| GENERAL COMMENTS AND QUERIES ON THE REVISED DOST-DA-DENR-DOH-DILG JOINT DEPARTMENT CIRCULAR | | |
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| **Name / Institution** | **Question and Comment** | **Response** |
| Carlo Custodio, Jr.<br>PBS Philippines | Will the PowerPoint be shared with us? | The slide presentation will be shared as requested. |
| | Please clarify Article V, Section 11. BPI solely determines if data set generated in other countries is applicable to the local setting? | The NCBP supported the proposal for the data transportability for Environmental Risk Assessment (ERA) of regulated articles intended for commercial propagation in the country subject to specific conditions wherein the conduct of contained use and confined test of foreign-developed and approved Genetically Modified plant and plant products may be waived only if our local regulatory body confirms that the data and information generated from other countries pertinent to the ERA are applicable under the Philippines' setting, with respect to the considerations, namely: a) biodiversity in the Phil, b) local weather and climate, and c) difference in agronomic practices done in the Phil as compared to other countries.<br><br>The NCBP suggested for the Department of Agriculture – Bureau of Plant Industry to lead in the determination of appropriate data set applicable to the local setting. |
| Edmund Jason Baranda | Rule presumes that applicant has an official website. What if they don't have one? | In the Joint Department Circular No.1, Series of 2016, applicants are required to publish PIS in two (2) broadsheets of national circulation. However, in consideration of public research institutions, the requirement was revised, only requiring PIS publication in one (1) broadsheet of national circulation to reduce the regulatory cost.<br><br>In return, the revised Joint Department Circular requires the posting of the approved PIS at the applicant's website. Hence, an applicant is required to have its official website. |

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| | Has the definition of an applicant been revised? Based on the current definition, foreign companies cannot be applicant? Appears to be limited to "juridical" persons (so natural person or individual cannot be an applicant). Foreign companies appear to be excluded | The Philippines' regulation requires that a local person or juridical person be the applicant. Should a foreign company be interested to apply for introduction of Genetically Modified plant and plant products in the Philippines, the proposed Joint Department Circular recommends that they should have a duly registered local office or subsidiary in the country, who will serve as the responsible party for the applications.<br><br>This has been the case since the Department of Agriculture Administrative Order No.8 (DA AO8) and the DOST-DA-DENR-DOH-DILG Joint Department Circular No.1, Series of 2016 (JDC1). |
| Bureau of Plant Industry Biotechnology Office | What is the role of IBC in direct use and propagation? Who will approve the composition? | The establishment of an Institutional Biosafety Committee (IBC) will not be required for Commercial Propagation and Direct Use under the revised Joint Department Circular, similar to the Department of Agriculture Administrative Order No.8 (DA AO8) and the DOST-DA-DENR-DOH-DILG Joint Department Circular No.1, Series of 2016 (JDC1). |
| | In Section 30. Management of Regulated Article. The Biosafety Committees of the DOST, DA, DENR, and DOH shall conduct regular review of management measures of regulated articles by biosafety permit holders. Please clarify if this is a joint review of separate review of committees. | Each Biosafety Committees shall conduct independent and regular reviews of technical and management concerns for the permits issued to the applicant. Should any of the Biosafety Committees come across new information that will bear upon on any of the permits issued, they would advise the Bureau of Plant Industry of such as necessary. The BPI would then act on such advice accordingly. |
| | For the JAG composition, can BPI establish a group which members will come from different agencies? | The JAG shall be composed of qualified representatives or personnel from the Biosafety Committees of DA, DOST, DENR and DOH. These Biosafety Committees are composed of members possessing scientific or technological knowledge necessary for the evaluation of applications under this Circular, in accordance with their Department's mandate. |

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| Roger Navarro, PhilMaize | Names of JAG members | The members of the Joint Assessment Group will be determined by each Department Biosafety Committees for each application. |
| Tracy Mae Cea, BPI Biotechnology Office | With regards to the effectivity of the revised JDC, will the existing pending applications, may it be an original application or for renewal, be covered by this new circular or will the process still be pursued under the JDC1? | For pending applications under JDC1 s2016 that will be affected by the adoption of the proposed JDC, a new subsection should be added under Transitory Provisions:<br><br>**B.** All new applications for Biosafety Permit for contained use, field trial, commercial propagation and direct use shall be processed in accordance with this new Circular.<br><br>**C. All pending applications for Biosafety Permits, both original and for renewal, filed under the DOST-DA-DENR-DOH-DILG Joint Department Circular no. 1, Series of 2016 shall be processed in accordance with the provisions thereof within eighty-five (85) working days from the acceptance of the application for biosafety permit under JDC1, s2016.**<br><br>**D.** All pending petitions for deregulation filed pursuant to Article IX of the DOST-DA-DENR-DOH-DILG Joint Department Circular no. 1, series of 2016, shall be resolved in accordance with the provisions thereof within twenty (20) working days from the effectivity of this Circular. |
| | What is the role of the IBC in commercial propagation and direct use? In the guidelines on planned release IBC has role only in contained and FT. | The same with DA-AO8 and JDC1 s2016, only applications for contained use and field trials would require the constitution of an IBC. |
| | Requirements for field trial, commercial and direct use includes the Import Permit#, IP should be issued only upon issuance of a Biosafety permit. | The comment is correct. The applicant may apply for a SPSIC only after the biosafety permit has been issued. Thus, the SPSIC shall be issued after (and not before) an application for a biosafety permit. |

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| | Does it mean that upon issuance of a biosafety permit for propagation and direct use the TE is deregulated? Who will monitor the conditions for approval? | Under the new proposed JDC, there will be no deregulation. However, the biosafety permit will be revoked for reasons set forth in Section 15J. *Revocation of Permit for Commercial Propagation* and Section 18J *Revocation of Biosafety Permit for Direct Use.*<br><br>The Bureau of Plant Industry shall monitor compliance to the permit conditions. It may consult with the Agency or Department Biosafety Committee that recommended a specific condition on how to monitor a specific concern. |
| Thelma Soriano, CropLife Asia | In Article V on Field trial of regulated article can we consider the inclusion in this circular a joint conduct of field trial for Biosafety permit of BPI and EUP of FPA? Because in the issuance of EUP, the applicant must comply with the requirements of FPA Implementing Guidelines on PIP or "Plant-incorporated protectant, which also requires field trial. | Please refer to the second paragraph of Article V, Section 12:<br><br>"For pest-protected plants, the applicant may apply for a field trial to meet the data requirements for biosafety evaluation under this Circular and PIP registration following FPA guidelines on the registration of biorational pesticides." |
| Dennis Guerrero | Have you considered imposing administrative sanctions on erring officials who delayed the processing of permits from 2016 to 2021? Are they part of the TWG who drafted revision? | Imposing administrative sanctions on "erring" officials who caused delays in processing biosafety permits under JDC1 s2016 is not part of the mandate of TWG. |
| | Can you create a biotech unit without any enabling law? | The revised JDC shall only refer to the Bureau of Plant Industry as reflected in Article III, Section 6:<br><br>"Bureau of Plant Industry (BPI). The Department of Agriculture-Bureau of Plant Industry shall provide frontline services for the processing of 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 |

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| | | consolidated report on the Public Information Sheet and announce at its website all applications and biosafety permits issued." |
| | Can you really study how a regulated article will affect the environment within 20 days? | Twenty days for risk assessment is doable with respect to ecological effects for field trial. There is nothing peculiar about ~~it~~ this process because the activity will be carried out in a well-characterized agricultural ecosystem. |
| Raul Boncodin, International Rice Research Institute | LGU Sanggunian has its own process, they have their 1st, 2nd, and 3rd readings that cannot be done in 10 days. | The case cited is for adopting an ordinance. The current and proposed JDC requires an LGU resolution only, which does not require three council readings.<br><br>It should be emphasized that even Local Government Units (LGUs) must comply with the timelines as provided in the Ease of Doing Business Law. |
| | Can we do away with the requirement for a LGU resolution as it "politicizes" the regulatory process? Proponent becomes also answerable to the LGU Sanggunian in the conduct of the field trial, not only to DA-BPI who issued the permit. | Public participation is already embedded in our NBF. To help ensure the safe and successful completion of the field trial, the participation of the local community in the decision-making process and the approval of the local Sanggunian are necessary. For a public consultation process that would not require input from the local government unit is out of the question.<br><br>Sections 26 and 27 of the "Local Government Code of 1991" require prior consultation with LGUs and relevant stakeholders to explain the goals and objectives of a project or a program, its impact upon the people and the community in terms of environmental or ecological balance, and the measures that will be undertaken to prevent or minimize the adverse effects. |
| | Suggestion is to make clear in the JDC which LGU Sanggunian we need to deal with -- city/municipal LGU but not provincial. | Section 13.F already specifies the C/MLGOO. For clarity, Section 13.G has been revised as follows: "… (2) the approval of the **City/Municipal** Sanggunian concerned pursuant to Section 27 of the Local Government Code. If |

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| | | the applicant fails to secure the **city/municipal** resolution within the required period ..." |
| Carla Dimalanta, University of the Philippines | Are the estimated no. of days for each of the steps in the flowchart based on actual processes? Same as the comments above, are the estimated timelines realistic? | The estimated number of days involved is realistic. Note that the reckoning of days for processing is stopped whenever the applicant needs to provide more information or clarification (stopping of the clock). |
| Tony Alfonso, Corteva Agrisciences | In the processing of applications, it has been a practice to "stop the clock" when the ball is in the applicant's hands, meaning additional data or information may have to be submitted. Does it still apply under the revised JDC1? If so, can the entire duration exceed 40 days and still be compliant with the EODBL? | If the applicant is unable to provide the information required by the JAG, s/he may request the JAG to "stop the clock" until such time that s/he is able to address the concerns raised during the JAG meeting. As has been the standard procedure under the current JDC1 s2016 (and even DA-AO8), "stopping of the clock" is not counted in reckoning the number of days. |
| KTrijiatmiko | In the earlier presentation, it was mentioned that one of the reasons for proposing the revised JDC is to address the delay in completion of the assessment. Have the actual reasons behind the delay in the completion of assessment been studied? How will the proposed revised JDC address the delay? | The Joint Assessment by the different Competent National Authorities (CNAs) representatives will facilitate the issuance of recommendations to the Director of the Bureau of Plant Industry.<br><br>The creation of the Joint Assessment Group is ~~seen~~ expected to reduce the time required for the risk assessment process to be carried out. Also, the new mechanism for processing of applications delineates the risk assessment from the public participation process. |
| | On Article III, Section III on IBC, I would like to kindly request that the responsibility of complying with the biosafety permit conditions stays with the applicant/permit holder instead of the IBC. It is also aligned in the definition of applicant in the definition of terms that the applicant shall ensure compliance on the conditions specified with the permit. Thank you! | The IBC approved by the DA-BC shall have joint responsibility with the applicant for the conduct of the initial risk assessment and preparation of proposals for risk management of the proposal for field trial. It shall also have joint responsibility with the applicant for ensuring compliance with any permit conditions that may be imposed. This text is reflected in Article III, Section 8. |
| Normita Ignacio | How about socio-economic impact? | Based on Article 26 of the Cartagena Protocol on Biosafety, Article II.3.D. of the proposed JDC states that, "Social, Economic, Ethical, and Cultural Considerations. In reaching a decision for the direct use as food and feed, or |

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| | | 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." During public consultation, the public can submit to the BPI Director issues or concerns on SEC related to Art II.3.D, and this will form part of inform the decision-making process in the approval or disapproval by the BPI Director of the permit application. of the BPI Director. |
| Rizza Eve Mendoza, IRRI | Just to ask if there is a deadline for submitting comments to the revisions of the JDC? Just to ask if there is a deadline for submitting comments to the revisions of the JDC? | The NCBP Secretariat will receive comments on the revised Joint Department Circular via e-mail until 11:59 p.m. of August 31. |
| Sonny Tababa, CropLife Asia | Definition of Terms:<br>Environmental Risk Assessment-suggest to limit scope consistent with the provisions of the Cartagena Protocol on Biosafety; to read as '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' | The revised Joint Department Circular will adopt the scope consistent with the provisions of the Cartagena Protocol on Biosafety. |
| Dr. Saturnina Halos BCP | My suggestion is to include a section on Monitoring of the implementation of JDC1 rev - those timelines are followed and to help resolve any kinks in the implementation. This should be done by the NCBP Secretariat which reports directly to the Chair, NCBP and if there are problems, the action by the NCBP members is more rapid. I also suggest that as a transitional activity all procedures and issuances in relation to the implementation of JDC1 and AO 8 should be reviewed as these may need to be updated or re-issued by the relevant agency. For example, the list of species subject to inspection and GM declaration needs to be updated. When it was released, there were only 5-6 crops | Aside from the five Departments involved in the implementation of the Joint Department Circular, namely the Department of Science and Technology (DOST), Department of Agriculture (DA), Department of Environment and Natural Resources (DENR), Department of Health (DOH) and the Department of the Interior and Local Government (DILG), other member Departments particularly the Department of Trade and Industry (DTI) and the Department of Foreign Affairs (DFA) are also part of the National Committee on Biosafety of the Philippines. Hence, the revised Joint Department Circular cannot impose duties to the National Committee on Biosafety of |

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| | that are genetically modified. Today, there are 32 species. Also, you should include in the transitional activity a re-training of regulators since the JDC was revised.<br><br>How do you put back the GM crop regulatory system as a reliable regulatory system: science-based, functional, predictable & transparent? This was the GM crop regulatory system established by BPI under AO8, a highly respected system. | the Philippines.<br><br>However, these recommendations will be forwarded to the NCBP for its consideration. |
| Joshua Sumague,<br>DA – Policy Research Service | We hope that the TWG could consider in changing the term "biosafety permit" to "biosafety clearance". The Department of Agriculture is currently developing its draft Administrative Circular that aims to institutionalize the harmonized definition of terminologies and streamlined requirements and procedures across DA regulatory agencies in granting authorization and recognition of business and regulated activities in the agriculture and fishery sector. Once issued, DA will no longer use the term "permit" in its regulatory issuances.<br><br>If we use the harmonized term of the draft AC, biosafety permit will fall under the nomenclature of "Clearance"<br><br>Section 4.f. Clearance refers to a permission embodied in a document, which is issued by the DA regulatory agency having jurisdiction to an authorized or recognized entity, for an activity or action to proceed after such has undergone necessary process and satisfied the requirements as prescribed under subsisting laws, rules and regulations.<br><br>Further, the term clearance shall be used for the authorization of or allowing an activity or action to proceed, such as but not limited to trade-related activities, | The term "permit" will be retained in the revised JDC as this is the nomenclature used under our current system. |

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| | i.e., importation, exportation and re-exportation, domestic movement, and transshipment; animal show; research/experimentation; purchase and redrying in the case of leaf tobacco; transport; construction of new fishing vessel; and collection of fish and fishery/aquatic products. | |
| Gabriel Romero, Philippine Seed Industry Association | Can the JAG meet virtually? | The Joint Assessment Group may adopt various methods of convening its meeting. |
| | Can signatories provide e-signatures? | There are already existing legislation and mechanisms on the use of electronic signatures for official documents, which can be employed by the JAG in its decisions and recommendations. |
| Martina Castellion, IRRI | As a formality, the acronym PIS is not properly defined in section 2 or elsewhere in the document. | The term "PIS" will be spelled out as "Public Information Sheet" in appropriate sections of the revised Joint Department Circular. |
| | As per section 2, the definition of plants is restricted to the plant kingdom. What regulation will be used for FTs for GMMOs for FTs for example for bacteria for bioremediation? | The Technical Working Group was commissioned by the National Committee on Biosafety of the Philippines to revise the DOST-DA-DENR-DOH-DILG Joint Department Circular No.1, Series of 2016 which specifically covers Genetically Modified plant and plant products. Other Genetically Modified organisms will be covered by other issuances. |
| Merle Palacpac | I think the number of days for getting approval of the Sanggunian is very short especially if you will get approvals for multi- location trials | The timeline was provided by the Department of the Interior and Local Government to the Technical Working Group. For multi-location trials, each transaction with specific Local Government Units is undertaken independently. |
| | Who will do the post approval monitoring for FTs and commercialization? | The post approval monitoring for Field Trials will be monitored by the Bureau of Plant Industry. For Commercial Propagation, post approval monitoring of IRM and WRM should be justified and will be monitored by the appropriate agency depending on the conditions provided in the biosafety permit for Commercial Propagation. |

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| | What is the role of other DA agencies like BAI, PPSSD of BPI in the risk assessment? *Meron pa ba*? | Members from these agencies are part of the Department of Agriculture-Biosafety Committee and may be appointed to the JAG. |
| | So if there is no deregulation, the permit conditions will have to be complied by the developer forever? | The permit conditions imposed may be time bound and subject to review of the Bureau of Plant Industry and other concerned regulatory agencies. |
| Cid Ryan Manalo, SEARICE | For genuine public comments to transpire, I believe the 10-day period for comments must be extended, especially if we are to consider various nature of organizations. | The proposed Joint Department Circular complies with the provisions of the Ease of Doing Business Law which is mandatory to all government offices. However, the public comment period has been extended in the updated draft from 10 to 15 working days. |
| | Given the complexity of the assessments; concurrently for substantial comments to be made why not have the exemption of the processess from the ease of doing business rather than a case per case basis? | The NCBP Secretariat will request from ARTA an omnibus exemption which shall apply to the processing of all applications. |
| Warlito P. Daus DILG-OUSPS | Page 6 *cc)*– SPS Clearances<br>…. spread of diseases among animals and plants…<br>Include **"humans"** | The scope or coverage of the Sanitary and Phytosanitary (SPS) Clearances issued by the Bureau of Plant Industry is an adoption of the Philippines' international commitment. |
| | Once biosafety permit has been issued and applicants already engaged in business, is it a pre-requisite in the issuance of business permit by the LGU<br><br>He suggested to include in the JDC, that in the issuance of business permit, biosafety permit is a pre-requisite. | The JDC only covers the processing of applications for biosafety permit. A biosafety permit does not exempt the applicant/permit holder from complying with the requirements of other agencies. |
| Dr. William Padolina, Former DOST Secretary and NCBP Chair | Which document will regulate transgenic animals including livestock and poultry? | The Technical Working Group was commissioned by the National Committee on Biosafety of the Philippines to revise the DOST-DA-DENR-DOH-DILG Joint Department Circular No.1, Series of 2016 which specifically covers Genetically Modified plant and plant products. Other Genetically Modified organisms will be covered by other issuances. |
| | Which document will regulate transgenic microorganisms, e.g., probiotics? | |
| Leonardo Gonzales, DOST Biosafety Committee | Under the JDC 2016, there was a full Article (Art IX) devoted to Deregulated Articles. How is this reflected in the | Under the new proposed JDC, there will be no deregulation. However, the biosafety permit will be revoked for reasons set forth in Section 15J. *Revocation of* |

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| | proposed JDC? How does this relate to the new process of revocation of permits? Are they related at all? | *Permit for Commercial Propagation* and Section 18J *Revocation of Biosafety Permit for Direct Use.* |
| Dennis Guerrero | Has there been an assessment of the implementation of JDC, s. 2016? What were the perceived defects? Are these related to implementation or in the prescribed process? | The result of the review of the implementation of the DOST-DA-DENR-DOH-DILG Joint Department Circular No.1, Series of 2016 informed the drafting of the revised Joint Department Circular. |
| | The EODB applies separately to the agencies involved so there are several 28-day period applicable to them. | Based on the consultation with the Anti-Red Tape Authority, the twenty (20) day working period for Highly Technical Applications under the Ease of Doing Business Law covers the entire process, from the acceptance of the application documents up to the issuance of the biosafety permit. |
| | If the sole basis for the revision is EODB, why are the other provisions not related to the law also amended? Like the confidentiality provisions and the deregulation. | The section on confidential information (Section 31) is also present in the current JDC1 s2016 (and even DA-AO8). Similarly, the requirement to protect confidential information has been tempered by what cannot be declared as confidential, as paragraph B of said section provides. The section on deregulation was removed as this became unnecessary with the issuance of biosafety permits that remain valid unless revoked for reasons set forth in Section 15J. *Revocation of Permit for Commercial Propagation* and Section 18J *Revocation of Biosafety Permit for Direct Use.* |
| | Why was deregulation removed? | The section on deregulation was removed as this became unnecessary with the issuance of biosafety permits that remain valid unless revoked for reasons set forth in Section 15J. *Revocation of Permit for Commercial Propagation* and Section 18J *Revocation of Biosafety Permit for Direct Use."* |
| Paz Benavidez II | Did the BPI actively participate in the revision of the JDC considering that the Director will issue the permit and all accountabilities will be his? He is given 3 days to decide. Is that enough? | The representatives of the Department of Agriculture in the Technical Working Group represent the concerns of the Department and its agencies, including the Bureau of Plant Industry. |

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| | At the end of the day, it is the Director of BPI who will issue the clearance and will also respond if there are issues/concerns, including cases filed. | The Director of the Bureau of Plant Industry makes the decision based on the recommendations submitted to his office. Further, these responsibilities were also vested to the BPI Director by the DOST-DA-DENR-DOH-DILG Joint Department Circular No.1, Series of 2016. |
| Amparo Ampil<br>DA – Policy Research Service | I think BPI mgt should be given the discretion to establish the BPI biotech secretariat or core team. It should not be laid down in the JDC | The proposed revised JDC shall only refer to the Bureau of Plant Industry as reflected in Article III, Section 6:<br><br>"Bureau of Plant Industry (BPI). The Department of Agriculture-Bureau of Plant Industry shall provide frontline services for the processing of 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." |
| Thelma Soriano | If ever there will be several applications to be evaluated at the same time, can the JAG that was created for that particular time conduct risk assessment of those applications? | If there are multiple applications, multiple Joint Assessment Groups will be created and each Joint Assessment Group will be responsible for the risk assessment of a specific application. |
| Jenny Panopio<br>Corteva Agrisciences | Will the permit conditions be retained for those with existing valid biosafety permits, or will those permit conditions will be revised based on the new guidance/ as provided in the amended JDC? | Permit conditions will be reviewed and revised as necessary. |
| Gabriel Romero | What are the measures to avoid recurrent queries that had been settled/addressed or proven to be irrelevant or based on recanted/recalled literature? | Under the revised Joint Department Circular, the system will try to accommodate all queries and address them accordingly. |
| June Cadalig | Will it be possible to share the presentation? | The presentation will be shared to interested parties. |

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| | After finishing all the 3 consultations, will there not be consultation like this for the members of the NCBP? | After the three consultations, the comments will be summarized point-by-point, revisions and recommendations will be presented to the NCBP for their action. |
| | Will the final version be presented to the stakeholders apart from members of the NCBP? | The National Committee on Biosafety of the Philippines will decide on this matter. |
| Dr. Ruben Villareal | What if a plant breeder develops high beta-carotene tomato, how much longer can he get a permit to grow commercially said tomato? (Comparison between a biotech product and a non-biotech product) | Registration with NSIC depends on the crop being applied. Usually for rice and corn, it takes about two (2) years or so. GM varieties that are essentially derived from existing NSIC-registered varieties may take less time to be registered with NSIC.<br><br>For variety registration under NSIC, both GM and non-GM can be registered. This entails National Cooperative Testing (NCT). But the GM variety first needs to have a biosafety permit for propagation prior to NCT.<br><br>For reference, the public may refer to NSIC Resolution No. 5, s. 2021: A resolution Adopting a Unified Policy by NSIC on Testing for Variety Registration of All Genetically Modified Crops. |
| Dr. Art Salazar | Biosafety in terms of: (corn as example)<br>Biodiversity<br>Health<br>Environment<br><br>Concern is contamination; will jeopardize native varieties | Health and environment are always included in safety assessment as we comply with the Cartagena Protocol since the Philippines is a signatory to the protocol. On the issue of "contamination", corn is an open-pollinated crop, so it intermingles with other white/yellow corn varieties<br><br>When the safety of Genetically Modified (GM) corn was assessed, the basis was comparison between the GM corn and non-GM corn whether it is comparable except for the trait that is inserted. If it is comparable, it is declared "as safe as". |

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| | | Regarding the concern on the environment, particularly on the planting of crops in sloping areas, the Department of Environment and Natural Resources implements Presidential Decree No. 705 *"Revised Forestry Code of the Philippines"* which regulates the utilization of sloping areas which are not suitable for agriculture. |
| Dennis Guerrero | Will the comments and the action taken thereon be put in a matrix and presented to the stakeholders? | The matrix of questions and comments vis-à-vis responses will be uploaded at the NCBP website. |
| | What is the scientific basis for the last sentence of Section 11 on field trial of regulated articles? | The last sentence is based on the NCBP resolution supporting data transportability only if our local regulatory body confirms that the data and information generated from other countries pertinent to the ERA are applicable to the Philippine context. |
| Gil Penuliar | Is there post monitoring after the biosafety permit has been issued? How will the agency concerned identify violations that may necessitate revocation of the biosafety permit issued? | All the agencies will regularly review literature for new information indicating that the regulated article poses greater risks to human health and the environment compared to its conventional counterpart. |
| | If there is significant modification in the application, how will this affect the turnaround time to get the permit, and will the second review require payment? | If there is a significant modification in the application, the applicant may be required to withdraw the current application and resubmit an application that reflects the said modification. The payment of fees will be the prerogative of the Bureau of Plant Industry. |
| Amparo Ampil | With biosafety permit, this is being used by regulatory agencies to regulate the permit holder. By virtue of this permit, they can impose like for example IRM, weediness control, invasiveness etc. How would the regulatory agencies be assured that the applicant/developer will comply with the conditions set in the permit, in the absence of regulatory tool. | Monitoring of the implementation of the biosafety permit conditions will be done by the Bureau of Plant Industry with the assistance of other agencies. |
| | What will the JDC accomplish when there's no renewal of permit anymore? | New information pertaining to greater risks to human health and the environment compared to its conventional counterpart will trigger the review of a previously approved regulated article. |

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| | | In the absence of new information informing the original safety assessment, renewals of permits would be unnecessary. |
| | The developer should have a liability provision in the permit in terms of protection of the environment and loss of biodiversity. | New information or field observations shall trigger a new assessment if they indicate that the regulated article poses greater risks to human health and the environment compared to its conventional counterpart. If so, the permit can be revoked for reasons set forth in Section 15J. *Revocation of Permit for Commercial Propagation* and Section 18J *Revocation of Biosafety Permit for Direct Use*.<br><br>The implementing agency shall use its existing administrative and legal remedies to pursue possible courses of actions, including issues on liability, when warranted. |
| Roden Lizardo, University of the Philippines Los Baños | If they are to tap the external experts, is it only during the joint assessment that they get to see the documents for risk assessment? | An external expert will be identified and briefed regarding the application before the Joint Assessment Group (JAG) meeting.<br><br>Only the materials from the dossier relevant to the technical issue being consulted will be provided to the external expert. The input from the external expert will be considered by the JAG in making its recommendations. |
| Roger Navarro, | Indemnification/compensation as part of stewardship<br><br>No organic expertise in the regulation so you are going to hire external experts and most of these experts work in the multi-national companies, so they are already biased.<br><br>If glyphosate is deregulated and manufactured by many companies already, why is GM/Bt corn not deregulated if its safe and be open to farmers? | These issues are not within the scope of the biosafety regulations for plant and plant products derived from the use of modern biotechnology. |

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| | Our question is there are non-gm market segment, aside from gm market segment. | |
| SEARICE | Following the ease of doing business law does not mean a sacrifice must be made on the conduct of extensive public participation in decision making, and exhaustive multi-stakeholder public consultation mechanisms. These mechanisms are missing or dissolved because of the proposed revisions. First, the Law does not include matters relating to biosafety, and even if it is a non-business-related transaction as provided by the law, the law does not contemplate covering matters involving health and environment as within the scope of this Act. Second, since this is a multi-agency government instrumentality, it makes the application of the law difficult and would require related agencies to first re-engineer their systems and procedures. Third, as the administrative framework attempts to harmonize five (5) agencies with distinct mandates who are expected to act independently, and within their mandates allow public dialogues independent of the other agencies. The creation of a Joint Assessment Group removes this possibility. Ultimately, the decisions and permits to be issued of much public interest that encompass public health and safety, the environment, agricultural biodiversity, and direct/indirect effects to marginalized and cultural communities. Thus, it requires providing ample opportunity and enabling spaces for several stakeholders to be included in the discussions and allow ample space for comments, this has been significantly reduced.<br><br>a) The intent of The Ease of Doing Business and Efficient Government Service Delivery Act of 2018 is to increase efficiency of government offices for service delivery, especially in relation to simple bureaucratic | The present draft of the revised JDC is a result of consultation among the five Competent National Authorities (CNAs) involved in the implementation of the JDC. The timeframe reflected in the document has also been consulted with the ARTA.<br><br>The proposed Joint Department Circular complies with the provisions of the Ease of Doing Business Law which is mandatory to all government offices. However, the public |

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| | procedures. The approval of biosafety permits is much more complex and fall under "highly technical application". An exemption to the law must be made for the issuance of biosafety permits – specifically on FFP and commercialization, rather than a case-to-case basis. In addition to it being highly technical, the administrative framework changes through the proposed Joint Assessment Group merges supposedly independent agency mandates, which support this argument for the exemption. Section 9b, gives space to seek for exemption to government instrumentalities: "For applications or requests involving activities which pose danger to public health, public safety, public morals, public policy, and highly technical application, the prescribed processing time shall in no case be longer than twenty (20) working days or as determined by the government agency or instrumentality concerned, whichever is shorter."<br><br>b) When this exemption is made, this would allow for public dialogues and consultations at every level – ideally within the biosafety committees of each agency, and the public comment period before a permit is issued by the DA-BPI. The reduction of public comment period is incredibly alarming - the space for concerned and aggrieved stakeholders from 60 days to 10 days in FFP and Commercialization. This drastic reduction is unrealistic and goes against Article 2, Section 3F, on the Transparency and Public Participation which acknowledges the need for adequate timeframes to consult on independent experts, among many others. We must acknowledge that for genuine, relevant, and extensive public comments to transpire it must be given ample time and space. Further it must be acknowledged that social organizations are not always vertically organized like private companies or the | comment period has been extended in the updated draft from 10 to 15 working days. The NCBP Secretariat will request from ARTA an omnibus exemption which shall apply to the processing of all applications. |

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| | government bureaucracy, there are those which are much more dynamic and horizontally organized like farmers organizations and civil society organizations and require more time to consolidate positions. It is inexcusable to use the ease of doing business law to reduce the space and time for public consultations.<br><br>c) Several words used in the revised JDC also have implications. In several parts of the document, when referring to the need to consult stakeholders, the term "shall" from the 2016 JDC is conveniently replaced by "may" which are completely different. The former denotes a requirement, the latter denotes an option. (Article 2, Section D - Social, Economic, Ethical and Cultural Considerations; Section F, No. 3 - Transparency and Public Participation) We urge to retain the former. Once again, we remain that the fast-tracking of bureaucratic procedures must not sacrifice these public consultation mechanisms, rather it must be expanded. | The Cartagena on Protocol on Biosafety states that the parties *"may take into account"* socio-economic considerations arising from the impact of living modified organisms in reaching a decision. |
| | One of the fundamental concerns for JDC is the absence of liability and redress mechanism after the approval of these biosafety permits/clearances. This is an issue of accountability, and the document must direct the responsible agencies, and provide mechanisms for redress from any untoward effects.<br><br>Aside from being grossly inadequate in dealing with current regulatory concerns from liability and redress, including the monitoring of synthetic biology developments, including food safety should also be considered.<br><br>This framework is backward-looking and does not address the future regulatory concerns arising from liability and | *Section 36. Remedies* of the revised Joint Department Circular provides that the listed remedies shall apply in cases of violations of laws, rules, and regulations related to biosafety. Our negotiations on the NKL-SPLR must be aligned with the laws of the land. |

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| | redress, notwithstanding the fact that the DA has stonewalled Philippine accession to the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol, a glaring admission of its vested interest not to forestall the development of agricultural biotechnology in the country. | |
| | While the updated Philippine Development Plan 2017-2022 (see http://pdp.neda.gov.ph/wp-content/uploads/2021/03/20210310-Pre-publication-copy-Updated-Philippine-Development-Plan-2017-2022.pdf) is replete with references to nanotechnology, synthetic biology, bioeconomy (production of goods from renewable biomass/synthetic biology such as biofuels and artificial photosynthesis), including gene-editing, the Philippines should step up in ensuring a sound, independent and credible regulatory framework that prioritizes the urgent environmental concerns and socio-economic, cultural and ethical concerns of the current times, not to prop up industry interests that will further strangle the development of the Philippine agriculture sector. | Nanotechnology and synthetic biology are not covered within this Joint Department Circular. |
| | The substantive and procedural problems in public participation pointed out by Supreme Court Justice Marvic Leonen in the BT talong case have not been adequately addressed in the draft. *In ISAA v Greenpeace, Southeast Asia Dec. 8, 2015, GR No. 209271,* Justice Leonen detailed the defects of the public participation process in DAO in the following way:<br><br>a) The applicant chooses the members of the Institutional Biosafety Committee (IBC - the entity that initially screens the application for GMO field trial) and this is problematic because the applicant does not have any incentive to choose the critical | The membership of the IBC is thoroughly screened by the DA-BC. Community representatives follow certain qualifications for approval by the DA-BC, as provided for in the JDC. |

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| | community representatives. The tendency would be to choose those whose dissenting voices are tolerable. | |
| | b) The National Committee on Biosafety of the Philippines, apart from not being a sufficient oversight for people's participation, is a government body. A government body is not the community that should supposedly be represented in the IBC. | The NCBP mandate has been provided by Executive Order 514, series of 2006, "*The National Biosafety Framework of the Philippines*". |
| | c) The posting in the Public Information Sheet in two conspicuous places near the field-testing site is not enough to raise awareness regarding the field testing being applied for. The subject matter in transgenic transformation is too complex and its consequences too pervasive as to simply leave this through the fictional notice of public posting. | Field trial is a transient activity that is time and space limited. It is not expected to bring irreparable harm to human health and environment. |
| | d) The Scientific and Technical Review Panel, a group of 3 independent scientists that reviews the risk assessment conducted by the IBC does not have a community representative. It is also tasked to evaluate - based on the individual scientist's own standards –whether the proposed field testing poses significant risks on human health and the environment. How the points raised during the mandatory public hearings will be considered in the issuance of the field- testing permits is not covered by DAO 08-2002 (*sic*). In this regard, there is no standard or process. | The revised JDC does not include the participation of the STRP. Assessments will be made jointly by representatives from the Biosafety Committees of Competent National Authorities. |
| | e) The nonchalant attitude of the regulatory framework is best seen when petitioners alleged there was some public consultation prior to field testing. These consultations, however, were not documented. The only proof of it was a bare | The public hearing is documented. The proof of the conduct of the public hearing is the LGU Resolution to be issued by the *Sanggunian*. |

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| | allegation in the affidavit of one witness of the DA in her affidavit.<br>f) The absence of an effective mechanism for public feedback during the application process for field testing means the administrative order failed in meeting the public participation requirement of the Cartagena Protocol.<br>g) The insouciant approach to public participation during the application process is obvious as there is no appeal procedure for third parties. The administrative regulation only deals with appeals by any person whose permit has been revoked or has been denied a permit or whose petition for delisting has been denied by the Director of the Bureau of Plant Industry. | The public is given the opportunity to give their comments during the public comment period. The public can also participate in the public hearing co-organized by the Sanggunian to make their sentiments heard.<br><br>Section 35 of the revised Joint Department Circular provides that an aggrieved party may file a request for the reconsideration of the decision on applications for field trial, commercial propagation, and direct use. |
| | **ARTICLE II. BIOSAFETY DECISIONS**<br>**Section 3. Guidelines in Making Biosafety Decisions.**<br><br>A. Standards of Precaution.<br><br>Recommendation: It should be stated clearly and specifically how the precautionary principle is to be applied. The decisions should clearly and specifically state how the precautionary principle was applied. In determining the acceptable level of risk, the inputs from public participation, especially key stakeholders, should be paramount. The applicant and the regulatory agencies have the duty to fully communicate risks to health, to the environment, and to socio-economic (cultural and ethical) considerations to the public that they may be guided in the determination of the acceptable level of risk. | The Cartagena Protocol on Biosafety refers to *precautionary approach*, and not the *precautionary principle*. |

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| | *Rationale: Cartagena, Art 10 (Decision procedure) -11 (Procedure for LMOs intended for direct use as food or feed, or for processing), Annex III (Risk assessment). In its decision, the Supreme Court pronounced that the precautionary principle "entailed inputs from all stakeholders, including the marginalized farmers, not just the scientific community."*<br><br>**C. Environmental and Health Risk Assessment.** In making biosafety decisions under this Circular, government departments and agencies shall consider the environmental and health risks of the proposed activity. **For this purpose, the evaluation of environmental and health risks and impacts are integrated into this Joint Department Circular, consistent with the substantive requirements of the EIS System pursuant to P.D. No. 1586, the NBF and R.A. No. 10611. Specifically, the public consultation requirements shall be integrated in the various public participation components under this Circular. The DENR and DOH, through their respective Biosafety Committees, shall conduct the evaluations and submit their findings on compliance with environmental and health impact assessment to the BPI for consideration in the processing of the biosafety permits. DOH evaluation shall be based on the Philippine National Framework and Guidelines for Environmental Health Impact Assessment.**<br><br>*Rationale: The current formulation in the existing JDC 2016-01 is preferable compared to what is in the draft, thus we lift and add it here. In fact, given the Universal Health Care Act or Republic Act 11223, provisions of the law on health impact assessment (sec. 33) and health technology assessment (sec. 34) should also be integrated in the decision-making process* | The revised Joint Department Circular complies with the Cartagena Protocol on Biosafety. The risk assessment is based on science. The socio-economic considerations falls under the purview of the BPI Director when he decides on the action to take on the application, which would consider public comments on socio-economic considerations.<br><br>The JAG is composed of representatives from the concerned departments, which include DOH and DENR. The environmental and health considerations will be addressed by their representatives during the JAG meetings. |

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| | *concerning health-related concerns. They should by the way be separate, the environmental and health risk assessment.*<br><br>**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 **shall be considered,** especially with regard to the value of biological diversity to indigenous and local and cultural communities.<br><br>*Rationale: Please see General Comment 1.* We also note that this omits *the framework explicitly called for by the NBF in sec. 5.4* whereby the *NCBP shall issue guidelines consistent with internationally accepted standards relating to the conduct of social, economic, ethical, cultural, and other assessments, as appropriate, prior to decisions to commercialize products of modern biotechnology.*<br><br>**E. Access to Information.** Government departments and agencies shall respect the right of the public and stakeholders to **timely access to information** relevant to biosafety decisions including information on applications, results of risk assessments, environmental, health and 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.<br><br>Rationale: this should be timely access to information, given recent experience where the BPI and the DA delayed | The Cartagena Protocol on Biosafety clearly 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.<br><br>Public documents on the biosafety decisions are freely available to any interested parties. Information on the status of applications is uploaded at the BPI Biotech Website promptly. |

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| | providing information on the status of Golden Rice while the entire process is playing out, which makes a mockery of this requirement under the previous regulation. This should also consider current administrative regulations on freedom of information, particularly Executive Order No. 2, series of 2016 issued by President Duterte | |
| | **F. Transparency and Public Participation.**<br><br>**3. Public consultation, as a way to secure wide input into decisions to be made.** This **must include** conduct of formal hearings in certain cases, or solicitation of public comments, particularly where there is public controversy surrounding the proposed activities... The networks of agricultural and fisheries councils, indigenous peoples and community-based organizations in affected areas **shall be utilized**.<br><br>*Rationale: Please see General Comment 1. Especially in matters of public controversy, formal hearings must be in place that ensures the widest participation of aggrieved stakeholders.*<br><br>**5. Consideration of public concerns in the decision-making phase following consultation and submission of written comments.** Public concerns as reflected through the procedures for public participation shall be considered in making the decision. The public shall be informed of the final decision promptly and **have access to the decision. Submitted public comments shall be responded to accordingly, provided with the reasons and considerations resulting in the decision.**, upon request. | The public hearing is only required during field trial application. The participation of indigenous peoples is required if the field trial site is within the ancestral domain.<br><br>The public has access to the decision at all times through the BPI Website. (biotech.da.gov.ph) |

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| | *Rationale: Please see General Comment 1. The public must not only be informed but have access to the decision and submitted public comments must be responded accordingly. Suggestion to delete phrase "upon request" to denote that this is a requirement.*<br><br>**H. Appeal Procedure**<br><br>*Rationale: An appeal procedure must be added to address the several issues in the past and must provide in detail the mechanism of the appeal procedure to aggrieved.* | The Petitions for Reconsideration will be channeled through the existing mechanisms of the Department of Agriculture since biosafety permits are issued by the Bureau of Plant Industry. This is already covered in Section 35. Petition for Reconsideration. |
| | **ARTICLE III. ADMINISTRATIVE FRAMEWORK Section 8. Institutional Biosafety Committee (IBC)**<br><br>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.<br><br>The IBC shall be composed of at least five (5) members, three (3) of whom shall be designated as scientist-members and the other two (2) shall be community representatives... The community representatives must not be affiliated with the applicant and must be in a position to represent the interests of the communities where the activities are to be conducted**. One of the community representatives shall be an elected official in the LGU. The other community representative shall be selected from residents who are members of the Civil Society Organizations. For multi-location trials, community representatives of the IBC shall be designated per site. If the activity may affect ancestral domain or ancestral land, or protected area, the second community** | The requirements for community representatives in the Institutional Biosafety Committee are adopted from Executive Order No. 514, series of 2006: *The National Biosafety Framework of the Philippines*. |

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| | **representative should represent the indigenous people or protected area management board, as applicable.**<br><br>*Rationale: These are important omissions from the JDC 2016 Version and its removal entails a furthering of the problems of public participation as laid out in general comment 3. LGUs must directly participate, and the JDC must respect the recognition and protection of Indigenous Peoples and it includes actively including them in the process.* | |
| | **ARTICLE V. FIELD TRIAL OF REGULATED ARTICLES**<br><br>**On the policy on field trial of regulated articles in sec. 11** - While regulated article refers to genetically modified plants and plant products, what happens to the field trials of organisms intended for bioremediation, the improvement of forest genetic resources, and wildlife genetic resources, and applications of modern biotechnology with potential impact on the conservation and sustainable use of biodiversity which the NBF says is within the competence of the DENR?<br><br>*Recommendation: Those regulated articles should at least be referenced here and the details of securing Biosafety Permits for such types of GMOs be left to the discretion of the DENR, however it may regulate them.*<br><br>**Still on this policy on field trial of regulated articles, the new addition in the draft not found in JDC 2016- 01, regarding regulated articles developed in other countries,** the procedure on how this decision is arrived at by the BPI should be outlined in the draft not just referenced via a footnote where all safeguards and checks are also indicated; considering that this decision is done by BPI, this is just another instance of the lack of credibility of | The revised Joint Department Circular specifically covers Genetically Modified plant and plant products.<br><br>The NCBP assigned the function to the Bureau of Plant Industry, which decision was adopted during its 21st meeting held on 26 March 2021. Regulated articles developed in other countries shall undergo similar procedure with that of locally developed product. |

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| | this process considering that BPI is acting as both a regulator and promoter of the regulated article, which should not have been the case here.<br><br>*Recommendation: The procedure on how this decision is arrived at by the BPI should be outlined in the draft not just referenced via a footnote where all safeguards and checks are also indicated.*<br><br>**On the procedural requirements for securing a biosafety permit for field trial in sec. 12 -** the current draft has removed the mention of "other considerations" which is found in JDC 2016-01. This omission is fatal as this "other considerations" is a distinct category of risks that is provided for sec. 5.4 of the NBF separate even from "socio-economic, ethical and cultural" considerations.<br><br>*Recommendation: Retain the phrase "and other considerations".*<br><br>**In the processing of application in sec. 12 - there are questionable items here, such as the following:**<br><br>a.) At least the JDC 2016-01 allowed for the STRP, DENR-BC and DOH-BC to submit their independent reports to the BPI within thirty (30) days from its receipt of the copy of the application. Now, in this draft, the JAG has obliterated the independence of that process. With the JAG being chaired by the DA Biosafety Committee, it is the height of hubris to assert that this process is independent when a previous process ensuring independence in the previous regulation has been jettisoned. | Other considerations that may be relevant for the decision-making process for an application falls under the purview of the BPI Director.<br><br>JAG representatives from different departments are on equal footing during their evaluation or deliberation and in making their recommendation. |

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| | b) The previous JDC 2016-01 also required the applicant to do a public consultation and secure the endorsement of the Sangguniang Panlungsod/Bayan, so now this is cumbersome that this is also dispensed with in the deliberations in the processing of the information? It is not clear if the report of the applicant on the public consultation particularly mentioned in sec. 13 (F) figured at all in the deliberations of the JAG in sec. 12. (C)(6) as mere "supporting documents".<br><br>**In sec. 13 on public participation for field trial** - this is not just about public participation but more importantly, the process of securing the endorsement of the local Sanggunian, which is a major requirement of the Local Government Code.<br><br>*Recommendation: The draft is silent about this, but it should be stated explicitly that should the Sanggunian not endorse the field trial, that should be the end of the application.* | The output from the public consultation, together with the technical report from the Joint Assessment Group, will be used by the Bureau of Plant Industry Director in arriving at his decision on the permit application.<br><br>Section 13.F. of the revised Joint Department Circular provides that if the applicant fails to secure the LGU resolution within the required period of submitting the report, the applicant may request the BPI Director for extension of time to comply with this requirement. |
| | **ARTICLE VI. COMMERCIAL PROPAGATION OF REGULATED ARTICLES**<br><br>**On the policy on commercial propagation of regulated articles in sec. 14** - the food and feed safety standards mentioned here should include those that will be developed by NFA, for rice, corn, and other grains, as well as the BAFPS, as provided for by sec. 16 of RA 10611.<br><br>**Still on the same policy stated in sec. 14 -** the risks to biodiversity have been omitted here in this draft, which was found before in JDC 2016-01, though the draft mentions "environment". | As per Article VI, Section 15.J of the proposed JDC: "The Biosafety Permit for Commercial Propagation shall not excuse the applicant from complying with relevant regulations of other government agencies."<br><br>Environment is a broad term that includes "biodiversity". |

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| | *Recommendation: Biodiversity is more appropriate here since "environment" would be a broader concept, though the conduct of environmental impact assessment should ideally cover the broad notion of environment which includes biodiversity.*<br><br>**On the procedural requirements in sec. 15 - the following items stand out:**<br><br>a) At least JDC 2016-01 provided as a requirement information on socio-economic, cultural, and ethical considerations but now the draft has dropped this. But the NBF is explicit in requiring in sec. 5.4 that "the NCBP shall issue guidelines consistent with internationally accepted standards relating to the conduct of social, economic, ethical, cultural, and other assessments, as appropriate, prior to decisions to commercialize products of modern biotechnology.". This has not been accounted for by this draft.<br><br>b) Also, the JDC 2016-01 mentioned as an optional procedure the expert evaluation of any socio-economic, ethical, or cultural considerations, as may be required by the BPI. The JAG procedure in the draft does not even bother with it, even if it's the same discretionary manner, when it is a mandatory requirement prior to commercialization as indicated above in the NBF.<br><br>c) On the matter of perpetual validity of permit in sec 15 (G), this poses a serious risk most especially when | Section 5.4 of the NBF also states that "…. Concerned departments and agencies may take into account socio-economic considerations arising from the impact of regulated articles on the conservation and sustainable use of biological diversity, …"<br><br>The DENR addresses issues on biodiversity.<br><br>The JAG is not involved in Socio-economic Considerations. The Cartagena Protocol on Biosafety clearly 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. |

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| | confronted with the rapidly changing climate and added threats and risks. These permits expire because it required reevaluation. Should the TWG insist on its proposal, a mechanism of regular, timely monitoring and evaluation of the approved permits must be in place and explicitly stated here.<br><br>d) On the matter of labeling as part of the permit condition in sec. 15 (H) (3), it should also be a permit condition that the regulated article to be commercially propagated is a GMO, in addition to what is required here, that the product is not to be commercially propagated in prohibited areas.<br><br>**On public participation in commercial propagation in sec. 16 -** given that the draft again repeats the discredited PIS procedure here to purportedly enable public participation, at least **there should be a public hearing done in key areas of the country to determine public sentiments and perspectives on the issue.** Why is it that when it is a field trial there's a consultation with the local Sanggunian and now that the release of the regulated article is more widespread, even nationwide, this is now not required? As stated in the general comments, we remain that the public comment period must be longer than the prescribed 10-day period and must apply to all permits.<br><br>*Recommendation: Insert the requirement on public hearing and consultation, and a retention of the public comment period.* | There will be a regular review of biosafety permit conditions (Section 31. Management of Regulated Article). The revised JDC also provides grounds for the revocation of biosafety permit.<br><br>The issue of labelling is not part of the revised Joint Department Circular.<br><br>Genetically modified crops would only be planted on areas that allow cultivation of such varieties. |
| | **ARTICLE VII. DIRECT USE OF REGULATED ARTICLES FOR FOOD AND FEED, OR FOR PROCESSING** | |

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| | The same concerns raised above for commercial propagation are also relevant here it will be superfluous to repeat them here. | Same answers as stated above. |
| | **ARTICLE IX. IMPORTATION OF REGULATED ARTICLES**<br><br>**On the policy on the importation of regulated articles in sec. 24 -** while it is understandable the DA Circular on importation of plant and plant products for commercial purposes was mentioned here, there should be a broader scope for the types of GMOs that are imported to the country, especially those that will come under the regulatory scope of non-DA agencies, like DENR, DOH or DOST. When this is contemplated, then the procedures of the Cartagena Protocol on advance informed agreement (AIA), notification and decision as well as their respective timeframes, including handling, transport, packaging, and identification should also be included in the draft, for completeness.<br><br>**Provision for unintentional transboundary movements and emergency measures -** while the draft is clear about the intentional importation of regulated articles, it should also provide for unintentional transboundary movements and emergency measures as provided by article 17 of the Cartagena Protocol. | The scope of this circular is specific to Genetically Modified plants and plant products.<br><br>This concern is covered by other regulations, such as the Sanitary and Phytosanitary (SPS) Measures. Section 37 of the revised Joint Department Circular also provides remedies in cases of violations of laws, rules, and regulations related to biosafety. |
| | **ARTICLE X. MISCELLANEOUS PROVISIONS**<br><br>**On Monitoring for Compliance with Permit Conditions in sec. 26** - it is difficult to ensure this is adequately complied with when the submission of regular monitoring reports by the applicant is only explicitly mentioned in the | Monitoring is carried out on a case-by-case basis, depending on the trait of the GM crop. Monitoring activity is hypothesis driven. |

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| | field trials of regulated articles, but only implied during the commercial propagation and direct use for food, feed, or processing. This requirement for monitoring reports should be explicitly stated as part of the permit conditions instead in these omitted stages in the use of these regulated articles so that the agencies concerned that will do monitoring will have something to monitor as also mentioned in sec. 30 of the draft. | |
| | **On confidential information in sec. 31 -** the following should also be NOT confidential: summary of the results of any socio-economic, cultural, ethical, and other considerations done on the regulated article and the status of litigation on the regulated article anywhere it is sold globally, to inform the user of any risks of litigation when the regulated article is used. | Consolidated reports/results of evaluation can be viewed at the *BCH Pilipinas* Portal. Biosafety permits can be viewed and accessed at the BPI Biotechnology website. |
| | **On petition for reconsideration in sec. 34 -** it is not clear what is being reconsidered here, the decisions by the JAG or the BPI Director, what about the agency decisions not the DA, to which authority should reconsideration be made? **Ultimately the requirement for payment of fees for the reconsideration of the decision is uncalled for; this serves to penalize the aggrieved party when they are already aggrieved by the decision being reconsidered; this is also anti-poor and unconstitutional for being violative of the due process right of the aggrieved party.**<br><br>*Recommendation: Remove the inserted phrase on "requirement for payment of fees".* | The JAG does not make decisions. It only provides recommendation to the BPI Director based on its risk assessment.<br><br>Fees may be collected as provided for any national and legal authorization. |

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| | Additional Recommendations:<br><br>2. There must be a distinct agency created for the purpose, with urgency. SEARICE invites the agencies involved to develop a legislative measure for this.<br><br>With this, we wish to be informed of the changes made after due consideration of these comments. We also wish to participate should there be another session on discussing these changes. | Noted.<br><br>The draft JDC will be submitted to the NCBP. The NCBP may make further changes to the submitted version of the document. The public will be informed of the changes through posting at the NCBP Website. |
| PhilMaize | ***Non-conformity with the NBF; NBF may not be amended by a mere JDC***<br><br>While the proposed JDC purports to adhere to EO 514, it ransacks the mandate of the four competent national authorities. Under EO 514, the CNAs shall each have a separate biosafety committee with functions according to the mandate of their respective agency. These are done away with in the proposed JDC and instead a joint advisory group is created from selected members of the biosafety committees to usurp the mandate that belongs to each of the competent national authority. It is submitted that the JAG cannot substitute its assessment for that of the biosafety committees.<br><br>Moreover, in case of applications for field trials, commercial propagation and direct use, the proposed JDC states that: Should any implementing agency be unable to send representatives to the JAG or perform any of functions within the periods prescribed in this Circular, the | PhilMaize's concerns are more imaginary than real. Under the draft JDC, all applications for field trial biosafety applications shall be transmitted to the DOST, DA, DOH, and DENR Biosafety Committees within three (3) working days from receipt of the application. These Biosafety Committees shall then designate two (2) representatives each to the Joint Assessment Group (JAG), which is required to hold a meeting within 13 working days from receipt of the application. Hence, by the time the first meeting of the JAG is held, the Biosafety Committees concerned shall have had at least 10 working days, or two weeks, to review the application and its supporting documents. If areas of concern have been identified during this period, then the presumption is, the relevant Biosafety Committee should have communicated this to the JAG during or even before its first meeting.<br><br>The various Biosafety Committees are presumed to have regularly performed their respective mandates under the NBF and the JDC. The presumption of regularity in the performance of official duties is an aid to the effective and unhampered administration of government functions. Without such benefit, every official action could be |

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| | evaluation of the remaining members of the JAG shall proceed, and the application shall be processed on the presumption that the said agency poses no objection to the conclusions reached and recommendations made by the JAG." The designated competent national authorities are not mere rubber stamps, and a careful, scientific and deliberate evaluation of an application cannot be sacrificed at the altar of expediency. | negated with minimal effort from third parties, regardless of merit or sufficiency of evidence to support such challenge. Hence, if no objections are raised or communicated by a Biosafety Committee to the JAG, it is but proper to assume that, based on such Biosafety Committee's findings, the proposed field trial poses no significant risk to the environment, as well as human and animal health and safety. After all, this position is consistent with the underlying principles of Republic Act No. 11032, otherwise known as the "Ease of Doing Business and Efficient Government Service Delivery Act of 2018." |
| | ***Circumvention of law with non-application of PD 1586***<br><br>Applications for Biosafety Permit are subject to the EIA requirement under Presidential Decree No. 1586 pursuant to the NBF and the Supreme Court's ruling in International Service for the Acquisition of Agri-Biotech Applications, Inc. vs. Greenpeace Southeast Asia (Philippines) ("2015 SC decision"). | Section 5.3 of the NBF leaves the EIA System's application to biosafety decisions to the discretion of the concerned departments (i.e., the DENR-EMB), subject to the requirements of law and the standards set by the NCBP. The EMB, which administers the EISS, has determined that the activities covered by the proposed JDC are outside the coverage of the system. The 2015 SC decision relied upon by PhilMaize was set aside by the Supreme Court in 2016. It dismissed the case for mootness and held that no discussion on the merits of the case should be made. It also bears noting that under the 2007 Revised Procedural Manual of DENR-EMB, proponents of unclassified projects, which pertain to projects that use new processes/technologies with uncertain impacts not listed in other groups, are only required to submit a project description and not an EIA. Thus, even if the field testing of GM crops is considered as an unclassified project as suggested in the 2015 SC decision, the same is still not covered by the EIA requirement. |
| | ***Dilution of people's right to public participation*** | The claim of diminution of the right to public participation is not true. As can be gleaned from the detailed Section 13 |

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| | Ostensibly, the proposed JDC recognizes the people's right to public participation. However, the time frames provided therein are too limited and unreasonable to allow public participation. After publication and/or posting, the public is given only a period of ten (10) working days within which to submit written comments on an application. Moreover, without providing a reason therefor, the requirement of public consultation in the case of field trials is done away with. This cannot be done. The NBF expressly requires concerned Department and agencies to utilize the network of agricultural and fisheries councils, indigenous peoples and community-based organizations. The Supreme Court had admonished the Department of Agriculture for its failure to do the same in the above-captioned case. But even without the NBF and the Supreme Court decision cited above, an applicant must still comply with Republic Act No. 7160. | (Public Participation for Field Trials) under Article V (Field Trial of Regulated Articles), public participation is explicitly and demonstrably required for applications for Biosafety Permit for Field Trials.<br><br>Aside from the conduct by the local Sanggunians of the public hearing, the applicant is also required to involve the public through the posting of the PIS for Field Trial that invites public participation in the public hearing and solicits public comments within a ten-working day period. The further claim that the public comment period is too short, considering the level of technicality involved, fails to take into account the mandatory periods within which the BPI shall render a decision on the application. The timeframe has been vetted by the DILG and it is the same Department (which has supervision over LGU officials and activities) that recommended the number of days involved in the public consultation process. Viewed in the light of this bigger picture, the 10-working day period for public comment is reasonable. |
| | ***On social, economic, ethical, and cultural considerations (SEC)***<br><br>The proposed JDC is a surrender of the regulatory powers of BPI since under Article II, Section 3.D, SEC is not required to be taken into account. | Article II, Section 3.D is, in fact, consistent with, if not identical to Section 5.4 of the National Biosafety Framework and as importantly, Section 28 of the Cartagena Protocol on Biosafety. |
| | ***On confidential information***<br><br>The proposed JDC is a surrender of the regulatory powers of BPI since it gives to the applicant the opportunity to characterize certain information as "Commercial-in-Confidence". (See Art. X, Sec. 31A). Certain information | The provisions of the proposed JDC providing mechanisms for the protection of confidential information are consistent with the Cartagena Protocol and the NBF. Thus, PhilMaize cannot validly oppose the said provisions on the tenuous ground that they will unduly undermine public's right to information and participation. |

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| | listed in Sec. 31B cannot be considered as CIC. However, notwithstanding Secs. 31A and B, the disclosure of information may still be appealed by the applicant and BPI is required to give it the right to consult and review the decision of BPI before disclosure. Confidentiality is used as weapon against meaningful public participation. | The Cartagena Protocol states:<br>Article 21<br>CONFIDENTIAL INFORMATION<br>1. The Party of import shall permit the notifier to identify information submitted under the procedures of this Protocol or required by the Party of import as part of the advance informed agreement procedure of the Protocol that is to be treated as confidential. Justification shall be given in such cases upon request.<br>2. The Party of import shall consult the notifier if it decides that information identified by the notifier as confidential does not qualify for such treatment and shall, prior to any disclosure, inform the notifier of its decision, providing reasons on request, as well as an opportunity for consultation and for an internal review of the decision prior to disclosure.<br>3. Each Party shall protect confidential information received under this Protocol, including any confidential information received in the context of the advance informed agreement procedure of the Protocol. Each Party shall ensure that it has procedures to protect such information and shall protect the confidentiality of such information in a manner no less favourable than its treatment of confidential information in connection with domestically produced living modified organisms.<br>4. The Party of import shall not use such information for a commercial purpose, except with the written consent of the notifier.<br>5. If a notifier withdraws or has withdrawn a notification, the Party of import shall respect the confidentiality of commercial and industrial information, including research and development |

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| | | information as well as information on which the Party and the notifier disagree as to its confidentiality.<br><br>Meanwhile, the NBF provides:<br>6.1 Information on Applications. Concerned departments and agencies shall, subject to reasonable limitations to protect confidential information as provided below, disclose all information on such applications in a promptand timely manner. Such departments and agencies may require applicants to provide the information directly to concerned stakeholders.<br>6.2 Confidential Information. In all applications for approvals, whether domestic or foreign, concerned departments and agencies shall ensure that it has procedures and regulations to determine and protect confidential information; Provided, however, that the concerned agencies may refuse declaring the confidentiality of such information if it is necessary to enable the concerned stakeholders to effectively conduct a scientific risk assessment. |
| | ***Unjustified removal of the provisions on deregulation/delisting***<br><br>The proffered reason for the adoption of the proposed JDC is the passage of Republic Act No. 11032. Otherwise known as the "Ease of Doing Business and Efficient Government Service Delivery Act of 2018." However, we do not see this recent law as sufficient to warrant the removal of the article on deregulation/delisting. | The TWG examined laws, executive issuances, rules and regulations relating to biosafety, as well as the Cartagena Protocol. However, the TWG was not able to find any provision on petition for deregulation or delisting. Thus, the same may be dispensed with at the discretion of the departments. This is especially true where the provisions of the current JDC on deregulation or delisting fail to provide clear criteria for delisting, as in fact the requisites mentioned are the very same conditions that justify regulation. |
| University of the Philippines Diliman | **Article I, Section 1. Applicability** | Noted. |

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| | New Plant Breeding Techniques (NBTs), products of NBTs that do not contain novel genes (such as those produced by genome editing) are not covered by the Joint Circular. | |
| | **Article II, Section 3. A. Standard of Precaution**<br><br>It should not prevent government decisions, but decisions should still be based on or justified by scientific evidence wherein benefits outweigh the harms. Also, the decisions should be in consideration of health, biodiversity, and the society, in general. | Noted. |
| | **Article II, Section 3. C. Environmental and Health Risk Assessment**<br><br>Who will carry out the Environmental and Health Risk Assessment? What parameters need to be evaluated during the risk assessment?<br><br>There must be a well-defined evaluating system/rubric that can be validated. | The conduct of Environment and Health Risk Assessment is part and parcel with the assessment to be undertaken by representatives of the Competent National Authorities participating in the Joint Assessment Group. |
| | **Article III, Section 8. Institutional Biosafety Committee**<br><br>If the institution has an existing IBC but has no technical expertise related to plant and plant products, can the IBC endorse the protocol directly to DOST-BC for risk assessment and review? | No, there should be someone within the institution who can undertake the initial risk assessment for the IBC. Each institution who wishes to undertake activities involving Genetically Modified plants and plant products is required to have an IBC composed of members with appropriate expertise. |
| | **Articles V, VI, and VII**<br><br>Review process flow based on the timeline of the BPI-Biotech; 40 days may not be enough especially for the highly technical issues.<br><br>*Suggested duration: 60 working days* | The Ease of Doing Business Law provides for the maximum number of working days that an application for biosafety permit should be evaluated and acted upon in the Joint Department Circular. The timeframes reflected in the document are consulted with the Anti Red Tape Authority and the CNAs. |
| | **Article V. Sec. 11. Policy on Field Trials of Regulated Articles** | The conduct of in-country field trials is required prior to filing of applications for Commercial Propagation. |

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| | Regarding the application for permits for regulated articles developed in other countries, it is also suggested to secure local studies (i.e., local bioefficacy testing and resistance monitoring, since the technology will be used against local populations with different genetic diversity). | |
| | **Article Vi. Section 15. Procedural Requirements for Securing a Biosafety Permit for Commercial Propagation**<br><br>To address specific issues in the application, it is suggested to include DILG in the membership of the Joint Assessment Group (JAG).<br><br>It is also suggested that all applications be posted on the BPI website. | The role of the DILG in the implementation of the Joint Department Circular is on the conduct of public hearing for securing a favorable LGU resolution for the conduct of field trial under its jurisdiction.<br><br>This practice is already being implemented at present. |
| | **Article VI., Section 15. J.2. Revocation of Biosafety Permit for Commercial Propagation: Discovery of new, relevant and significant information that the regulated article poses greater risks to human health and environment compared to its conventional counterpart.**<br><br>It is suggested to include examples or a list of expected new, relevant and, significant information. | It is on a case-to-case basis and would depend, among others, on the crop utilized, the local environment conditions, and the cultural practices in a specific country. |
| | **Article VIII. Section 20. Regulation of Stacked Events**<br><br>This is possible provided that all the traits within the stacked events have previous approval as single events.<br><br>If there is a single trait/gene within a stack, which is not approved, approval of the said stack is required. | Stacks cannot be registered if any of its component single events has no existing biosafety permit. |
| | **Article X. Section 41. Effectivity** | This suggestion will be forwarded to the NCBP. |

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| | It is suggested to also publish this JDC in the official website of BPI as well as DOST, DA, DENR, DOH, DILG, and JAG. | |
| | **Other concerns**<br><br>STRP and IRMAT had played a very important role in safeguarding the biosafety of Genetically Modified Plant and Plant Products derived in the country. | The function of STRPs is subsumed by the JAG and the external experts who may be consulted, as necessary.<br><br>As necessary, risk management teams may be formed by the Bureau of Plant Industry to provide advice on the management of specific post-approval monitoring concerns. |
| | In case there is a "breach" in the protocols, what are the protocols for notification and management? | Breach of protocols can be a cause for revocation of the permit. |
| | The specific changes from 2016 JDC to the current proposed JDC such as the creation of Joint Assessment Group, transparency and public consultation, more efficient and prompt action on application and the current improvements in the guidelines for a more streamlined process were noted. There are no objections to the proposed joint circular. | Noted. |