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Proposal to elaborate guidelines for biopesticides (Prepared by Chile)

I. Introduction

1. According to the current Strategic Plan of the Codex Alimentarius Commission (CAC) 2017-2019, in the Strategic Objective 1, the objective 1.2 is to actively identify emerging issues and the necessities of members, and, where appropriate, to develop food standards or related texts

II. Backgrounds

2. At the 40th Session of the Codex Alimentarius Commission (CAC), the Chilean delegation requested the Commission guidelines about the way in which the current lack of definitions regarding biopesticides, biofertilizers and biostimulants (CAC/40 CRD 28) should be addressed, including the possibility of submitting a discussion document on this topic, to a pertinent subsidiary body of the Commission.

3. As a result, the commission emphasized the following:

- i) countries were starting to develop national legislation, which could benefit from international guidance;
- ii) these substances were increasingly being used as an alternative to or to complement traditional agricultural practices, yet sufficient scientific assessments still must be made to ensure their safety;
- iii) clear definitions of these substances and their safe use and appropriate residue levels should be addressed; and
- iv) the technical nature of the issue required consideration by specialized subsidiary bodies of the Commission.

4. After the discussion, the Commission concluded the following:

- i) *It acknowledged the relevance of this issue and the support for the proposal made by Chile;*
- ii) *It recommended Chile to submit a discussion paper for consideration by the CCFL, the CCPR and the CCCF.*

III. Analysis

5. In response to the mandate of the CAC40, Chile submitted the document CX/FL 17/44/2 Add. 2 for revision, at the 44th Session of the Codex Committee on Food Labeling (CCFL), requesting guidance to address the topics related to biopesticides, biostimulants and biofertilizers, concluding that:

“This was a very technical issue; b. a document on the subject would also be submitted to the Codex Committee on Pesticide Residues (CCPR), so the CCFL would wait to see if there were labeling issues to address”.

6. In view of these circumstances, it has been concluded that the way to approach this work is to start only with pesticides of biological origin. Therefore, fertilizers and stimulants of biological origin will remain pending for future work. This was reported to the 12th Session of the Codex Committee on Contaminants in Foods (CCCF), which took place the week of March 12 of 2018 in the Netherlands.

IV. Proposal

7. Chile proposes to develop, in the framework of the CCPR, a new work with guidelines and harmonized orientations on Biopesticides, allowing its safe use. This work is expected to cover all pesticides of biological origin, establishing definitions, classification, safe use and possible listings of this type of products.

Proposal to elaborate guidelines for biopesticides

(Prepared by Chile)

1. Objective and scope

The objective is to elaborate a document providing harmonized orientations and guidelines regarding biopesticides, in order to allow its use.

Regarding the scope, it is expected to address all pesticides from biological origin, establishing definitions, classification, safe use and possible lists of this kind of products.

2. Relevance and Timeliness

The global regulatory scenario for pesticides of chemical origin is increasing the restrictions on this type of product, both in terms of its authorization and the maximum residue limits allowed in food and feed. This is a consequence of public health concerns expressed by scientific bodies, consumers and several risk assessment and management agencies worldwide.

The described scenario has encouraged the development of new plant protection products based on products of biological origin, which are increasingly used as an alternative to traditional agricultural practices or to complement them. Hence, it would be very useful to have a guideline that includes clear definitions and safe use forms, as well as the appropriate residue levels.

In recent years, there has been a significant increase in the worldwide use of Biopesticides, both in traditional agriculture and in organic production. According to Dunham Trimmer (2017)¹, the market for biopesticides has grown between 12 and 17% per year during the last 5 years, representing a growth from two to three times faster than the market for traditional pesticides.

The above coincide with some of the Sustainable Development Goals (SDG), signed in 2015 at the United Nations Sustainable Development Summit, established in its Agenda 2030, referring to: the sustainability of food production systems (SDG 2); the goal of significantly reducing, by 2030, the number of deaths and diseases caused by hazardous chemicals, contamination and air, water and soil pollution (SDG 3 at its goal number 9); and finally, the commitment to achieve an ecologically sound management of chemical products, and significantly reduce their release to the atmosphere, water and soil, in order to minimize their adverse effects on human health and the environment (SDG 12).

At the level of Codex Alimentarius, there are no specific guidelines for these products, however, there is some guidance related to this topic in the document "*Guidelines for the production, processing, labeling and marketing of organically produced foods (GL 32-99)*", prepared by the Codex Committee on Food Labeling (CCFL), which presents a list of substances allowed for organic production in its Annex 2, table 2, including some products classified as Biopesticides .

On the other hand, at the 40th Session of the Codex Alimentarius Commission (CAC), Chile set out the need to create guidelines for these products, considering that several countries stated that they already had regulations in this area and others were starting to create national laws.

In this sense, it is possible to verify that there are different definitions for this type of products. The Organization for Economic Cooperation and Development (OECD), in its Program of Biological Pesticides, defines this type of products as those that can be made from microorganisms such as bacteria, algae, protozoa, viruses and fungi; semiochemicals; macro organisms and invertebrates such as insects and nematodes; as well as botanical extracts. On the other hand, the International Union of Pure and Applied Chemistry IUPAC, has proposed a scheme for the definition and classification of Biopesticides, both from the nature of their active ingredients, as well as the use they are intended to. Thus, it is possible to recognize microbiological pesticides, protectors incorporated to plants and biochemical pesticides (*State of the art and elements for the elaboration of a political proposal and institutionality for Bioinputs in Chile, Inter-American Institute for Cooperation on Agriculture IICA - Chile, November 2014*).

Considering backgrounds, the mandate of this Committee and the definition of pesticides in the Codex Alimentarius Procedures Manual (Twenty-fifth edition), it is considered appropriate for the CCPR to address this matter.

3. Main issues to address

Given the purpose and scope of this Guideline, definitions, classification, safe use, and potential lists of this type of product should be addressed.

¹ Dunham Trimmer, International Bio Intelligence (2017) Biopesticides Market, Key to Growth.

5. Evaluation against the criteria for the establishment of work priorities.

General criterion

Relevance in the strategic objectives of Codex.

The development of this work will contribute to the Strategic Objective 1 of the Strategic Plan 2014 - 2019 "Establish international food standards that address current and emerging food issues", specifically to objective 1.2 which is "Proactively identify emerging issues and Member needs and, where appropriate, develop relevant food standards".

Criteria applicable to general issues.

a. Diversification of national legislations and resulting or potential impediments to international trade.

As shown in the following examples, the legislation in different countries addresses the issues related to Biopesticides in different ways, which could lead to repercussions in international trade, due to the current lack of harmonized normative concepts.

In the case of biological products used as pesticides, also called Biopesticides, the use and commercialization in the territory of the member countries of the European Union must be approved in accordance with Regulation No. 1107/2009, which establishes criteria to authorize the trade of phytosanitary products, including those Biopesticides based on microorganisms or natural substances.

On the other hand, the registration and authorization of pesticides in the United States is based on two regulations that consider the use of "Biotechnological" products, including among them, Biopesticides obtained on the basis of genetically modified microorganisms or the incorporation of "Protectors" from several microorganisms to a specific plant. On the one hand, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides the legal requirements of the registration process for any pesticide to be evaluated for registration, by the Environmental Protection Agency (EPA), which are described in a Pesticide Registration Manual. EPA has a division specialized in issues related to Biopesticides and Contamination. In addition, the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality and Protection Act (FQPA), mentions the requirement for the establishment of maximum limits or their exception, in the presence of pesticide residues in food, both for human and animal use. Before authorizing the commercialization of any pesticide, EPA must perform a risk analysis to ensure that the product does not represent a risk to people or the environment. This analysis should incorporate risk assessment studies for people and the environment.

The regulation for Biopesticides in India, is based on the Insecticides Act (1968), which established that any microorganism manufactured or commercialized must be registered in the Central Insecticides Board CIB of the Ministry of Agriculture. In order to promote the registration of Biopesticides, the registration process of these products has priority and is subject to simplified procedures, as well as the acceptance of generic data of strains already registered (*State of the art and elements for the preparation of a political proposal and institutionality for Bio-inputs in Chile, Inter-American Institute for Cooperation on Agriculture IICA - Chile, November 2014*).

At the Latin American level, Colombia, in its national regulations in force in the Resolution of the Colombian Agricultural Institute (ICA) No. 000698 of February 4, 2011 establishes that: "by which the requirements for the registration of technical departments of efficacy trials, producers and importers of bio-inputs for agricultural use are established and other provisions are dictated".

In Chile, pesticides of biological origin are authorized under the same regulations that apply for the authorization of traditional pesticides.

b. Scope of work, set of priorities among the different sections of the work.

It is proposed to begin by agreeing on a definition, then moving forward in establishing a classification and, finally, according to the foregoing, to elaborate a potential list of compounds.

b. Work already initiated by other international organizations in this field and/or proposed by the relevant international intergovernmental organization or organizations.

The OECD, which depends on the *Environment Health and Safety Division* and under the Working Group on Pesticide, has the *Expert Group on Biopesticide*, which is currently working on the subject.

c. Feasibility of the subject of the proposal for standardization.

The proposal is considered feasible, since like other works developed at the Codex level, the regulations of the existing Members could be used as a base, and the advances in this matter developed by other international organizations of intergovernmental nature could be used as reference.

d. Examination of the global magnitude of the problem or issue.

Although there are gaps in the official information regarding the commercialization and use of biopesticides globally, and currently, it is not possible to present a final examination of the magnitude of the issue worldwide, there are some studies indicating that the biopesticides market has grown significantly in recent years, reaching values close to USD 3,000 million in 2016, with market growth rates between 12 and 17% per annum over the last 5 years².

4. Information on the relationship between the proposal and existing documents of Codex

The proposed work has not yet been addressed by the Codex Alimentarius.

The only document of Codex Alimentarius mentioning this type of product is the *"Guidelines for the production, processing, labeling and marketing of organically produced foods (GL 32-99)"* prepared by Codex Committee on Food Labeling (CCFL), which presents a list of substances with pesticide effect allowed for organic production. However, as its name indicates, the scope of this Guideline only focuses on organically produced foods.

5. Identification of the availability of scientific experts when necessary

For the elaboration of this Guideline, the opinions of the JMPR, JEMRA, FAO and WHO should be taken as reference.

6. Identification of any need for technical contribution to a standard from external organizations.

At the moment, no need for contributions has been identified for this stage.

7. Proposed calendar for the development of the new work

PROCEDURE	DATE
Approval by the CCPR to develop a Guideline	April 2018
Adoption of the proposed new work by the CAC	July 2018
Presentation of the draft project at the 51st CCPR Meeting	April 2019
Proposed date for the adoption of the draft Guideline by the CAC	July 2022

² Dunham Trimmer, International Bio Intelligence (2017) Biopesticides Market, Key to Growth.