COMMENTS AND SUGGESTIONS ON THE LANGUAGE OF THE DOST-DA-DENR-DOH-DILG REVISED JOINT DEPARTMENT CIRCULAR			
Name / Institution	**Article/Section on the revised JDC**	**Proposed Edit and/or Comments**	**Response**
Bureau of Plant Industry (BPI)	General Comment	Revise all mentions of *"Plant Quarantine Service (PQS)"* to *"National Plant Quarantine Services Division (NPQSD)"*	All the references to "PQS" in the revised Joint Department Circular will be replaced with "NPQSD".
	ARTICLE I. GENERAL PROVISIONS Section 2. **Definition of Terms**	Include definition for novel combinations stated in Section 1. Applicability	The definition and interpretation of novel combinations stated in Section 1. Applicability has already been made in the National Committee on Biosafety of the Philippines Resolution No. 001, Series of 2021, *"The Regulation of Plant and Plant Products Derived from the Use of Plant Breeding Innovations (PBIs) or New Plant Breeding Techniques (NBTs)"*.
	ARTICLE I. GENERAL PROVISIONS Section 2. **Definition of Terms** a) "*Applicant*" – refers to the juridical person who, ... An applicant may be: (1) any of the departments or agencies of the Philippine Government; (2) a university-based research institution in the Philippines; ...	Proposal to add a) "*Applicant*" – refers to the juridical person who, ... An applicant may be **one of the following**: (1) any of the departments or agencies of the Philippine Government; (2) a university-based research institution in the Philippines; ...	The proposed addition does not change the context of the definition of who an *"applicant"* is.
	ARTICLE III. ADMINISTRATIVE FRAMEWORK Section 7. **Bureau of Plant Industry Biotechnology Unit**. The Department of Agriculture – Bureau of Plant Industry shall establish a Biotechnology Unit with dedicated staff **and based**	Omit *"National Plant Quarantine Services Division"* Section 7. Bureau of Plant Industry Biotechnology Unit. The Department of Agriculture – Bureau of Plant Industry shall establish a Biotechnology Unit with dedicated staff to provide frontline	The revised JDC shall only refer to the Bureau of Plant Industry as reflected in Article III, Section 6: "Bureau of Plant Industry (BPI). The Department of Agriculture-Bureau of Plant Industry shall provide frontline services for the processing of

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	within the National Plant Quarantine Services Division to provide frontline services for the processing of applications for field trial, commercial propagation, and direct use permits. The BPI Biotechnology Unit shall also provide technical and administrative assistance to the Joint Assessment Group.	services for the processing of applications for field trial, commercial propagation, and direct use permits. The BPI Biotechnology Unit shall also provide technical and administrative assistance to the Joint Assessment Group.	applications for field trial, commercial propagation, and direct use permits. The BPI shall open an application file for all biosafety permit applications and keep updated its Approval Registries. During the processing of an application, the BPI shall provide technical and administrative assistance to the Joint Assessment Group. The BPI shall also prepare the consolidated report on the Public Information Sheet and announce at its website all applications and biosafety permits issued."
	ARTICLE VIII. GENETICALLY MODIFIED PLANTS AND PLANT PRODUCTS WITH STACKED EVENTS Section 20. **Regulation of Stacked Events**. Plants produced through conventional breeding of approved genetically modified parental lines and their derived products are not considered novel. The BPI can be requested to register stacked events in the BPI Approval Registry for Propagation or BPI Approval Registry for Direct Use, as the case may be.	Propose to revise the second sentence, as follows: Section 20. Regulation of Stacked Events. Plants produced through conventional breeding of approved genetically modified parental lines and their derived products are not considered novel. **The applicant may request for the registration of their stacked events in the BPI Approval Registry for Propagation or BPI Approval Registry for Direct Use, as the case may be.**	The proposed revision will be adopted.
	ARTICLE VIII. GENETICALLY MODIFIED PLANTS AND PLANT PRODUCTS WITH STACKED EVENTS Section 21. **Regulation of Stacked Events**	The term *"sub-stacks"* may be change into ***"intermediate stacks"*** to conform with the term used in previous issuances.	The term *"intermediate stacks"* will be adopted as a synonym for *"sub-stacks"*.

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	ARTICLE IX. IMPORTATION OF REGULATED ARTICLES Section 24. **Policy on the Importation of Regulated Articles**. All importations of regulated articles shall be covered by Department of Agriculture Circular no. 04, series of 2016, being implemented by the BPI-Plant Quarantine Service (PQS)….	The title of the document Department of Agriculture Circular no.04, series of 2016, and the Section shall be read as follows: Section 24. **Policy on the Importation of Regulated Articles**. All importations of regulated articles shall be covered by **Department of Agriculture Circular no. 04, series of 2016: *"Guidelines on the Importation of Plants, Planting Materials, and Plant Products for Commercial Purposes"*,** being implemented by **the BPI-National Plant Quarantine Services Division (NPQSD)...**	The proposed revision will be adapted, as reflected below: Section 24. **Policy on the Importation of Regulated Articles.** All importations of regulated articles shall be covered by the Department of Agriculture general guidelines on the importation of plants, planting materials, and plant products, which is being implemented by the BPI-National Plant Quarantine Services Division (BPI-NPQSD) ...
	ARTICLE X. MISCELLANEOUS PROVISIONS Section 28. **Application File**. The BPI shall open an application file for every accepted application in accordance with this Circular. The application for a biosafety permit, its supporting documents, evaluation reports, written comments submitted by other government agencies and the public, and any and all documents relating to the application shall form part of the application file. Each application file shall be assigned an identification number for reference purposes.	Replace *"evaluation reports"* to *"recommendation document"* Section 28. **Application File**. The BPI shall open an application file for every accepted application in accordance with this Circular. The application for a biosafety permit, its supporting documents, **Joint Assessment Group (JAG) recommendation reports,** written comments submitted by other government agencies and the public, and any and all documents relating to the application shall form part of the application file. Each application file shall be assigned an identification number for reference purposes.	The proposed revision will be adopted.

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Tebtebba	**Article II. Biosafety Decisions** **Section 3. Guidelines in Making Biosafety Decisions** **D.** *Social, Economic, Ethical, and Cultural Considerations*. In reaching a decision for the direct use as food and feed, or for processing, or the commercial propagation of a regulated article, social, economic, ethical, and cultural consideration arising from the impact of regulated articles on the conservation and sustainable use of biological diversity may be taken into account, especially with regard to the value of biological diversity to indigenous and local and cultural communities.	**Proposed revision:** Social, Economic, Ethical, and Cultural Considerations. In reaching a decision for the direct use as food and feed, or for processing, or the commercial propagation of a regulated article, social, economic, ethical, and cultural consideration arising from the impact of regulated articles on the conservation and sustainable use of biological diversity may be taken into account, especially with regard to the value of biological diversity to **indigenous peoples or indigenous cultural communities. In the conduct of SEC, the 'Guidance on the Assessment of SEC in the context of Article 26 of the CPB,' shall be adopted (COP-MOP decision 9/14).** SEC has been delimited 'for the direct use as food and feed, or for processing, or the commercial propagation of a regulated article' that is not consistent with Article I Section I (This Joint Department Circular shall apply to the research, development, handling and use, transboundary movement, release into the environment, and management of plants and plant products derived from the use of modern biotechnology.) and Article V Section 12 A 7&8	Commercial Propagation and Direct Use as Food, Feed, or for Processing (FFP) are the activities with direct impact to the socio-economic conditions of a given locality. The Field Trial, on the other hand, will only occur at a very limited time and space and is not expected to bear upon the existing socio-economic conditions of a locality.

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		Propose to replace last phrase with indigenous peoples or indigenous cultural communities (basis RA8371 Section 3 h) Propose to add at the end: In the conduct of SEC, the 'Guidance on the Assessment of SEC in the context of Article 26 of the CPB,' shall be adopted (COP-MOP decision 9/14)	The revised Joint Department Circular adapts the language used in the Cartagena Protocol on Biosafety. The Cartagena Protocol on Biosafety states that social, economic, ethical and cultural considerations may be considered in making biosafety decisions. During the comment period for commercial propagation and direct use for FFP, any interested person may submit to the BPI written comments regarding the application, which may include issues related to social, economic, ethical, and cultural considerations arising from the impact of regulated articles on the conservation and sustainable use of biological diversity, especially with regard to the value of the affected biological diversity to local and indigenous cultural communities.
	Article II. Biosafety Decisions **Section 3. Guidelines in Making Biosafety Decisions** E. Access to Information. Government departments and agencies shall respect the right of the public and stakeholders to information relevant to biosafety decisions including information on applications, results of risk assessments, environmental, health and	To insert result of Social. Economic, Ethical and Cultural Considerations required in Article II Section 3 D and result of FPIC process required in NCIP AO No. 3 s, 2012.	The Cartagena Protocol on Biosafety states that social, economic, ethical and cultural considerations may be considered in making biosafety decisions. During the comment period for commercial propagation and direct use for FFP, any interested person may submit to the BPI written comments regarding the application, which may include issues related to social, economic, ethical, and cultural

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	food safety assessments, public participation processes, and other information on which biosafety decisions are made, subject to the protection of confidential business information that does not impair the ability of stakeholders to effectively conduct a scientific risk assessment.		considerations arising from the impact of regulated articles on the conservation and sustainable use of biological diversity, especially with regard to the value of the affected biological diversity to local and indigenous cultural communities.
	Article II. Biosafety Decisions **Section 3. Guidelines in Making Biosafety Decisions** F. *Transparency and Public Participation.* 3. Public consultation, as a way to secure wide input into decisions to be made. This may entail the conduct of formal hearings in certain cases, or solicitation of public comments, particularly where there is public controversy surrounding the proposed activities. Public consultations shall encourage exchanges of information between applicants and the public before the application is acted upon. Dialogue and consensus-building among all stakeholders shall be encouraged. Concerned departments and agencies shall specify in their	Propose to place indigenous peples before networks of... 3. Public consultation, as a way to secure wide input into decisions to be made. This may entail the conduct of formal hearings in certain cases, or solicitation of public comments, particularly where there is public controversy surrounding the proposed activities. Public consultations shall encourage exchanges of information between applicants and the public before the application is acted upon. Dialogue and consensus-building among all stakeholders shall be encouraged. Concerned departments and agencies shall specify in their appropriate rules and regulations the stages when public consultations are appropriate, the specific time frames for such consultations, and the circumstances when formal hearings will be required, including guidelines to ensure orderly proceedings. The	Not all applications will involve ancestral domains and issues on Indigenous People. If applicable, an application for a field trial shall require submission of a National Commission on Indigenous People (NCIP) Certification Precondition. Likewise, if the field trial site is within an ancestral domain or ancestral land, the applicant shall secure the Free and Prior Informed Consent (FPIC) of the concerned Indigenous People/ Indigenous Cultural Community in accordance with the Indigenous People's Rights Act.

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	appropriate rules and regulations the stages when public consultations are appropriate, the specific time frames for such consultations, and the circumstances when formal hearings will be required, including guidelines to ensure orderly proceedings. The networks of agricultural and fisheries councils, indigenous peoples and community-based organizations in affected areas may be utilized;	indigenous peoples, networks of agricultural and fisheries councils, in affected areas may be utilized.	
	Article III. Administrative Framework Section 4. **Role of National Government Agencies**	Possibility of adding letter F., to include role of associated departments and agencies i.e., National Commission on Indigenous Peoples (refer to Section 4.11 of Executive Order No. 514)	Not all activities will involve the participation of the National Commission on Indigenous Peoples (NCIP).
	Article V. Field Trial of Regulated Articles Section 12. **Procedural Requirements for Securing a Biosafety Permit for Field Trial.** Any applicant who desires to conduct field trial of regulated articles shall submit an application to the BPI Director through the Biotechnology Unit. An application for field trial of a regulated article may cover single or multiple field trial sites, the size and duration of which will be specified by the applicant. The suitability of each field trial site shall be assessed separately for purposes of	Propose to add at the end of the paragraph: *"social, economic, ethical, and cultural to be consistent with Article II, Section 3D."*	Field trials are not expected to bear heavily or influence the socio-economic conditions and norms of a locality because of limited time and space involved in the activity.

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	determining any potential risks to the environment or health.		
	A. **Filing of Application Form and Supporting Documents for Field Trial** 7. National Commission on Indigenous People (NCIP) Clearance (if applicable);	NCIP does not issue clearance but can only issue Certification Precondition (NCIP AO No. 3 s, 2012)	This is noted. The term "NCIP clearance" will be changed to "NCIP Certification Precondition."
	Section 12. **Procedural Requirements for Securing a Biosafety Permit for Field Trial.** A. **Filing of Application Form and Supporting Documents for Field Trial** 8. If the site is within an ancestral domain or ancestral land, the applicant shall secure the Free and Prior Informed Consent (FPIC) of the concerned Indigenous People/ Indigenous Cultural Community in accordance with the Indigenous People's Rights Act. If the site is within a protected area under the National Integrated Protected Area System, the applicant shall secure an endorsement from the Protected Area Management Board of the protected area; and	FPIC guidelines is contained in NCIP AO No. 3 s, 2012 or customary law of the indigenous community	Since the FPIC Guidelines has the force and effect of law, it is already considered as written into Article V, Section 12(A)8 of the draft JDC. Hence, this proposal to have this provision expressly refer to NCIP AO No.3 is unnecessary, if not ill-advised. It should be noted that Article V, Section 12(A)8 of the draft JDC already refers to the Indigenous People's Rights Act (IPRA). This would already suffice. It is also pointed out that NCIP AO No.3 is merely and administrative issuance, which may be amended by the NCIP from time to time. Hence, it may not be advisable for the JDC to expressly refer to NCIP AO No.3 as there may be a need to amend or re-issue the JDC in the event NCIP AO No.3 is revoked or superseded by another issuance. Reference to the IPRA should suffice.
	Article V. Field Trial of Regulated Articles		

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	Section 12. **Procedural Requirements for Securing a Biosafety Permit for Field Trial.** D. **Action on Application.** The Director of the Bureau of Plant Industry shall issue a decision to approve or disapprove the application within three (3) working days upon receipt of the recommendation document from the JAG, based on the following considerations: 1. Compliance with administrative procedure and requirements; 2. Recommendation of the Joint Assessment Group; 3. Issues and concerns raised during the public participation period; and 4. Applicant's response to the issues and concerns raised for the applied regulated article.	To be inserted after D.3. *"3b. Issues and concerns raised during the FPIC process (to be consistent with Article V, Section 12 A 7&B)* D. **Action on Application.** The Director of the Bureau of Plant Industry shall issue a decision to approve or disapprove the application within three (3) working days upon receipt of the recommendation document from the JAG, based on the following considerations: 1. Compliance with administrative procedure and requirements; 2. Recommendation of the Joint Assessment Group; 3.a. Issues and concerns raised during the public participation period; **3.b. Issues and concerns raised during the FPIC process (to be consistent with Article V, Section 12 A 7&B);** and 4. Applicant's response to the issues and concerns raised for the applied regulated article.	A biosafety application for field trial will undergo the FPIC process only if the selected site is within an ancestral domain or ancestral land defined by the law. Should this be the case, the issues and concerns raised during the FPIC process shall be subsumed in the public participation process for Field Trial applications.
	Article V. Field Trial of Regulated Articles Section 12. **Procedural Requirements** H. **Permit Conditions**. 2. The permit holder shall immediately notify the Director of BPI, in writing, should any of the following cases occur:	To include risks to social, economic, ethical, and cultural to be consistent with Article II Section 3 D	Field trials are not expected to bear heavily or influence the socio-economic conditions and norms of a

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	a. In the event that new information becomes available, indicating that the regulated article would pose greater risks to human health and the environment as compared to its conventional counterpart;		locality because of limited time and space involved in the activity.
	Article V. Field Trial of Regulated Articles Section 12. **Procedural Requirements** J. **Submission of Report**. Within ninety (90) working days from the completion of the field trial, the applicant shall submit to the BPI two (2) hard copies and a soft copy of the terminal report on the results of the field trial. The report shall be in the format prescribed by the BPI and state, among others, whether the objectives of the field trial were achieved; a description of any unforeseen risks to human health and environment observed during the conduct of the field trial; the steps taken by the applicant to mitigate them; and the final disposition of the regulated article. Such report must be endorsed by the IBC. The first copy shall be retained by the BPI and the second copy shall be transmitted to NCBP for its reference and file.	In the phrase 'a description of any unforeseen risks to human health and environment observed during the conduct of the field trial' to **include description of risks to social, economic, ethical, and cultural to be consistent with Article II Section 3 D.**	Field trials are not expected to bear significant and irreversible changes to the socio-economic conditions and norms of a locality because of limited time and space involved in the activity.

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	Article V. Field Trial of Regulated Articles Section 12. **Procedural Requirements** K. **Revocation of Biosafety Permit for Field Trial.** 2. Discovery of new, relevant and significant information that the regulated article poses greater risks to human health and the environment compared to its conventional counterpart;	To include **risks to social, economic, ethical, and cultural** to be consistent with Article II Section 3 D	Field trials are not expected to bear significant and irreversible changes to socio-economic conditions and norms of a locality because of limited time and space involved in the activity.
	Article V. Field Trial of Regulated Articles Section 13. **Public Participation for Field Trial** E. The applicant, in consultation with the C/MLGOO, shall convene the public hearing for purposes of consulting local communities, stakeholders, and local government officials and functionaries.	Propose to add or change local communities with 'indigenous peoples/indigenous cultural communities' to be consistent with IPRA E. The applicant, in consultation with the C/MLGOO, shall convene the public hearing for purposes of consulting **indigenous peoples / indigeneous cultural communities**, stakeholders, and local government officials and functionaries.	The participation of Indigenous Peoples and Indigenous Cultural Communities shall be required if the selected field trial site is within an ancestral domain or ancestral land defined by the law. Hence, if such is the case, an application for a field trial will require the submission of a National Commission on Indigenous People (NCIP) Certification Precondition and the Free and Prior Informed Consent (FPIC) of the concerned Indigenous People/Indigenous Cultural Community in accordance with the Indigenous People's Rights Act.
	Article VI. Commercial Propagation of Regulated Articles		

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	Section 15. **Procedural Requirements** A. **Filing of Application Form and Supporting Documents for Commercial Propagation.** 1. Application Form. – A printed copy and an electronic copy of the Application for Commercial Propagation; 2. Technical dossier consisting of scientific literature, unpublished studies or test data, or such other scientific materials relied upon by the applicant to show that, for the use it is intended, the regulated article does not pose greater risk to human health and the environment as compared to its conventional counterpart; 3. Applicant's Risk Assessment Report for Commercial Propagation endorsed by its IBC; 4. Copy of the proposed Public Information Sheet for Commercial Propagation; 5. Import Permit Number/Code (if applicable); and 6. Proof of payment of application fee.	**Section 15 A2. To include risks to social, economic, ethical, and cultural** to be consistent with Article II Section 3 D. To **include in the application form and supporting documents** for commercial propagation **Section 12 7&8 of Article V (on Certification Precondition and FPIC process)**.	The Cartagena Protocol on Biosafety states that social, economic, ethical and cultural considerations may be considered in making biosafety decisions. During the comment period for commercial, any interested person may submit to the BPI written comments regarding the application, which may include issues related to social, economic, ethical, and cultural considerations arising from the impact of regulated articles on the conservation and sustainable use of biological diversity, especially with regard to the value of the affected biological diversity to local and indigenous cultural communities.
	Article VI. Commercial Propagation of Regulated Articles Section 15. **Procedural Requirements**	To insert after D3.	The FPIC process will be required for Field Trial applications if the trial site

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	D. **Action on the Application**. The Director of the Bureau of Plant Industry shall make a decision to approve or disapprove the application within three (3) working days upon receipt of the recommendation document from the JAG, based on the following considerations: 1. Compliance with administrative procedure and requirements; 2. Recommendation of the Joint Assessment Group; 3. Issues and concerns raised during the public participation period; and 4. Applicant's response to the issues and concerns raised for the applied regulated article.	*3bis. Issues and concerns raised during the FPIC process; (to be consistent with Article V Section 12 A 7&8)* D. **Action on the Application**. The Director of the Bureau of Plant Industry shall make a decision to approve or disapprove the application within three (3) working days upon receipt of the recommendation document from the JAG, based on the following considerations: 1. Compliance with administrative procedure and requirements; 2. Recommendation of the Joint Assessment Group; 3.a. Issues and concerns raised during the public participation period; **3.b. Issues and concerns raised during the FPIC process; (to be consistent with Article V Section 12 A 7&8);** and 4. Applicant's response to the issues and concerns raised for the applied regulated article.	selected falls within an ancestral domain or ancestral land. For commercial propagation, during the public consultation period, any interested person may submit to the BPI written comments regarding the application, which may include issues related to social, economic, ethical, and cultural considerations arising from the impact of regulated articles on the conservation and sustainable use of biological diversity, especially with regard to the value of the affected biological diversity to local and indigenous cultural communities. Such submissions will be considered by the BPI Director, together with the JAG technical recommendation, in the decision on the permit application.
	Article VI. Commercial Propagation of Regulated Articles Section 15. **Procedural Requirements** H. **Permit Conditions.** 2. In the event new information becomes available indicating that the regulated article could pose greater risks to human health and the	To include **risks to social, economic, ethical, and cultural** to be consistent with Article II Section 3 D.	The FPIC process will be required for Field Trial applications if the trial site selected falls within an ancestral domain or ancestral land. For commercial propagation, during the public consultation period, any interested person may submit to the

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	environment as compared to its conventional counterpart, the applicant shall, on its own, immediately take measures necessary to protect human health and the environment;		BPI written comments regarding the application, which may include issues related to social, economic, ethical, and cultural considerations arising from the impact of regulated articles on the conservation and sustainable use of biological diversity, especially with regard to the value of the affected biological diversity to local and indigenous cultural communities. Such submissions will be considered by the BPI Director, together with the JAG technical recommendation, in the decision on the permit application.
	Article VI. Commercial Propagation of Regulated Articles Section 15. **Procedural Requirements** J. **Revocation of Biosafety Permit for Commercial Propagation** 2. Discovery of new, relevant and significant information that the regulated article poses greater risks to human health and the environment compared to its conventional counterpart;	To include **risks to social, economic, ethical, and cultural** to be consistent with Article II Section 3 D	The FPIC process will be required for Field Trial applications if the trial site selected falls within an ancestral domain or ancestral land. For commercial propagation, during the public consultation period, any interested person may submit to the BPI written comments regarding the application, which may include issues related to social, economic, ethical, and cultural considerations arising from the impact of regulated articles on the conservation and sustainable use of biological diversity, especially with regard to the value of the affected biological diversity to local and indigenous cultural communities. Such submissions will be considered by the

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			BPI Director, together with the JAG technical recommendation, in the decision on the permit application.
	Article VII. Direct Use of Regulated Articles for Food and Feed, or for Processing Section 18. **Procedural Requirements** A. **Filing of Application Form and Supporting Documents for Direct Use.** 1. Application Form. – A printed copy and an electronic copy of the Application for Direct Use; 2. Technical dossier consisting of scientific literature, unpublished studies or test data, or such other scientific materials relied upon by the applicant to show that, for the use it is intended, the regulated article does not pose greater risk to human health and the environment as compared to its conventional counterpart; 3. Applicant's Risk Assessment Report for Direct Use endorsed by its IBC; 4. Copy of the proposed Public Information Sheet for Direct Use; 5. Import Permit Number/Code (if applicable); and 6. Proof of payment of application fee.	Section 18 A2. To include **risks to social, economic, ethical, and cultural** to be consistent with Article II Section 3 D To **include in the application form and supporting documents** for commercial propagation **Section 12 7&8 of Article V (on Certification Precondition and FPIC process)**.	The Cartagena Protocol on Biosafety states that social, economic, ethical and cultural considerations may be considered in making biosafety decisions. During the comment period for direct use for FFP, any interested person may submit to the BPI written comments regarding the application, which may include issues related to social, economic, ethical, and cultural considerations arising from the impact of regulated articles on the conservation and sustainable use of biological diversity, especially with regard to the value of the affected biological diversity to local and indigenous cultural communities.

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	Article VII. Direct Use of Regulated Articles for Food and Feed, or for Processing Section 18. **Procedural Requirements** D. **Action on the Application**. The Director of the Bureau of Plant Industry shall make a decision to approve or disapprove the application within three (3) working days upon receipt of the recommendation document from the JAG, based on the following considerations: 1. Compliance with administrative procedure and requirements; 2. Recommendation of the Joint Assessment Group; 3. Issues and concerns raised during the public participation period; and 4. Applicant's response to the issues and concerns raised for the applied regulated article.	To insert after D3. *3bis. Issues and concerns raised during the FPIC process; (to be consistent with Article V Section 12 A 7&8)* D. **Action on the Application**. The Director of the Bureau of Plant Industry shall make a decision to approve or disapprove the application within three (3) working days upon receipt of the recommendation document from the JAG, based on the following considerations: 1. Compliance with administrative procedure and requirements; 2. Recommendation of the Joint Assessment Group; 3.a. Issues and concerns raised during the public participation period; 3.b. Issues and concerns raised during the FPIC process; (to be consistent with Article V Section 12 A 7&8); and 4. Applicant's response to the issues and concerns raised for the applied regulated article.	The FPIC process will be required for Field Trial applications if the trial site selected falls within an ancestral domain or ancestral land. For direct use, during the public consultation period, any interested person may submit to the BPI written comments regarding the application, which may include issues related to social, economic, ethical, and cultural considerations arising from the impact of regulated articles on the conservation and sustainable use of biological diversity, especially with regard to the value of the affected biological diversity to local and indigenous cultural communities. Such submissions will be considered by the BPI Director, together with the JAG technical recommendation, in the decision on the permit application.
	Article VII. Direct Use of Regulated Articles for Food and Feed, or for Processing Section 18. **Procedural Requirements**	To include risks to social, economic, ethical, and cultural to be consistent with Article II Section 3 D.	The FPIC process will be required for Field Trial applications if the trial site selected falls within an ancestral domain or ancestral land. For direct

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	J. **Revocation of Biosafety Permit for Commercial Propagation** 2. Discovery of new, relevant and significant information that the regulated article poses greater risks to human health and the environment compared to its conventional counterpart;		use, during the public consultation period, any interested person may submit to the BPI written comments regarding the application, which may include issues related to social, economic, ethical, and cultural considerations arising from the impact of regulated articles on the conservation and sustainable use of biological diversity, especially with regard to the value of the affected biological diversity to local and indigenous cultural communities. Such submissions will be considered by the BPI Director, together with the JAG technical recommendation, in the decision on the permit application.
CropLife Philippines	**Article I. General Provisions** Section 2. **Definition of Terms**	**We propose to include "Conventional Breeding" in the Definition of Terms:** "*Conventional breeding*"- refers to crossing together plants with relevant characteristics, and selecting the offspring with the desired combination of characteristics, as a result of particular combinations of genes inherited from the two parents. Source of definition: UK Royal Society, CropLife Australia	The proposed inclusion of the definition of *"conventional breeding"* will not be adopted.
	Article I. General Provisions Section 2. **Definition of Terms**	**We propose to insert the highlighted text:**	The language used in the Cartagena Protocol on Biosafety will be adopted.

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	j) *"Environmental risk assessment (ERA)"* – refers to the evaluation of the likelihood that adverse effects may occur as a result of exposure to a regulated article;	j) "*Environmental risk assessment (ERA)*" – refers to the evaluation of the likelihood that adverse effects on the conservation and sustainable use of biological diversity may occur as a result of exposure to a regulated article; Comment/justification: In JDC 1, ERA refers to "potential adverse effects of regulated articles on the conservation and sustainable use of biological diversity in the likely potential receiving environment". The definition should refer to adverse effects on biodiversity (to be consistent with the CBD) because as is, "adverse effects" could capture almost anything.	
	Article I. General Provisions Section 2. **Definition of Terms** k) "*Field trial*" – refers to any intentional introduction of a regulated article into the environment, as authorized by the Bureau of Plant Industry, wherein specific isolation and mitigating measures are imposed to restrict movement outside an approved site;	**We propose to insert the highlighted text:** k) "*Field trial*" – refers to any intentional introduction of a regulated article into the environment, as authorized by the Bureau of Plant Industry, **for purposes of research and development** wherein specific isolation and mitigating measures are imposed to restrict movement outside an approved site; Comment/justification: JDC 1 states "…for purposes of research and development"	The original definition for *"field trial"* will be retained since this was agreed upon between the Department of Agriculture and Department of Science and Technology. Field trial activities are not solely for Research and Development, such as in the case of performance trial.
	Article I. General Provisions Section 2. **Definition of Terms**	**We propose to insert the highlighted text:**	The proposed revision will be adopted.

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	ff) "Transformation event" – refers to the uptake and integration of specific sequences of DNA in a cell in which the introduced DNA is intended to change the phenotype of the recipient organism in a predictable manner.	ff) *"Transformation event"* - refers to the uptake and integration of specific sequences of DNA **in the genome of the host organism** in which the introduced DNA is intended to change the phenotype of the recipient organism in a predictable manner.	
	Article III. Administrative Framework. Section 4. **Role of National Government Agencies.** A. *Department of Agriculture (DA).* As the principal agency of the Philippine Government responsible for the promotion of agricultural and rural growth and development so as to ensure food security and contribute to poverty alleviation, the DA shall take the lead in addressing biosafety issues related to the country's agricultural productivity and food security. In coordination with other concerned departments and agencies, and consistent with the requirements of transparency and public participation, it shall exercise such jurisdiction and other powers that it has been conferred with under existing laws. It shall also take the lead in the evaluation and monitoring of regulated articles.	A. Department of Agriculture (DA). As the principal agency of the Philippine Government responsible for the promotion of agricultural and rural growth and development so as to ensure food security and contribute to poverty alleviation, the DA shall take the lead in addressing biosafety issues related to the country's agricultural productivity and food security. In coordination with other concerned departments and agencies, and consistent with the requirements of transparency and public participation, it shall exercise such jurisdiction and other powers that it has been conferred with under existing laws, **including, but not limited to, the issuance of cease and desist orders and abatement of any use, propagation, commercialization, or other activities relating to the**	The original text will be retained. The proposed additional text will not be adopted.

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		regulated articles without the necessary permits or compliance with the procedures herein, after due notice and hearing, to ensure biosafety. It shall also take the lead in the evaluation and monitoring of regulated articles. **Comment/justification:** This is to enable BPI to exercise effectively its regulatory authority	
	D. *Department of Health (DOH)*. The DOH, as the principal authority on health, shall formulate guidelines in assessing the health impacts posed by modern biotechnology and its applications. The DOH shall also require, review and evaluate results of the applicable health impacts assessments related to modern biotechnology and its applications. In coordination with other concerned departments and agencies, it shall exercise such jurisdiction and other powers that it has been conferred with under existing laws. It shall also take the lead in evaluating and monitoring processed food derived from or containing genetically modified organisms.	**We propose to edit the text as highlighted:** D. Department of Health (DOH). The DOH, as the principal authority on health, shall formulate guidelines in assessing the potential health **risks** posed by modern biotechnology and its applications. The DOH shall also require, review and evaluate results of the applicable health **risk** assessments related to modern biotechnology and its applications. In coordination with other concerned departments and agencies, it shall exercise such jurisdiction and other powers that it has been conferred with under existing laws. It shall also take the lead in evaluating and monitoring processed food derived from or containing genetically modified organisms.	The original text will be retained since this was consulted with the representatives from the Department of Health, who provided the specific text reflected in this sub-section.
	ARTICLE III. ADMINISTRATIVE FRAMEWORK	**We propose to insert the highlighted text:**	The original text will be retained.

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	Section 8. **Institutional Biosafety Committee (IBC)**. The company or institution applying for permits for contained use or field trial of a regulated article shall constitute an IBC. The membership of the IBC shall be approved by the DOST-BC for contained use or by the DA-BC for field trial.	Section 8. **Institutional Biosafety Committee (IBC)**. The company or institution applying **for biosafety permits** for contained use or field trial of a regulated article shall constitute an IBC. The membership of the IBC shall be approved by the DOST-BC for contained use or by the DA-BC for field trial.	
		We propose to add the below text as a new Section: **Section xx. The responsibilities of the IBC approved by DOST-BC for contained use are in accordance with the *Biosafety Guidelines for Contained Use of Genetically Modified Organisms* approved by the National Committee on Biosafety of the Philippines.**	The proposed section will not be adopted since the Philippine Biosafety Guidelines for Contained Use of Genetically Modified Organisms is a distinct and separate issuance from the Joint Department Circular.
	E. If the application is approved, a Biosafety Permit for Field Trial shall be issued. The original copy of the biosafety permit shall be transmitted to the applicant. Other copies shall be provided to the DA, DOST, DENR, DOH, NCBP, and the DA Regional Executive Director concerned. The BPI Director shall keep a duplicate copy for documentation and to maintain the application file.	We propose the edit in the highlighted text: E. If the application is approved, a Biosafety Permit for Field Trial shall be issued. The original copy of the biosafety permit shall be transmitted to the applicant. **Duplicate copies** shall be provided to the DA, DOST, DENR, DOH, NCBP, and the DA Regional Executive Director concerned. The BPI Director shall keep a duplicate copy for documentation and to maintain the application file.	Instead of duplicate copies, the CNAs, NCBP and DA regional Executive Director will be provided with **"certified true copies"** of the biosafety permit.

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	K. Revocation of Biosafety Permit for Field Trial. A Biosafety Permit for Field Trial may be revoked for any of the following grounds: 1. Provision of misleading information in the Application; 2. Discovery of new, relevant and significant information that the regulated article poses greater risks to human health and the environment compared to its conventional counterpart;	We propose the edit in the highlighted text: 2. Discovery of new, relevant and significant information **on the regulated article that poses adverse effect** to human health and the environment compared to its conventional counterpart. Comment/justification: The proposed statement regarding the safety or risk-based triggers for reporting adverse effects of GM traits were adapted from the EU GM food regulations 18.10.2003; USDA, FDA 1992 policy; Canada CFIA GM regulation.	The original text will be retained to put emphasis that a biosafety permit for Field Trial may be revoked on this ground: if the regulated article will pose a GREATER risk as compared to its conventional counterpart.
	ARTICLE V. FIELD TRIAL OF REGULATED ARTICLES Section 12. **Procedural Requirements for Securing a Biosafety Permit for Field Trial.** Any applicant who desires to conduct field trial of regulated articles shall submit an application to the BPI Director through the Biotechnology Unit. An application for field trial of a	Any applicant who desires to conduct field trial of regulated articles shall submit an application to the BPI Director through the Biotechnology Unit. An application for field trial of a regulated article may cover	The additional paragraph proposed will be adopted.

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	regulated article may cover single or multiple field trial sites, the size and duration of which will be specified by the applicant. The suitability of each field trial site shall be assessed separately for purposes of determining any potential risks to the environment or health.	single or multiple field trial sites, the size and duration of which will be specified by the applicant. The suitability of each field trial site shall be assessed separately for purposes of determining any potential risks to the environment or health. **For pest-protected plants, the applicant may apply for a field trial to meet the data requirements for biosafety evaluation and PIP registration following FPA guidelines on the registration of biorational pesticides.** Comment/justification: Second paragraph has been consulted with FPA.	
	ARTICLE V. FIELD TRIAL OF REGULATED ARTICLES Section 12. **Procedural Requirements for Securing a Biosafety Permit for Field Trial.** H. **Permit Conditions.** 2. The permit holder shall immediately notify the Director of BPI, in writing, should any of the following cases occur: a. In the event that new information becomes available, indicating that the regulated article would pose greater risks to human health and the environment as compared to its conventional counterpart;	We propose the edit in the highlighted text: a. In the event **the permit holder becomes aware of additional information**, indicating that the regulated article would pose greater risks to human	New information may come from the Competent National Authorities provided that it is logical, tenable, and possible. Hence, the original text will be retained.

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		health and the environment as compared to its conventional counterpart; Same with other relevant section: Article VI. Section 15. H.	
	ARTICLE VI. COMMERCIAL PROPAGATION OF REGULATED ARTICLES J. **Revocation of Biosafety Permit for Commercial Propagation.** A Biosafety Permit for Commercial Propagation may be revoked for any of the following grounds: 1. Provision of misleading information in the Application; 2. Discovery of new, relevant and significant information that the regulated article poses greater risks to human health and the environment compared to its conventional counterpart;	**We propose the edit in the highlighted text:** 2. Discovery of new, relevant and significant information **on the regulated article that poses adverse effect** to human health and the environment compared to its conventional counterpart. Comment/justification: The proposed statement regarding the safety or risk-based triggers for reporting adverse effects of GM traits were adapted from the EU GM food regulations 18.10.2003; USDA, FDA 1992 policy; Canada CFIA GM regulation.	The original text will be retained.
	ARTICLE VII. DIRECT USE OF REGULATED ARTICLES FOR FOOD AND FEED, OR FOR PROCESSING	**We propose the edit in the highlighted text:**	The original text will be retained.

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	Section 18. Procedural Requirements for Securing a Biosafety Permit for Direct Use for Food and Feed, or for Processing J. Revocation of Biosafety Permit for Direct Use. A Biosafety Permit for Direct Use may be revoked for any of the following grounds: 1. Provision of misleading information in the Application; 2. Discovery of new, relevant and significant information that the regulated article poses greater risks to human health and the environment compared to its conventional counterpart;	2. Discovery of new, relevant and significant information **on the regulated article that poses adverse effect** to human health and the environment compared to its conventional counterpart. Comment/justification: The proposed statement regarding the safety or risk-based triggers for reporting adverse effects of GM traits were adapted from the EU GM food regulations 18.10.2003; USDA, FDA 1992 policy; Canada CFIA GM regulation.	
	ARTICLE VIII. GENETICALLY MODIFIED PLANTS AND PLANT PRODUCTS WITH STACKED EVENTS Section 20. **Regulation of Stacked Events**. Plants produced through conventional breeding of approved genetically modified parental lines and their derived products are not considered novel. The BPI can be	**We propose the edits in the highlighted text:** Section 20. **Regulation of Stacked Events**. Plants produced through conventional **breeding of parental lines containing** approved **individual** genetically modified **events** and their derived products **do not require separate regulatory**	The proposed revision will be adopted.

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	requested to register stacked events in the BPI Approval Registry for Propagation or BPI Approval Registry for Direct Use, as the case may be.	**assessment**. The BPI can be requested to **list** stacked events in the BPI Approval Registry for **Commercial Propagation** or BPI Approval Registry for Direct Use, as the case may be.	
	ARTICLE VIII. GENETICALLY MODIFIED PLANTS AND PLANT PRODUCTS WITH STACKED EVENTS Section 23. **Registration under the Fertilizer and Pesticide Authority.** For the commercial propagation of plants with stacked events involving multiple plant-incorporated protectants (PIP), aside from the requirement that the component single PIPs must have been previously registered under the Fertilizer and Pesticide Authority, the stacked PIP x PIP must also be registered as a new product under the FPA based on its own guidelines on the registration of biorational products. The FPA registration of stacked PIPs will involve desktop evaluation of interaction effects, particularly the potential synergy between the registered component PIPs to determine non-negligible risk to non-target organisms allowing for data transportability where these are deemed acceptable.	**We propose the edit in the highlighted text:** Section 23. **Registration under the Fertilizer and Pesticide Authority**. For the commercial propagation of plants with stacked events involving multiple plant-incorporated protectants (PIP), aside from the requirement that the component single PIPs must have been previously registered under the Fertilizer and Pesticide Authority, the stacked PIP x PIP must also be registered as a new product under the FPA based on its own guidelines on the registration of biorational products. The FPA registration of stacked **PIP x PIP** will involve desktop evaluation of interaction effects, particularly the potential synergy between the registered component PIPs to determine non-negligible risk to non-target organisms allowing for data transportability where these are deemed acceptable.	The proposed revision will be adopted.
Bayer CropScience	**ARTICLE X. MISCELLANEOUS PROVISIONS**	**We propose to add in this portion after the highlighted text:**	The original text for *"A. Administrative Remedies"* will be retained. The

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	Section 36. **Remedies**. In cases of violations of laws, rules and regulations related to biosafety, the following remedies shall apply: *A. Administrative Remedies*. The concerned departments and agencies shall ensure, in accordance with law, that administrative remedies, including the right to appeal, are available to applicants and stakeholders in biosafety decisions.	**In the event of non-compliance with or grievances in connection with the compliance or implementation of this issuance, the existing rules of procedures in administrative proceedings in each Department shall be applied in the handling of such grievance and violations committed under this issuance and any implementing rules or guidelines that may hereafter be issued. The procedures under Executive Order No. 292 or the Administrative Code of 1987 shall be applicable in a suppletory manner. In grievances and proceedings involving non-compliance with or violations of this issuance and its implementing rules or guidelines, reasonable temporary precautionary or preventive measures may be exercised by the Secretary of the DA as the lead agency in addressing biosafety issues and in evaluating and monitoring regulated articles, as may be recommended by the DOST-BC, the DA-BC, the DENR-BC, or the DOH-BC in accordance herewith and existing laws and regulations.**	suggested additional paragraph will not be adopted.
	ARTICLE X. MISCELLANEOUS PROVISIONS	We propose to add the highlighted text as a new section: "**Section xx - Unlawful Regulated Articles. Natural or juridical persons committing offenses in violation of existing laws shall be prosecuted and**	The proposed additional section will not be adopted.

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		penalized in accordance with such laws. International legal norms and Philippine laws on liability and compensation for damages shall likewise apply in accordance with such norms and laws. The Rules of Procedure for Environmental Cases shall primarily govern the procedure for civil, criminal and special civil actions filed involving the enforcement or violation of this Circular. **Nothing in this Circular shall impair or impede in any manner whatsoever the power and authority of the Director of the BPI as the Executive Director of the National Seed Industry Council (NSIC), or his duly authorized representative, to seize and condemn genetically modified seeds unlawfully distributed by persons or entities that have not secured the appropriate biosafety permits, or have secured biosafety permits but using false documents and certifications, pursuant to Section 18 of Republic Act No. 7308 (1992), even in the absence of any biosafety or health issue. Further, nothing herein shall affect the authority of the BPI, as the appropriate food safety regulatory agency for plant foods, to suspend the distribution of genetically modified seeds, in conjunction with the Food Safety Regulation Coordinating Board (FSRCB), if these are likely to constitute**	

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		serious risk to human health under Section 24, Republic Act No. 10611 (2013).”	
Amparo Ampil, *DA Policy Research Service*	**Preambulatory clause:** WHEREAS, the Departments of Agriculture, Health, and Interior and Local Government, are responsible for the enforcement of food safety and sanitary rules and regulations, including inspection and compliance, under Republic Act No. 10611, otherwise known as the “Food Safety Act of 2013”;	**Proposed revision:** WHEREAS, the Departments of Agriculture, Health, and Interior and Local Government, are responsible for the enforcement of food safety and sanitary rules and regulations, including inspection and compliance, and **formulation of food safety control measures**, under Republic Act No. 10611, otherwise known as the “Food Safety Act of 2013”;	The proposed revision will not be adopted. The proposed revision suggests that DILG has the power to formulate food safety control measures, under the Food Safety Act. However, the Food Safety Act does not give such authority to the DILG.* The power to formulate food safety standards and regulations as well as the implementing rules and regulations of the Food Safety Act is vested with the DA and DOH. * Section 19 of the Food Safety Act states: *Specific Responsibilities of the DILG and the LGUs.* – The DILG and the LGUs shall bear the following responsibilities: (a) The LGUs shall be responsible for the enforcement of the “Code on Sanitation of the Philippines” (Presidential Decree No. 856, December 23, 1975), food safety standards and food safety regulations where food is produced, processed, prepared and/or sold in their territorial jurisdiction. This shall include, but shall not be limited to, the following: (1) Sanitation particularly in public markets, slaughterhouses, micro and

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			small food processing establishments and public eating places; (2) Codes of Practice for production, post-harvest handling, processing and hygiene; (3) Safe use of food additives, processing aids and sanitation chemicals; and (4) Proper labelling of prepackaged foods. (b) The DILG shall support the DOH and the DA in the collection and documentation of food-borne illness data, monitoring and research. (c) The DILG and the LGUs shall participate in training programs, standards development and other food safety activities to be undertaken by the DA, the DOH and other concerned national agencies.
	Article VI. Commercial Propagation of Regulated Articles **Section 15. Procedural Requirements for Securing a Biosafety Permit for Commercial Propagation** **H. Permit Conditions.**	**Proposed addition:** THE HOLDER SHALL BE SUBJECT TO A LIABILITY CLAUSE RE: THE HOLDER SHALL BE LIABLE FOR ANY DAMAGE TO HUMNAS, PALNTS, ANIMALS AND THE ENVIRONMENT RESULTING FROM THE CONDUCT OF THE COMMERCIAL PROPAGATION OF THE ARTICLE, EXCEPT THOSE THAT ARE BEYOND HIS CONTROL SUCH AS FORTUITOUS EVENTS AND THE HOLDER SHALL BE SUBJECT TO	The revised Joint Department Circular already provides that Philippine laws on liability and compensation shall apply to all damages and injuries arising from any violation thereof. The additional permit conditions on liability suggested implies a departure from our law on torts, which requires proof of breach of duty (a legal wrong) before damages may be awarded.

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		DENR REGULATIONS SUCH AS EIA OR ANY IMPACT TO THE ENVIRONMENT THROUGHOUT THE OF PROPAGATION	
	Article VII. Direct Use of Regulated Articles for Food and Feed, or for Processing **Section 18. Procedural Requirements for Securing a Biosafety Permit for Direct Use as Food and Feed, or for Processing** **H. Permit Conditions**	**Proposed addition:** THE HOLDER SHALL BE SUBJCT TO LIABIITY. THE HOLDER SAHLL BE LIABLE FOR ANY DAMAGE TO HUMANS, PLANTS, ANIMALS AND THE ENVIRONMENT FOR ANY FFP APPROVED UNDER THIS REGULATIONS, WHETERH FOR CONSUMPTION OR RELEASE INTO THE ENVIRONMENT.	

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