STDF Standards and Trade Development Facility

STDF PROJECT PREPARATION GRANT (PPG)
APPLICATION FORM

The Standards and Trade Development Facility (STDF) provides Project Preparation Grants (PPGs), up to a maximum of US$50,000, for the following purposes (or a combination thereof):

- application of SPS-related capacity evaluation and prioritization tools;
- preparation of feasibility studies that may precede project development to assess the potential impact and economic viability of proposals in terms of their expected costs and benefits; and/or
- preparation of projects proposals that promote compliance with international SPS requirements, for funding by the STDF or other donors.

Applications that meet the STDF's eligibility criteria are considered by the STDF Working Group, which makes the final decision on funding requests. Complete details on eligibility criteria and other requirements are available in the *Guidance Note for Applicants* on the STDF website (www.standardsfacility.org). Please read the *Guidance Note* before completing this form. Completed applications should be sent by email (as Word documents) to STDFSecretariat@wto.org.

PPG Title	**Latin American Residue Mitigation through the Promotion of Biopesticides for Enhancement of Trade Opportunities**
Budget requested from STDF	**USD $ 32,928**
Full name and contact details of the requesting organization(s)	Ana Marisa Cordero. Coordinadora del Programa de Sanidad Agropecuaria Inocuidad de Alimentos y Calidad (SAIA). *Instituto Interamericano de Cooperación para la Agricultura (IICA)* Correo electrónico: ana.cordero@iica.int Teléfono: (506) 22160222 San José, Costa Rica.
Full name and contact details of contact person for follow-up	IR4 Michael Braverman IR-4, Rutgers University 500 College Road East, Suite 201W Princeton, New Jersey 08540 +1 (732) 932-9575 ext. 4610 mbrave@njaes.rutgers.edu Adriana Castañeda Consultant Carrera 7c # 126-48 Bogotá, Colombia +57 313 2865873 adriana.castaneda@minorusefoundation.org

I. BACKGROUND AND RATIONALE

1. What is the purpose of this PPG? Explain whether it is requested to: (i) apply an SPS-related capacity evaluation or prioritization tool; (ii) prepare a feasibility study (prior to project development) to assess the potential impact and economic viability of proposals in terms of their expected costs and benefits; and/or (iii) prepare a project proposal for consideration by the STDF or other donors?

Regional regulations on pesticide residues are becoming a serious barrier to market access and trade. The primary purpose of this PPG is to prepare a full project proposal for consideration by the STDF or other donors, based on a unique way to mitigate pesticide residues and facilitate trade. The aim of the project that will be considered, discussed, and planned by the project team is to mitigate pesticide maximum residue limit (MRL) export violations through the use of non-residue-generating biopesticides to control key pests especially at the end of the crop growing period (the period when pesticides mostly contribute to residues at the time of harvest). Hence, the purpose of the PPG is to apply an approach that is being tested in projects conducted in developing countries with similar conditions of Latin America, with a scientific rationale towards SPS related technical capacity development and evaluation. If this PPG is approved strategies for registration harmonization in the regions are going to be explored and proposed.

The main focus of the project however is residue mitigation, since regional projects that are currently being implemented in the central and Andean region, executed by IICA and USDA, can, at an early stage, support this STDF project, in the understanding that could advance work on the modernization of the regulatory framework for bio-pesticides and its harmonization. The IICA / USDA project intends to deal with bio-pesticides, specifically in what concerns the Central American legal framework on updating its legislation, and development of a regulatory framework on bio-pesticides in the Andean region and the promotion of a regulatory framework regional in Andean Community of Nations CAN.

The IICA / USDA Project started in 2019 for the Central American region and in 2020 for the Andean region. In both cases, efforts are being made to have modern, harmonized and scientifically supported regulatory frameworks for bio-pesticides by the end of the projected period (2024). In this sense, the project can lay the foundations for bio-pesticides to have adequate legal conditions to promote the production, use and commercialization of these products, becoming environmentally and economically viable phytosanitary solutions for producers. In both sub-regions, the project articulates work with regional integration forums (the Central American Agricultural and Regional Integration Councils and the Andean Community of Nations) which ensures that, if the normative process is completed, it would be mandatory for the countries with respect to its adoption.

Additionally, the project will include training components in the area of bio-pesticides, aimed at the technical bodies of the Ministries responsible for registering these products, in order to align and harmonize the knowledge base in the region. Training has already been implemented with good results in dietary risk assessment, and in various topics related to chemical pesticides and bio-pesticides that would complement the efforts of this PPG and future project.

Within the framework of the IICA / USDA Project, the biopesticides group has met twice (December 2020 and January 2021), in order to identify the priorities that should be addressed in the short term through training and to analyze the way of approaching the existing Central American technical regulations in biological and microbiological areas.

Regarding training issues, the Central American group identified the following issues:

1. Registration of botanical pesticides
2. Registry of Biofertilizers, Biostimulants
3. Principles of basic botany
4. Techniques for obtaining biological extracts
5. Mechanisms of action of biopesticides
6. New techniques, uses, applications and types of biopesticides of animal origin
7. Alternative pesticides (exemptions for low risk pesticides)
8. Biopesticides and allergens
9. Biological controllers
10. Toxicology
11. Eco toxicology
12. Chemical safety
13. Environmental risks (environmental fate and ecotoxicology)
14. Proper waste disposal
15. Updating of normative concepts and procedures
16. Exchange of experiences with countries such as Mexico, Colombia and Chile in strengthening the national regulatory framework.
17. Update on the work being carried out in Codex Alimentarius and its impact on national and regional regulations.

From this long list, topics 15, 16 and 17 were prioritized to be addressed in the short term. The training and the exchange of experiences will be carried out by virtual means between the months of March and May 2021.

This progress in the IICA / USDA project indirectly supports the preparation of the STDF PPG and its implementation, since it helps to identify critical issues and frees up training efforts that can be carried out in advance.

Biopesticides selected for this PPG would be based upon the target pest at the end of the season. Those same target pests are ones that have been the cause of conventional pesticide applications. Therefore, the primary premises of the process in project selection will be based upon the question "*What are the key residue issues of concern impacting international trade?"* The primary focus within the project will be to utilize microorganisms since they are not likely to have residue issues of concern for importing countries. On a global basis, the scope of what are referred to as biopesticides could include microorganisms, beneficial insects, biochemical (pheromones, plant extracts, minerals) entomopathogenic nematodes, and biotechnology. Beneficial insects fit well into IPM programs and would be considered, depending if that makes sense for the target pests. Genetically modified crops will not be considered. Entomopathogenic nematodes have a limited scope and in general are more expensive than other classes of biopesticides, so they are less likely to be considered. Biochemical biopesticides can be considered, especially pheromones, but some biochemicals under US definition such as potassium phosphite are not likely to be considered if they have regulated moieties and do not have a current tolerance or exemption in importing countries. IR4 and USDA have developed a harmonization list of US, EU, NZ and Australian tolerance exemptions and have been working with Chile and India on global codification of exemptions from tolerance. Biopesticides exempt in the importing country will be selected to facilitate trade.

IPM is the basis of reducing the use of conventional pesticides and will be a standard practice. Such standard practices will be part of the approach and in season reductions in the use of conventional pesticides may be realized. While IPM is an important strategy, conventional pesticides are still

needed when pest pressure increases, which commonly occurs in tropical countries. The reality is that residue violations still exist which are primarily driven by the last application. It is this last application that is the focus of the mitigation approach.

More specifically, the following points of discussion will be the focus of the preparation grant meeting and is why we are seeking funding through this PPG.

1. What are the primary crop export concerns for the countries involved- What are the conventional products causing trade irritants?
2. Which are the most limiting target pests in last application that cause to use conventional pesticides?
3. Differences in MRLs between producing and importing countries.
4. Are there biopesticides available to manage the late season pests selected? Are they registered?
5. Analyze use of other mitigation strategies, as decline curves/persistence of the conventional product causing residues, extension of the PHI, retreatment interval will be considered to understand the likely length of control from the last application of a conventional product, extrapolation from products with abundant data in MRL.
6. Incorporate experiences from comparable projects being performed in Africa and Asia.

The project proposal resulting from this PPG will develop decline residue data and better understanding of how time, IPM production practices and end of season mitigation impact residues. All available tactics will be utilized to determine how to best avoid residue trade issues, including data generation to support extrapolation from other products with MRL established. This will also result in more active interaction between Latin American countries that will derive in the first step to establish a collaborative network in pesticide residues management and a proposal in good regulatory practices for the region.

The experiences acquired in the STDF projects in Asia and Africa will have different implementation moments, but they may provide lessons and recommendations to the Latin American process by transferring experiences that they can provide us in those fields that merit inter-regional articulation and south-south cooperation.

Experiences and lessons learned in field procedures, in agricultural extension techniques, in public-private coordination, in the political positioning of the project, in challenges of normative harmonization, will be some of the fields that can be addressed between the different regions.

The project may, within its possibilities, collaborate with its strategic partners in the implementation of exchange of experiences on policies to promote the production and use of bio-pesticides. These will include growers and biopesticide producers' associations, government regulatory bodies, University Systems and international organizations. This will allow participants to learn about successful development policies related to regulatory frameworks, production, agricultural extension and use of bio-pesticides, market differentiation, among others.

2. Explain the key SPS problems and/or opportunities to be addressed. Clarify why these issues are important, with attention to market access and poverty reduction. Describe, if relevant, how these issues relate to SPS priorities in the Enhanced Integrated Framework's Diagnostic Trade Integration Studies (DTIS), the findings of SPS-related capacity evaluations, national poverty reduction strategies, sector development strategies or policies, etc. See Qn. 7. (b) – (d) of the Guidance Note.

Despite some efforts made in recent years, some developing economies in Latin America still face increasing challenges in complying with Codex and other trade partner pesticide maximum residue levels (MRLs), either because these MRLs are not established or because they are too low to reasonably comply with real-world use patterns by farmers. A previously funded STDF pesticide residue data generation project, executed with the assistance of IICA, did help to strengthen national capacity to generate Codex MRLs. As a follow-up, there is a regional training in the National University in Colombia, and a new set of residue collaborative or individual studies in Costa Rica, Panama, Colombia, Ecuador, Peru and Bolivia in essential species for the region as cacao, pineapple, banana and papaya.

Globalization of the food supply has the potential to expose consumers worldwide to food hazards and many countries rely heavily on imports for their food security. Increasingly, governments worldwide are moving toward implementing risk-based approaches to food safety management that requires all operators in the supply chain to share responsibility for food safety and apply measures to reduce food safety hazards. In addition, developed countries are setting increasingly restrictive pesticide MRLs, or removing pesticide MRLs, including those for many of the tropical crops produced in Latin America. This represents a significant barrier to market access for Latin America producers of specialty crops.

These obstacles, and calls for collaborative action, have been highlighted at the 3rd Global Minor Use Summit (Montreal, October 2017), the World Trade Organization Sanitary and Phytosanitary Committee (Geneva, May 2018) in terms of technical and training activities, the 11th Session of the WTO Ministerial Conference (Argentina, December 2017), and most recently at the Conference of Ministers of Agriculture of the Americas 2019 Inter-American Board of Agriculture (IABA). At these international conferences, it was recognized that the foundation of working toward aligned maximum residue limits (MRLs) and providing critical pest control tools for farmers originates with strong and coordinated national pesticide registration systems. It was also evident that many regions had already being working as a block in North America, Europe, Asia and Africa, however Latin America needs more work in this effort. This initiative would be crucial to help create a network of collaborative effort to equilibrate levels of biopesticides development and use promotion among Latin American countries as well as implementation of Good Regulatory Practices among the region. Biopesticides include microorganisms (such as fungi and bacteria), and biochemicals (such as plant extracts, minerals, pheromones, etc). Biopesticides are different from synthetic pesticides in that they have natural origins and many do not produce chemical residues. Utilization of biopesticides late in the growing season, as an alternative to conventional pesticides, is one way to mitigate residue violations in export markets while providing pest control during the pre-harvest interval (PHI). For some lower middle-income economies, it may also help stimulate industries for new plant extracts and alternative measure.

Most biopesticides by their nature are not subject to MRLs, and the residues of microorganisms used for pest management are therefore not subject to regulatory enforcement by importing countries. It is anticipated that the primary type of biopesticide to be utilized in residue mitigation would be microbial products using biopesticides as a last application of the growing cycle can help reduce residues of many conventional pesticides. Substituting the last application with biopesticide would be cheaper, faster and would need less training than generating residue data and submitting new MRL packages to Codex. In addition to developing a framework for conducting coordinated studies, the full proposal developed from this preparation grant will facilitate the integration of biopesticides as a good agricultural practice of tropical crops. The common practice of intercropping complicates conventional pesticide practices, in that residue labeled uses and MRLs for understory crops often differ significantly, from tree crops, resulting in off-target applications and unintended residues on

understory crops. Therefore, the use of biopesticides will have additional risk benefits by reducing chemical residues on off-target crops.

The Codex Alimentarius is the globally recognized body responsible for setting food safety standards to help in the facilitation of international trade in safe foods. The WTO SPS Agreement encourages WTO Members to harmonize or base their national measures for food safety on the international standards, guidelines and recommendations developed by Codex. IPM approaches have included utilization of biopesticides to overcome resistance issues and maintenance of beneficial insects. Pesticide residues are primarily determined by the last application; therefore, simply including a biopesticide in a rotation is not likely to result in decreased residues of conventional products and will not help trade. A purely biopesticide program would result in lower residues but may not be sufficient alone to control the pest or be financially viable.

This PPG aims to balance the advantages of conventional pesticides (generally lower cost and generally greater efficacy) with the advantages of a biopesticide at the end of the season (to result in lower residues while providing sufficient extension of pest control caused by extending the PHI of the conventional product). In consultation with the researchers and regulators from FAO, National Institutions, Universities, private companies as Crop Life, biopesticide producers and growers, with the support of experts from USDA, IICA, IR4 and MUF, it will be decided which crops will be included, using IR4 as a model system where all parts combine their expertise and select the crop pest combination based on residue concerns.

As an outstanding agenda item of the CCPR, Codex Committee on Pesticides Residues, specialty crops and tropical crops have been a major priority to most Latin America countries because of the high value and vast market including niche markets of EU and North America for these commodities. Among the specialty crops considered within Codex, tropical fruits dominate the list of Latin American exports and a broad survey of farming practices across the region show that the rural farming communities rely on tropical fruits as the primary source of income. If producers are unable to meet export market requirements, market access is impeded, resulting in loss of income for subsistence farmers. Hence, building capacity in this regard is critical to achieving poverty alleviation in rural region. In terms of international standards, there are still no Codex MRLs for most of the tropical fruits groups and specialty crops exported from Latin America. This is largely because of lack of economic interest by pesticide registrants to generate the residue data needed to establish Codex MRLs. As a result, many governments/regions are establishing "minor use" programs to help fill these data gaps and take a more active role in identifying, registering, and setting trade standards to support their agricultural sectors. Building the capacity of developing countries to generate residue data that is mitigated through the adoption of biopesticides will effectively enhance access to newer, low-toxicity biopesticides for farmers - an important priority for Latin America.

Over the past several years, some Latin American countries have participated in pesticide-related training programs led by the U.S. Department of Agriculture (USDA), the United Nation's Food and Agricultural Organization (FAO), CropLife Latin America and other organizations. Many Latin American countries are now demonstrating a better understanding of the process of pesticide MRL establishment and assessment of the risk from dietary intake of residues. The next step to support countries is to work toward implementing concrete actions to address specific barriers to expanding trade.

In brief, the ultimate benefits of the project to be developed through this PPG, to the region will be:

- Facilitate the registration, access, and use of biopesticides to mitigate residues of conventional pesticides which is a unique way to facilitate compliance with MRLs

- Overcome obstacles to export (and regulated domestic) markets access due to the absence of corresponding pesticide trade standards for specialty crops (fruits and vegetables) and other tropical crops of importance to Latin America.
- Decrease exposure of consumers to conventional pesticide residues that result from off-target applications.
- Decrease exposure of farmers to higher-risk synthetic pesticides in cases where proper handling practices are not followed.
- Increase technical expertise concerning residue analysis and monitoring in laboratories as well as a better understanding of residue decline over time.
- Build a sustainable and harmonized process for regional data generation required for the registration of biopesticides for Latin America priority crops such as in order to comply with Good Regulatory Practices.
- Develop a grower outreach program to promote the use of biopesticides in export promotion programs and domestic markets, based on scientific generated data.
- Create a regional network for data generation in MIP applied to crops of common interests.
- Reduce gaps between countries in the same region, in the regulatory field, institutional procedures and commercial opportunities.

3. Which government agencies, private sector, academic or other organizations support this PPG request? Letters of support from each of these organizations would be advantageous (Appendix 1). See Qn. 7. (e) of the Guidance Note.

We will gather information on crop exports concerns from national institutions as well as from growers' associations and pesticides companies. Information from research by the academia will also be analyzed and also from the information obtained in the training center. After information is organized and ranked, virtual meetings will be performed to analyze this information and select regional or subregional priorities. Biopesticides companies and associations will also be consulted on availability of solutions in each on the countries involved, so no imports need to be done. Since there is no complete, updated information about the baseline of local production and use of biopesticides, part of the objectives of this project will be to get this information and look for strategies to improve conditions found.

The following government agencies support holding a PPG workshop to develop a framework for establishing a collaborative biopesticide project, which will then be drafted into a full STDF Project Grant (PG) proposal with commitments from participating agencies. Letters of support are included in Appendix 1.

- Argentina-Servicio Nacional de Sanidad y Calidad Agroalimentaria (Senasa)
- Paraguay-Servicio Nacional de Calidad y Sanidad Vegetal y de Semillas (SENAVE)
- Ecuador-Agrocalidad
- Perú-Servicio Nacional de Sanidad Agraria (Senasa)
- Bolivia-Servicio Nacional de Sanidad Agropecuaria e Inocuidad alimentaria (SENASAG)
- Colombia-Ministerio de Agricultura y Desarrollo Rural (MADR)
- Guatemala – Viceministerio de Sanidad Agropecuaria y Regulaciones VISAR - MAGA
- El Salvador – Dirección General de Sanidad Vegetal – Ministerio de Agricultura.
- Honduras – Servicio Nacional de Sanidad e Inocuidad Agroalimentaria (SAG-SENASA)
- Nicaragua - Instituto de Protección y Sanidad Agropecuaria (IPSA)
- Costa Rica – Servicio Fitosanitario del Estado (SFE)

- CropLife para Latinoamérica
- Asociación Colombiana de Bioinsumos (ASOBIOCOL)
- Asociación Gremial de Exportadores de Pasifloras de Colombia-AVANCE PASIFLORAS

It is hoped that a full Project Grant will involve three regions: Central America, Andean community and the South Cone, as an effort to contribute on the south-south cooperation. In each region there would be a leading country chosen based on the develop they have accomplished in the area that would serve as a trainer and coordinator to the remaining countries.

Commitments to provide technical support for this PPG (and the resulting project) have come from the U.S. Inter-regional Research Project (IR-4)[1], the United States Department of Agriculture (USDA) , the Global Minor Use Foundation (MUF)[2] , IICA and the private sector (CropLife and ASOBIOCOL). Contacts for these organizations are listed below. In addition, a letter of support is included from industry groups.

IICA
Ana Marisa Cordero. Coordinadora del Programa de Sanidad Agropecuaria Inocuidad de Alimentos y Calidad (SAIA).
Instituto Interamericano de Cooperación para la Agricultura (IICA)
Correo electrónico: ana.cordero@iica.int
Teléfono: (506) 22160222
San José, Costa Rica.

IR4, MUF
Michael Braverman
IR-4, Rutgers University
500 College Road East, Suite 201W
Princeton, New Jersey 08540
(732) 932-9575 ext. 4610
braverman@aesop.rutgers.edu

USDA
Nigel Hunter
Foreign Agricultural Service
U.S. Department of Agriculture
1400 Independence Ave. SW, Rm 3243
Washington, DC 20250 USA
202.720.8096
Nigel.Hunter@usda.gov

4. How does this PPG complement and/or build on past, ongoing and/or planned national programmes and/or donor-supported projects? See Qn. 7. (f) of the Guidance Note.

A Project titled “strengthening capacity in Latin America to meet pesticide export requirements”

[1] The IR-4 Project was established in 1963 as a partnership between USDA and the state agricultural experiment stations to assist specialty crop growers by developing data that is necessary to support the registration of safe and effective crop protection chemicals (pesticides) on fruits, vegetables, herbs, and other specialty horticultural crops.
[2]The Minor Use Foundation (MUF) is a 501(c)(3) non-profit with the goals to refine and implement processes for generating global, regional or national residue data to establish Codex MRLs (and/or other national MRLs).

STDF/PG/436 was completed in November 2016. It was initiated by USDA in collaboration with the IICA Secretariat in 2010 with the aim to enhance capacity of some Latin American states to meet pesticide-related export requirements based on international (Codex) standards in order to improve market access of Latin American agricultural commodities.

Under this project led by IR-4, pesticide residue studies were carried out on avocado, pineapple and banana after conducting a series of trainings and planning sessions. Field trials and laboratory analysis work was completed for all studies under the project. The project helped Latin American countries by providing theoretical and practical experiences in conducting field trials, laboratory analysis by exposure to practice, techniques and expertise of GLP studies. It improved the capability of Latin American countries to generate quality data for establishing an MRL based on international guidelines (e.g., OECD-GLP, EPA-GLP, FAO Manual (2009). Latin American member scientists networked to learn and share experiences on the coordination of work and capacity building efforts, between government regulatory officials, laboratory and field technicians, as well as pesticides industries. Most importantly, JMPR reviewed and recommended establishment of new CODEX MRL's based on the data generated from this project and the Codex MRL for Spinetoram/avocado and Piriproxyfen/banana were established on 2018 and 2019 respectively.

During the Global Minor Use Summit 3 in Canada, one of the new efforts has been for Harmonization of Exemptions from Tolerance, which focuses on biopesticides. IR-4 in cooperation with the EU Minor Uses Coordination Facility is leading the effort to extend the recognition of exemptions from tolerance. Through this planning grant, we can discuss the application of exemptions of tolerance and how this can involve the regulatory authorities to facilitate biopesticide registration. This PPG will also learn from and cooperate with the existing STDF project PG/634 in Asia and PPG/694 in Southern Africa that have shown significant advances, where members from this proposal are attending virtual meetings and field and laboratory trainings. From these experiences and having into account that many changes had to be done due to Covid-19, aspects from organization, prioritization, strategy and objectives from the other projects will be taking into account if project is approved.

The use of biopesticides is expanding rapidly worldwide. According to the report by Dunham-Trimmer$_2$ and Markets and Markets 2019, global Biocontrol Market is $3.0 Bn in 2018 and will continue growing to over $11 Bn in 2025. Latin America is growing fastest and will overtake Asia as third largest region in the world market by 2025 by growing about 18%.

Bautista et al 2018[2] showed that in Latin America the production of Bt, a toxin produced by *Bacillus thuringiensis* that has been widely used in biocontrol, and fungal biopesticides constitute the majority of biopesticides with 40% and 48% respectively. However, production is made with low technology and high manual labor and most of the time by the very same producers. The same review shows that most publications concentrate in biopesticides selection and low technology development.

There is growing investment of major multinational companies in the biopesticides space. The organization CropLife LatinAmerica has the infrastructure needed to facilitate outreach within the farmer community and to advocate for good regulatory principles among the government co-operators that will be involved in this project. In addition, this will help increase the demand for biopesticides as a method of producing a crop without residues. Also, as stated above, this would be

[2] http://wrir4.ucdavis.edu/events/2017_SLR_Meeting/Presentations/GeneralPresentations/1%20Trimmer%20-%20Global%20Biocontrol%20Market%202017.pdf

in addition to standard IPM practices, so the residue mitigation is the primary research variable, but not the sole component. Residue mitigation is an end of the season approach besides standard IPM practices.

The state of biocontrol registration has been reviewed by Ceballos in 2016[3]. Almost all countries in Latin America have legislation with different levels of development as well as with different objectives and scope. A need for harmonization is recommended to stay aligned with Good Regulatory Practices. An approach in this PPG would be to evaluate a plan to harmonize legislation in the region as well as to level implementation and use of biopesticides in the region.

The countries of the Central American region have two technical regulations: RTCA 65.05.62.11 BOTANICAL PESTICIDES FOR AGRICULTURAL USE. REQUIREMENTS FOR REGISTRATION and RTCA 65.05.61.11 MICROBIOLOGICAL PESTICIDES FOR AGRICULTURAL USE. REQUIREMENTS FOR REGISTRATION, both regulations constitute the normative base and mandatory compliance for countries, however, their characteristics are very close to the requirements of chemical pesticides, which constitutes a disincentive for their manufacture, registration and use. All Andean countries have national regulations on bio-pesticides, however there is still no harmonized regional regulation in this field. The two countries with the most advanced regulatory development in this field are Colombia and Argentina.

A strategy for expanding the acceptance or recognition of tolerance exemptions was approached by IR-4 and Chile on international biopesticide regulatory harmonization that is being done through the Codex Committee on Pesticide Residues. IICA, through its project on capacity building for the CCLAC countries in Codex Alimentarius, will be able to support the link between the countries and the result of the Codex-CCPR process in bio-pesticides. Additionally, it will be able to support the coordination between the project countries and the coordination of the CCLAC (Ecuador) to establish training processes, implementation and follow-up of the project results in CCPR. This was identified as one of the priorities to promote international harmonization of products that are of extremely low toxicity, where many countries do not set MRL standards.

The work with OECD and Chile is continuing and IR-4 is involved. It focuses on recognizing existing biopesticides and to develop a method for recognizing the exemption from tolerance across multiple regulatory authorities to avoid residue issues. We will be sure that the biopesticides we utilize in this project are ones that fit the criteria for mutual recognition of exemptions from MRLs.

In June 2020 the electronic working group, sent a draft guideline for compounds of low public health concern that may be exempted from the establishment of codex maximum residue limits or do not give rise to residues. It was distributed among members for comments to be received until August this year. The objectives of this document are:

(a) To develop common criteria for the identification of compounds of low public health concern that may be exempted of CXLs and/or that do not give rise to residues.
(b) Provide harmonized Codex definitions as appropriate.
(c) Provide examples of compounds that meet the criteria to facilitate the development of the guidelines (such examples will not necessarily remain in the final document).
(d) Based on the above considerations, present a proposed Guidelines for consideration at CCPR52.

[3]https://www.researchgate.net/publication/309348281_ARTIULO_RE}SENA_Registro_sanitario_de_bioplaguicidas_microbianos_en_America_Latina_y_Cuba_Caso_de_estudio_bionematicida_cubano_KlamiCR

5. Have you discussed this PPG request – or funding for the project proposal which would result from it – with any potential donors (bilateral, multilateral, Enhanced Integrated Framework, etc.)? If so, provide details below and indicate potential sources of funding for the resulting project. See Qn. 7. (g) of the Guidance Note.

During the development of the full proposal we will discuss the potential of other donors to contribute. Based on the previous projects, Latin America Pesticide Residue Generation Project, industry through CropLife Latin America provided technical expertise and the products and analytical standards used for the analysis of the residues. We anticipate that similar contributions will be available for this actual project as well. National Institutions also contributed with funding supporting countries participation in the studies. Due to recent world developments this planning meeting will be mostly virtual in March 2021. Wherever possible we will try to join other meetings organized by CropLife or Biopesticide manufacturers to increase interaction and decrease meeting costs.

Local registrants (manufacturers of biopesticides) will be consulted during the preparation of the full proposal so that the biopesticides are utilized in the correct matter of application and economics of different use rates will be considered. We will also seek donations of biopesticides to test, so they will also help to access and maximize the potential economic impact of this project.

USDA, MUF and IICA are committed to provide in-kind support for this PPG by providing time to help design and direct the plans along with FAO experts. Once the project concept has been strengthened through support of this PPG, multiple partners will be included in developing the full project grant to STDF. Several partners will be approached to support the project either in-kind or financially, including National authorities and private sector as biopesticide manufacturers. We will follow guidelines set forth by STDF for matching funds depending on the degree of development of the countries involved in the full proposal. FAO will be requested to contribute in the steering committee to ensure that that the resulting project complements the existing efforts of FAO. CropLife Latin America will also be consulted, since have promoted the need to harmonise pesticide registration, including biopesticides, across Latin America member states to support world trade.

A larger, primary goal of this project would be to ensure its sustainability by securing long-term financial commitments from these various organizations. This in turn, would continually establish crop/pesticide priority lists and assist local registrations and data generation to establish trade standards. If this project is implemented successfully, we believe that there will be significant incentives for a long-term program to be established through partnerships between the public, and private sectors.

6. Briefly explain how cross-cutting issues (e.g. related to gender, the environment) are relevant for this PPG and, if appropriate, how they will be addressed.

The majority of the research staff that will meet to develop the research proposal are women. A core team of the women who held lead roles in the previous Latin American residue project will be part of this project as well. In the previous residue project, women led both field, laboratory analytical and sponsorship activities. Women do most of the jobs involved in horticulture, especially vegetable production. Conceivably, the reduction of off-target application of conventional pesticides will directly and indirectly improve the livelihood of women and their families in target countries by

reducing unintentional pesticide exposure and increasing the exportability and trade of smallholder crops.

By reducing the use of conventional pesticides in horticultural crops and reducing off-target applications, exposure to bees and other sensitive species in the environment will decrease. Although conventional pesticides are safe when used appropriately, in reality, good agricultural practices are not often followed in developing countries. In these cases, use of lower-risk biopesticides also protects the environment and provides ecological sustainability by conserving natural enemies and biodiversity.

In preparing the project, those responsible for IICA in the area of gender, youth, the environment and the bio-economy will be able to analyze how to develop a component aimed at these aspects.

II. IMPLEMENTATION & BUDGET

7. Who will take the lead in implementing this PPG? If particular national experts and/or international consultants are proposed, attach a copy of their Curriculum Vitae and record of achievements (Appendix 2). If no names are provided, the STDF will provide a shortlist of consultants if the PPG request is approved.

IICA with a group of experts form IR4 and MUF will lead the logistical implementation of the PPG with support of sub-contracts, and USDA and country´s technical experts through direct consultation. The PPG will facilitate the development of details and arrangements for project implementation.

All partners will ensure that the PPG is used to develop a project that links to similar and related efforts in the target countries including FAO, CropLife Latin America, pesticide manufacturers, exporter organizations, growers' associations, national institutions, etc.

As part of south - south cooperation, this PPG, involves three representative areas from the region including Central America, Andean region and the South Cone. In each region there would be a leading country (Costa Rica, Colombia and Argentina) that will help plan and guide. Nicaragua, Guatemala, Honduras and El Salvador (lower middle income) in Central America and Bolivia (lower middle income), Ecuador and Peru (upper middle income) in the Andean region and Paraguay (upper middle income) in the south region. This aims to develop a framework for conducting coordinated studies to mitigate conventional pesticide residues through the incorporation of biopesticides into national Integrated Pest Management (IPM) programs. As leading countries may have some progress in policy fields (such as biopesticide registration), advances in the development and use of biopesticides, and experiences within the framework of associativity, they will be able to be incorporated into training and transferring processes, such as virtual experience-sharing events, specific virtual trainings, or participation as experts in the training to be developed at the academy. During this PPG, Universities from leading countries will be identified to participate in the project and attend training in a way to maintain sustainability with new students and participants in their own countries. The way this continuity will be assured, will be developed in the PG.

Some of these countries previously participated in the STDF residue project (STDF/PG/436) that helped establish national study teams in selected Latin American countries, which will be utilized to

further this work on biopesticides[4]. These national study teams along with others invited to be part of this PPG are also participating during preparations for the global minor use foundation workshop https://minorusefoundation.org/events/gmup-workshop-2020/, which help established a base in terms of countries' communications, platforms for meetings, countries and regions needs and biopesticides research, availability and products.

This project and the previous STDF project are similar in that both focus on pesticide residues. The first Project involved the development of new MRL's. For this project, we will not involve development of new MRLs but will involve residue mitigation, which is a way to reduce residues of pesticides to levels below existing MRLs.

The activities planned for this PPG will start with a steering committee meeting to present the document and get the member´s feedback. That will continue with a kickoff workshop that due to the circumstances will be completely virtual. Participants to invite will include national authorities, growers' associations, national university of Colombia and pesticide and biopesticide producers and associations. In that meeting the PPG is going to be presented and the survey will be explained and asked to be completed.

Considering that the three regions have different crops that could result in different or overlapping results, three virtual meetings are going to be held to discuss and select priorities and will include regional leaders and IR4, IICA and MUF consultants. Results from these meetings would be collected and processed and presented to biopesticide producers to get possible solutions from them. As a result, a list of priorities of crop/pest/residue/biopesticide will be selected for the subregions or depending on the result, for the region. These results are going to be presented then with potential partners, private sector, international organizations, donors to get interest support for the future project. Before drafting the final document, a final workshop is going to be held with participants for its validation and final discussion.

To carry out the project formulation, basic information is required for the definition of the baseline of countries and regions. This information should cover three fields: (i) Regulatory information, composed of the regulatory framework and its characterization, emphasizing existing registration procedures and registrations of biopesticides; (ii) Commercial information identifying products, markets and access problems generated by chemical pesticide residues; (iii) typification of biopesticide production.

Given the impossibility of making face-to-face visits to regions or countries, short consultancies will be used to get this necessary information, coordinated by IICA. The information generated will be used by the project's drafting team to establish priorities in terms of training, decision-making for the development of the crop matrix – residue – biopesticides.
The role of consultants will be solely as information providers and should not participate or have an active role in the workshops. The number of countries in the project does not indicate that all activities should be carried out in each one of them, the elaboration of the project will help confirm which countries can be leaders or implementers of actions. Additionally, it is important to mention that harmonization is carried out on a regional basis, since there is no international regulation with which to harmonize, therefore, it is absolutely strategic that the countries that make up the regional integration bodies are present to promote the processes of harmonization.

[4] Colombia, Guatemala, Costa Rica, Panama and Bolivia participated.

We contemplated the formation of a Steering Committee, composed of IR4, IICA, representatives from the leading countries in each of sub regions and FAO (Regional Office for Latin America and the Caribbean, through Marisa Caipo, Regional Specialist in Food Safety). In addition, representatives of the Asian and South African STDF Projects on Residue mitigation and regulatory harmonization will be invited to participate to ensure cross fertilization and learn from each other's success and challenges. This is also an opportunity to understand trade in a cross-cultural forum. The Steering Committee will help to incorporate good practices of coordination, prospecting, and strategy throughout the entire process since it is seen as the managing and coordinating body from the realization of the PPG until the implementation of the project.

It is expected that the combination of the strengths of each organization that participates in the Steering Committee will generate a tangible benefit to the project. IR4's experience in field and laboratory work, institutional presence and participation in regional forums that IICA has, and FAO's experience in Integrated Pest Management will help to comprehensively recommend a set of good practices for the correct implementation of the PPG.

FAO's participation will allow consultations with its experts on what they have determined to be the best IPM practices for Latin America. Using IPM as standard practice, we will select with FAO which crop residue situations we intend to focus on.

The experience of IR4, IICA and FAO in previously implemented projects will help guide the preparation and orientation of the project, as well as its implementation, based on much of the experience obtained in the projects in Africa and Asia.

For the southern region, Argentina is one of the countries with the most advanced bio-pesticide regulatory framework in the region, so it will be able to support Paraguay and all the countries participating in this PPG to harmonize and advance in this field.

The project will call upon expert knowledge of minor use research by IR-4, USDA and technical country experts. This will involve the selection of field trial locations, crops/biopesticides, development of trial protocols to demonstrate biopesticide efficacy, and coordinating efforts for data reports and utilisation. The project will aim to demonstrate efficacy of biopesticides and to promote their use through increased commercialisation and registration and thus availability to producers.

Activity	**Responsible**	**Tentative date of Completion**	**Expected output**
Steering committee meeting	IICA IR-4 MUF USDA	Mid-April 2021	Discussion, feedback
PPG virtual workshop will include country representatives from participant countries (11) to get elements for the development of the PG proposal.	IICA IR-4 MUF USDA	Late - April, 2021	Term of reference (TOR) drafted Participating countries identified

Regional workshops	IR-4 IICA MUF USDA Latin American representatives	May 28th, 2021	Priority list of crop/conventional pesticide/ Capacity of participating countries evaluated for making assignments
Meeting with bioproducers associations	IICA IR4 MUF USDA	June 30, 2021	Priority list of crop/conventional pesticide/biopesticide
Discussions with potential partners, private sector, international organizations, donors	IICA IR-4 USDA Latin American representatives	July 28, 2021	Priority list of crop/conventional pesticide/biopesticides to address under the project Capacity of partners and other projects to add synergy identified
Draft proposal	IICA – IR4-MUF	August 5th, 2021	Develop full project grant proposal for STDF
PPG virtual workshop with country representatives to present and validate the draft PG proposal	IICA-IR4-MUF	August 19th 2021	Validation workshop and finish
Continue planning and addition of new elements in anticipation of potential project approval	IR-4 IICA MUF	October 29, 2021	Study protocols developed; timing, rates, field locations, etc.
Send final proposal to the STDF	IICA	November 26th 2021	Final Project

Budget

Activity	Responsible	Estimated Budget (US$)
Expertise *International Consultant: IR-4*	Technical guidance by IR-4 to develop planning meeting agenda, lead discussions, identify interested participating countries, develop country team members, consult with participating experts to determine priority crops/pesticides/biopesticides to include in the design of the project IR-4 advisor: **4.000** IICA technical inputs on crops, biopesticides,	USD $7,000

	markets and partners. **$3.000** *USDA and IICA to provide in-kind support for technical expert for planning and project development. IICA will also provide technological platforms for communication and logistics.	
Travel *Project Management (IICA)/Technical Advisor and International Consultant (IR-4, MUF)*	Travel and per diem fund. Reserve if necessary, for coordination, preparation and teamwork activities. *USDA to provide in-kind support for technical expert travel	0
Stakeholder virtual meetings and workshops *If appropriate, include travel of participants, hire of venue, facilitator, etc.*	Translation services	USD $1,000
Project proposal compilation	MUF, 10 days at 500 per day = **$5.000** IR-4 ,5 days at $660 per day = **$3,300** **Country´s consultants per product $1100 per country = $12.100**	US$20,400
Validation stakeholder workshop	Translation services	USD$ 1,000
Subtotal		29,400
Other costs (describe)	indirect costs at 12%	USD $3,528
TOTAL		**USD $ 32,928**

Appendixes

Appendix 1: Letters of support from each of the organizations supporting this proposal.

Appendix 2: Letter of Cooperation between IR-4 and IICA and Curriculum Vitae.