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**Committee on Sanitary and Phytosanitary Measures** Original: English

# ENABLING ACCESS TO TOOLS AND TECHNOLOGIES: TOWARDS SAFER AND MORE SUSTAINABLE AGRICULTURE THROUGH REGULATORY COLLABORATION

SUBMISSION FROM BRAZIL, KENYA, PARAGUAY AND THE UNITED STATES OF AMERICA

The following communication, received on 5 July 2019, is being circulated at the request of the Delegation of Brazil, Kenya, Paraguay and the United States of America.

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## 1 INTRODUCTION

1.1. In G/SPS/W/305, the cosponsors noted that collaboration at the regional and international level to streamline and improve regulatory approaches to pre-market approvals and inspection systems with respect to products to manage fall armyworm (FAW) could support national and regional efforts to increase access to those products. In particular, the cosponsors noted that approaches that reduce unnecessary burdens and increase the efficiency and predictability of science-based outcomes could help put urgently needed tools in the hands of farmers while protecting public health and the environment.

1.2. At the Committee's thematic session on fall armyworm held on 19 March 2019, presenters echoed the themes noted in G/SPS/W/305. Presenters emphasized the importance of integrated pest management (IPM) strategies, as well as national and regional strategies to coordinate in monitoring and surveillance activities, research and development, and in the evaluation and registration of control options. We appreciate the range of experiences presented at the thematic session on collaboration at the national, regional and international levels on systems and strategies to combat FAW.

1.3. The objective of this follow-on submission is to provide an initial compilation of concepts that support collaboration at the regional and international level and that can be employed, on a voluntary basis, to improve and streamline regulatory processes, while safeguarding human, plant and animal health. Such a compilation could serve as a resource, in particular, for authorities with capacity constraints to help identify regulatory efficiencies that can lead to greater and faster access to safe tools and technologies to manage FAW and other SPS challenges.

1.4. Brazil, Kenya, Paraguay and the United States propose that the concepts identified below could productively be a subject of further Committee discussion in connection with FAW and could be assembled into a Committee document, connected to the Fifth Review, on approaches to streamline regulatory processes with respect to FAW. We recognize these concepts can be helpful in addressing other SPS challenges as well, particularly for authorities facing capacity constraints. Such a document could assist Members in strengthening implementation of Article 9 of the SPS Agreement.

### 1.1 Data portability

1.5. Data produced in one locality can be relevant and useful to support the assessment of the same product in another locality.

1.6. **Background:** Across many sectors, data portability is a well-established and proven mechanism for reducing regulatory burdens and increasing both the speed and efficiency of

regulatory assessments and decision making. In its most basic form, data portability refers to the characteristics of the data that allow them to be used by others in decision-making processes.

### 1.1.1 Laboratory data

1.7. Laboratory data, by nature of being generated under very tightly controlled conditions, should always be geographically portable provided there is acceptance of the methodologies used in generating those data. In the context of FAW, laboratory data requirements may include toxicity studies of pesticides, biopesticides, or resistant plant varieties, or for purposes of food safety assessments, environmental chemistry, or impact on non-target organisms (where required).

### 1.1.2 Field trial data

1.8. For field studies, recent efforts to categorize agro-climate zones may allow field trial data to be portable across similar agro-climatic zones with similar field conditions where a product might be expected to perform similarly. In the context of FAW, field trial data may be required to support various regulatory actions, such as seed variety registration, biosafety review, and crop protection authorization. For certain regulatory actions, regulatory entities may require national field trials at multiple sites, and over multiple planting years. These trials come at a cost to the product developer or registrant and increase the workload of regulators, so there is interest in streamlining the process to lower budgetary and regulatory hurdles. Eliminating redundant field trials by acceptance of field trial data generated in comparable agro-climatic zones could reduce the time, effort and expense required to bring a useful and efficacious product to market.

1.9. **Relevant publications:** Nakai, Hoshikawa, Shimono, & Ohsawa, 2015; Garcia-Alonso et al., 2014; Draft Guidance Document on Crop Field Trials, OECD Environment, Health and Safety Publications, March 2016; Canada Food Inspection Agency Guidance for Plants with Novel Traits; Codex guidelines for foods derived from modern biotechnology; etc.

## 1.2 Common application dossiers

1.10. A common application dossier sets out a uniform format and standardized concepts for submission of data as part of an approval procedure.

1.11. **Background:** Most countries make use of substantially similar information for performance and risk analysis, based on international agreements, guidance from standard setting bodies and international norms. However, design of dossier specifications at the individual country level, absent coordination across countries, has developed a patchwork of application processes that requires companies to devote considerable resources to each individual country application, often repeating similar data but in a different format. These unique country-level dossier formats present a challenge, particularly when emergency responses are required in dozens of countries simultaneously, as in the case of FAW. Harmonizing application dossier formats across countries, feasible when there are compatible data requirements, reduces product registration costs for the company and facilitates information sharing between regulators across jurisdictions, reducing the time needed for product review. In cases where international standards exist, they can be used as the bases for a common dossier.

1.12. **Examples:** *Common Technical Document* (CTD) of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use; OECD dossier for pesticide maximum residue levels (MRLs); etc.

## 1.3 Joint risk assessments

1.13. Joint risk assessments are conducted collaboratively by two or more regulatory authorities (or delegated to an agreed-upon third entity) and are used as the basis for risk management decisions by each national authority.

1.14. **Background:** Joint risk assessments allow jurisdictions to share resources and capacities. Regulators work together to collect, review, and analyze data for a particular product. Joint assessments may be especially beneficial in cases, such as with FAW, where regional pest problems

are most effectively addressed by regional adoption of mitigation strategies. Involvement of regional economic communities, if applicable, can leverage national efforts.

1.15. **Examples:** Food Standards Australia and New Zealand (FSANZ) on food safety evaluations; Australia-Canada work; COMESA regional biotechnology framework; Joint FAO/WHO meeting on Pesticide Residues; Joint FAO/WHO Meeting on Pesticide Specifications; The Joint FAO/WHO Expert Committee on Food Additives; etc.

### 1.4 Adaptation to regional conditions

1.16. The use of integrated pest management (IPM) strategies, as well as the access to safe technologies should take into account the sanitary or phytosanitary characteristics of the area, including the level of prevalence of specific diseases or pests and the existence of eradication or control programmes.

1.17. **Background:** Taking into consideration that FAW is native to tropical and subtropical regions of the Americas and has been spreading rapidly through tropical and subtropical regions of Eastern, Western and Southern Africa, Members should consider the natural characteristics of agriculture in the tropics, particularly the pressures related to prevalence of pests in tropical climates. In that sense, best practices applied in other Member countries could be adapted to the regional conditions of affected countries, in order to promote sustainable agriculture practices in tropical areas.

1.18. **Example:** The FAW Study Tour, organized by national cooperation agencies of Brazil and the United States, in coordination with multilateral organizations, promoted knowledge of emergency strategies to combat and control the pest, based on the experiences of Brazil.

### 1.5 Unilateral recognition

1.19. Unilateral recognition occurs when one national authority recognizes data collected in another jurisdiction as being applicable to its own, or when it accepts the regulatory decisions of another body. An authority can do the former without the latter.

1.20. **Background:** Generally, unilateral recognition requires the country employing it to understand the data and regulatory process of the other country, and to have confidence that the other country's risk assessment will adequately meet its needs. When recognition is possible, it creates tremendous efficiencies in regulatory decision making, and could greatly improve the speed with which technologies can be deployed to combat pests such as FAW. Unilateral recognition does not require negotiation or permission from the country generating the assessment or issuing the decision, and implies but does not necessarily require formal harmonization. However, where a national authority wants to recognize data collected in another jurisdiction, the data must be portable and the assessment be publicly available for any country that wishes to use it.

1.21. **Examples:** Examples are plentiful and include recognition of residue limits for chemicals or pesticides in food or the FAO "GM Foods Platform" for food safety assessments of genetically engineered crops.

### 1.6 Mutual recognition

1.22. Mutual recognition is an arrangement between two or more national authorities to recognize one another's data or regulatory decisions. Such arrangements may, for example, provide for mutual recognition of one another's standards, data, conformity assessment results, or product approvals, and set out conditions or processes that each side must follow to allow for such mutual recognition. Mutual recognition agreements can allow decisions or data produced by one authority within the agreed terms to be automatically accepted by the other(s) and *vice versa*.

1.23. **Background:** Different from unilateral recognition, mutual recognition reflects an agreement between two or more national authorities to accept one another's data or regulatory decisions. Parties to a mutual recognition agreement generally have substantially similar regulatory aims, requirements, and capabilities which enables regulatory authorities to have confidence that any decision made by one party will sufficiently meet the requirements of the other(s). Although mutual recognition of both data and decisions is the best-case scenario, mutual recognition of data might

occur without the mutual recognition of regulatory decisions. A mutual recognition agreement is generally the result of a significant history of cooperation to develop the confidence needed to be able to accept data or decisions produced by parties to the agreement and takes time to negotiate. However, once in place, mutual recognition can provide regulatory efficiency and facilitate coordinated responses between countries to local and regional challenges like FAW. Importantly, commitment of Members to follow the principles laid out in the SPS Agreement represents a good starting point for discussions around mutual recognition.

1.24. **Examples:** Ongoing efforts in the East Africa Community (EAC) aim at the mutual recognition of pesticide registrations, which will reduce required field trials from sixteen down to three or four; OECD arrangement for mutual recognition of Good Laboratory Practice (GLP) data; regional seed trade harmonization initiatives in SADC and COMESA allow approved seed varieties to be traded among member States with similar agro-ecological zones once the variety is approved at the regional level.

### 1.7 Familiarity

1.25. Knowledge and experience with a specific product or similar product can be used to support regulatory assessment and decision making.

1.26. **Background:** Familiarity can refer to the product's or similar product's record of assessments and authorizations. It can refer to assessment and authorization experiences with products with the same mode of action, or for an existing product already labelled for use on other pests. Criteria can be established to determine when facilitated assessment and authorization based on familiarity would be applicable.

1.27. **Examples:** The US Department of Agriculture Animal and Plant Health Inspection Agency (USDA APHIS) Extension process for GE plants; US Food and Drug Administration (US FDA) biosimilar drug process; US Environmental Protection Agency (US EPA) Office of Pesticide Programs "me-too" pesticide product registration of pesticide products that are similar in formulation to pesticide products already registered by the US EPA.

### 1.8 History of safe use

1.28. In some circumstances, safety can be presumed from an absence of evidence of harm when a product has a sufficient history of use.

1.29. **Background:** Jurisdictions have used the term "history of safe use" to deem many products to be generally safe. Although determining a history of safe use requires familiarity with the product, some products with which a country is familiar might not have a history of safe use and therefore the terms are not equivalent.

1.30. **Examples:** Health Canada employs a category of foods for which there is "significant human consumption … (over several generations and in a large, genetically diverse population) and for which there exist adequate toxicological and allergenicity data to provide reasonable certainty that no harm will result from consumption of the food''; the US FDA has a category of foods that are "generally recognized as safe".

### 1.9 Equivalence

1.31. An equivalence process involves determining whether another jurisdiction's regulatory requirements or specific scheme in a particular area achieve the appropriate level of protection applied in one's own jurisdiction, where the exporting Member objectively demonstrates that its measure or measures meets the importing Members appropriate level of protection.

1.32. **Background:** Jurisdictions may have compatible protection goals, while differing in the regulatory process and measures used to achieve that goal. International standards and harmonized technical guidelines can facilitate equivalence. Countries can verify equivalency based on established criteria, or by bilateral agreements.

### 1.10 Harmonization

1.33. Members may establish, recognize, and apply, common standards, guidelines, recommendations, or regulatory approaches.

1.34. **Background:** Harmonization can be implemented at various levels. For example, the requirements for application dossiers, technical guidelines and guidance documents, data requirements, methodologies, terminologies or recommendations can be made consistent across jurisdictions to facilitate applications for authorization. Harmonized standards in data collection would support data portability across jurisdictions, reduce regulatory redundancy, promote access to scientific information across multiple jurisdictions, and could serve as the foundation for regulatory cooperation, unilateral recognition (section 1.5), mutual recognition (section 1.6) and equivalence (section 1.9).

### 1.11 Emergency Use Authorization

1.35. Emergency exemptions or authorizations (EUA) allow for unregistered use of products to address an urgent, non-routine situation that requires intervention. Often use is granted on a temporary basis and occurs while formal product registration is being pursued.

1.36. **Background:** In most countries, pesticides must be registered for specific crop-pest applications. As an invasive pest, FAW would be unlikely to have any existing product registrations even though effective pesticides may already be registered in an affected country for different crop-pest applications. In these cases, a EUA can draw on existing safety data from related pests for the pesticide in question, allowing it to be used for FAW. In rare cases, an entirely new product might be approved that does not have a label for any pest. A EUA is limited for the time of crisis and allows authorities to respond quickly and decisively to mitigate or contain the crisis. Criteria can be established to determine the trigger for a EUA, and EUAs can be time limited and/or geographically limited.

1.37. **Example:** South African and Kenyan Fall Armyworm Task Forces; US FDA Emergency Use Authorization authority to approve new drugs or new indications for previously approved drugs during a declared emergency; US EPA Emergency Exemptions to permit the unregistered use of pesticide in emergency pest conditions.