)					
	Proposed first aid measures and medical Treatment					
16.2	**Tier II**	**CR**				**R**
	Acute toxicology NOEL (mg/kg/day)					
	Subchronic toxicity/pathogenicity NOEL (mg/kg/day)					
16.3	**Tier III**	**CR**				**R**
	Reproductive/fertility effects (lifetime exposure) NOEL (mg/kg/day)					
	Carcinogenicity NOEL (mg/kg/day)					
	Immunotoxicity NOEL (mg/kg/day)					
	Infectivity/pathogenicity analysis					
	Teratogenicity NOEL (mg/kg/day)					
	Neurotoxicity NOEL (mg/kg/day)					
17	**Effects on wildlife and non-target organisms**	**R**				**R**
17.1	**Tier I** **The tier 1 tests are usually done at some higher than expected level (10 or 100x) from that proposed for use in the field.**					
	Birds (2 species) LD_{50} (mg/kg)	**R**	**R**			
	Fish or other aquatic vertebrates (2 species) LC_{50} (mg/ml)	**R**	**R**			
	Aquatic invertebrates LC_{50} (mg/ml)	**R**	**R**			
	Effects on algal growth EC_{50} (mg/ml)	**R**				
	Bees (mg/bee)	**R**	**R**			
	Earthworms or other relevant soil invertebrates The registrant should propose long-term testing when the comparison of the (predicted) environmental exposure with the results from the short-term toxicity test(s) indicates the need to investigate further the effects on terrestrial organisms. The choice of the appropriate test(s) depends on the outcome of this comparison. These studies do not need to be conducted if direct or indirect exposure of the soil compartment is unlikely.	**R**				
	Non-target soil microorganisms	**R**				
	Effects on aquatic or terrestrial plants	**CR**				
	Wild mammals	**CR**				

	Non-target terrestrial invertebrates	**CR**				
	Other terrestrial inverts	**CR**				
	Tier II					
	Data from expression tests if indications of toxicity in Tier I	**CR**				
	Tier III					
	Dose response tests if necessary indications from Tier I and Tier II	**CR**				
17.4	**Tier IV**					
	Field or simulated testing if necessary indications from lower Tiers	**CR**				
18	**Residues**					
18.1	**Residues in food or other materials to which applied** Nature of residues Taint (odour, taste, colour) in food Analytical methods **Acceptable daily intake (ADI)** **Data waivers** ***Rationale required for waiver based on a substantiated estimation that microbial active agent is unlikely to occur on treated food/feed stuffs in concentrations considerably higher than under natural conditions***	**R**	**R**		**R**	**R**
18.2	Nature of residues in plants and/or animals Residues in rotational crops	**CR**				
18.3	Analytical methods for residues in plants and/or animals	**CR**				
18.4	Storage stability **Shelf life is a critical factor for biopesticides in general because it is a key factor in farmers' acceptance.**	**CR**				
	Level of residue in plants	**CR**				
18.5	Level of residues in milk, meat, poultry and eggs	**CR**				
18.5	Level of residues in potable water, fish, and irrigated crops	**CR**				
19	**Residue and fate of metabolic products in the environment**		**R**			**R**
	Sufficient information on the origin, properties, survival and residual metabolites of the microorganism to assess its fate and behaviour in the environment. *Information provided in earlier parts of the toxicology data dossier may suffice*	**R**	**R**			
20	**Safety data sheet**	**R**	**R**			
	Safe handling including formulation, transport, sale, use **Safe disposal** **Procedures for decontamination of water and**					

	terrestrial environment in case of spillage **Emergency procedures in case of fire**					
21	**Packaging**	**R**		**R**	**R**	
	Type **Materials** **Size** *Include sample*					
22	**Labelling**	**R**		**R**	**R**	
	Specimen label in accordance with prescribed standards **Specimen of technical leaflet**					
23	**Advertising plans**	**R**		**R**	**R**	
	Type of media (billboards, promotional leaflets, TV, radio, etc.) **Indicative content**					
24	**Post-registration controls and other activities**	**R**		**R**	**R**	
	Provision to acquire emerging data and to notify authorities • Non-target effects • Injury from occupational exposure • Injury to bystanders • Loss of efficacy • Unforeseen problems arising from use					
	Training plans for distributors, extension workers and users					

25	**Declaration**	
	Name	
	Signature	**Date**
	Position	
	Signed on behalf of **(Registrant)** **Overlay stamp of registrant**	
	Received by registration authority **Name** **Signature** **Date** **(Apply (date) stamp if applicable)**	

Part 3: Checklist of data dossiers and other information files accompanying application for registration of microbial biopesticides

Section and identifier of Application Form	**No. and Title of Dossier or specimen**	**No. of pages**	**Explanation if not supplied** (e.g. data waiver accepted; not applicable; not required in Tiered risk assessment)
13. ***Technical leaflet(s) with details of use***			
Plant health use			
Animal health use			
Public health use			
15. Efficacy ***Data files for each trial according to specified uses***			
16. Primary toxicological data			
16.1 Tier I			
16.2 Tier II			
16.3 Tier III			
17. Effect on wildlife, etc.			
17.1 Tier I			
17.2 Tier II			
17.3 Tier III			
17.4 Tier IV			
18 Residues			
18.1 Residues in food			
18.2 Residues in plants/animals/crops			
18.3 Analytical methods			
19. Environmental residues and fate			
20. Safety data sheet			
21. Packaging details			

22. Labelling details			
24. Post registration controls			
Checklist prepared by **Name** **Position** **Signature** **On behalf of** **Date**			
Submissions verified by: **Name** **Position** **Signature** **On behalf of registration authority** **Date**			

Annex 3

Sample submission form for registration of microbial biopesticide

To be completed after Pre-Submission Consultation in accordance with directions from the registration authority.

Information required	**Details to be completed**
Temporary registration No.	
Name of microbial active agent	
Deposition No. and other details of culture in recognised collection	
Details of Technical Grade sample	
Identification No. and other details on container Type of container	
No. of samples of Technical Grade	
Details of Formulated Product sample	
Product Trade name Identification No. and other details on container Type of container	
No. of samples of formulated product	
Submitted by: Name Position On behalf of Registrant Signature Date	*Overlap with stamp of company*
Received by: Name Signature On behalf of <Registration Authority> Date	*Overlap with stamp of* <Registration Authority>

Additional notes or observations (Registrant)	
Additional notes or observations (Registration Authority)	

Annex 4

Model certificate of registration for a microbial biopesticide

<Pesticide Registration Authority of country/region>

Certificate of Registration of Microbial Biopesticide

<table>
<tr><td>Mode of Registration:

Temporary
Full
Provisional
Experimental use
(Delete as appropriate)

Registration No.

……</td><td>Previous registration No. if applicable. (See next column.)

----</td><td>Is this a modified or renewed registration?

☐Yes ☐No

Was the microbial biopesticide previously registered for experimental use only?

☐Yes ☐No.</td></tr>
<tr><td rowspan="2">Name of responsible person/certificate holder</td><td>Position</td><td>Pesticide Business Licence No.</td></tr>
<tr><td>Company

Address</td><td>Tel No.

Fax. No.

Email address</td></tr>
<tr><td>Emergency contact details</td><td>Tel. No. (landline)

Mobile No.</td><td>Fax No.

Email address</td></tr>
<tr><td>Microbial active agent(s)</td><td colspan="2"></td></tr>
<tr><td>Other active ingredients if any</td><td colspan="2"></td></tr>
<tr><td>Type of product registered in this certificate</td><td colspan="2">Active agent/technical grade/formulated product

(Delete any not applicable)</td></tr>
<tr><td colspan="2">Registration details of registration of other active agents/ component products still in force</td><td></td></tr>
<tr><td>Type of formulation (code)</td><td>Trade Name</td><td>% active agent(s)
(List all with %)</td></tr>
<tr><td>Use category</td><td colspan="2">General use/restricted/severely restricted

(Delete as appropriate}</td></tr>
<tr><td>Conditions of registration and use</td><td colspan="2">(Attach extra sheet as necessary)</td></tr>
</table>

Date registered:	**Expiry date:**	**Renewal application required by:**
Signed by or on behalf of Registrar of Pesticides	**Stamp of Registration Authority**	**Additional observations** (e.g. in case registration revoked)

Annex 5

Checklist for primary law provisions on pesticides relevant to biopesticide registration

Part A.

1. Does a relevant primary law exist?

If Yes, Go to **Part B**.

If No, Go to **Part C.**

Part B.

2. When was the primary law enacted?
3. Has this law been amended, and if so when?
4. Does the definition of 'pesticide', 'plant protection product', etc. encompass biopesticides?
5. Do definitions distinguish 'active ingredients' ('active substances') and '[formulated] products'
6. Is there a definition of 'biopesticides'
7. Is there provision for a Register of pesticides?
8. Is there provision for a Registration Committee and secondment of experts to perform specific risk assessments as required?
9. What categories of registration are provided for – provisional, full, etc.?
10. Are businesses importing, distributing, manufacturing, selling and otherwise handling pesticides commercially required to register and be subject to inspection?
11. Is there a Schedule or Annex with detailed data requirements for the registration dossier(s) and/or an application form?
12. What provisions are made to distinguish public and confidential data?
13. Do data requirements include plans or models for labelling and advertising?
14. Is there provision for post-registration/authorisation controls?
    a. Ensuring only registered pesticides are available
    b. Monitoring for expired, poor quality and fraudulent products
    c. Monitoring efficacy, toxicity and residues
15. Are applicants for registration required to provide details of post-registration controls?
16. Is there provision for revocation of registration by the authorities and/or voluntary withdrawal by the applicant?
17. Is there provision for using non-registered pesticides in an emergency?
18. Is there reference to policies to promote integrated pest management or biopesticide use?
19. Are fees fixed by statute or reviewable without reference to parliament?

Go to **Part D**.

Part C.

20. How might the absence of a relevant primary law governing pesticides be rectified?
    a. Drafting a new law – taking a long time before enactment
    b. Drafting regulations under another law
    c. Ignoring absence of primary law by drafting Presidential or Ministerial Decree or other 'stand-alone' legal instrument
    d. Preparing code of practice or administrative guidance document

Part D.

21. What amendments, if any, are necessary to the primary law to provide lawful authority for regulations (or non-legal instruments) on biopesticide registration?