

**Draft Administrative Circular on Harmonization of Terms and Streamlining of Requirements and Procedures for Authorization and Recognition
under the Regulatory Jurisdiction of the Department of Agriculture**
Partial Matrix of Public Comments/Inputs and DA TWG Responses

Inputs/Comments from Public Consultation	Response from DA TWG
<p>1. Request to have a status quo on requirements and procedures.</p> <p>a. Having a status quo over the documentary requirements will be much easier to secure the necessary authorizations and recognitions (<i>Manila HJR Marketing Corporation</i>).</p> <p>b. Inclusion of HS/AHTN code in the application form for licensing will cause delays especially when a company needs to update/amend their product lines. Currently, the HS/AHTN codes are only required in processing of clearances & certifications (e.g., SPS/Import Permit), which seems to be presently efficient since it can be released within a week. (<i>Cargill Philippines on Article 5 Section 12(d)</i>).</p>	<p>a. The intention of the draft AC is to reduce and harmonize the general documentary requirements as well as limit the technical documentary requirements to those which are necessary to assess the technical compliance of the applicant/product/activity with existing rules and regulations.</p> <p>b. Section 12(d) has been revised to ease the required information to chapter classification, instead of HS or AHTN code.</p>
<p>2. Request to include specific provisions in the definition of inspection, and procedures on audit.</p> <p>a. The definition of “Inspection” under Article 3 Section 5.d seems to be subjective: “<i>Inspection usually relies on the...</i>” The basis of inspection should be the capability and training of the inspectors and not their “<i>professional judgement and experience of the inspector</i>” (<i>Vet Specialists, Inc.</i>).</p> <p>b. The agency should conduct an unannounced audit to the establishment, to ensure that a product is manufactured in compliance with the quality management system of companies, clients, and government regulations. (<i>PRC Supply Chain Professionals, Inc. on Article 10 Section 62 Monitoring of Compliance and Conformance</i>).</p>	<p>a. Professionalism in the judgement and experience of the inspector is built through years of training and practical experience which strengthen his/her technical capability. Inspectors are selected based on competency, and they have special orders/deputation and mission orders.</p> <p>b. Section 62 is revised to specifically indicate modes of conducting the audit as suggested.</p>
<p>3. Include prescriptive turnaround time for various categories of regulatory authorizations and registrations in line with the Ease of Doing Business (EODB) Act of 2018 and ARTA Policy Issuances. This Administrative Circular (AC) can be further enhanced by <u>explicitly categorizing certain types</u></p>	<p>This is covered by Section 72 (a & b) which requires regulatory agencies to review and revise their respective citizen’s charter to comply with the provisions of the AC (once signed). Updating the charter will require agencies to explicitly categorize processes.</p>

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<p><u>of regulatory processes. Under EODB, the process could be classified as Simple (3-day transaction only), Complex (7-day), or Highly Technical Transactions (21-day). (Philippine Veterinary Drugs Association).</u></p> <p>Recommendation to add a provision (after Section 5d) which will include the processing time of each types of authorization and recognition. The reflected processing time should be referred from ARTA rules and regulations. (Nague, Malic, Magnawa and Associates Customs Brokers on Article 3 Section 5).</p>	
<p>4. Adopt de facto longer validity periods unless otherwise provided by law. <u>A blanket standard of five (5) years across all types of authorizations and recognitions, unless otherwise provided by law</u> will reduce the frequency of renewal applications as well as the compliance cost of each applicant. If this is too difficult to consider, the proposed alternative is to <u>adopt a risk-based validity period regime, where lower risk products, activities or entities can benefit from validity periods as long as five (5) or even more years (Pilmico, and Philippine Veterinary Drugs Association on Sections 22, 31, 40, 49 and 61 of the draft Administrative Circular).</u></p>	<p>Unfortunately, the AC cannot provide a blanket <i>de facto</i> longer validity period for the following reasons:</p> <ul style="list-style-type: none"> a. Republic Act No. 1556: Livestock and Poultry Feeds Act mandates yearly registration of animal feeds or feedstuffs. b. The validity of other technical documentary evidence, i.e., PRC license, FDA certificate, LTO vehicle registration, third-party laboratory assessment report, among others, normally ranges from one to three years. c. There will be implications on the regulatory fees. DA regulatory agencies will need to further consult respective stakeholders on the schedule adjustment. Charging stakeholders with a corresponding five-year regulatory fee should be carefully studied. <p>Nevertheless, a provision has been inserted in Section 72 (b), instructing regulatory agencies to review the validity period of recognition and authorization as part of the updating of citizen’s charter.</p>
<p>5. Simplify renewal procedures for those who have shown a consistent track record in regulatory compliance. An auto-renewal could be provided as an incentive for persons and entities who has good history of compliance. This recommendation will <u>incentivize compliance while ultimately easing the administrative burden of a more cumbersome renewal process requiring resubmission of documentation already in the hands of the regulators.</u> This would somewhat be akin with the “Super Green Lane Program” of the Bureau of Customs where entities, who have shown consistent and regular compliance,</p>	<p>Suggestion is adopted. Sections 23 (License renewal), 32 (Product registration renewal, if required under existing laws), and 50 (Official accreditation renewal) have been revised.</p>

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benefit from easier facilitation of transactions with the agency. <i>(Philippine Veterinary Drugs Association)</i> .	
<p>6. Adopt notification and mutual recognition system (with other countries). Notification and mutual recognition systems will allow less time spent on low-risk products, freeing up the DA's regulatory agencies to focus on the higher risk products and other parts of their mandates requiring more resources and attention <i>(Philippine Veterinary Drugs Association)</i>.</p>	<p>Technical documents from other countries will continue to be received and treated as reference materials in the conduct of regulatory/risk assessment. DA regulatory agencies will continue to welcome technical cooperation with other countries in the determination of equivalence or adoption of mutual recognition systems, which should also facilitate market access for Filipino products, within the context of bilateral or international agreements.</p>
<p>7. Institutionalize the mandatory conduct of regulatory impact assessments There should be a provision that shall mandate regulatory agencies to undertake stakeholder consultations with the affected entities of the new or modified policy. Similar rules should also apply when seeking to revise or introduce regulatory fees. <u>Standard Period to Comment should be at least fifteen (15) days.</u> Invitations to said consultations should further be disseminated to the widest audience possible through tri-media and social media platforms. In addition, Regulatory Impact Assessment should always be conducted which should be presented to stakeholders during the abovementioned consultations. <i>(Philippine Veterinary Drugs Association)</i>.</p>	<p>This is covered by a separate circular of DA directing mandatory conduct of RIA (i.e., <i>DA AC 08/2022: Requiring the Conduct of Regulatory Impact Assessment in the Modification, Repeal, or Formulation of Existing or New Regulations in the Department of Agriculture</i>).</p>
<p>8. Include list of entities, persons, activities and products covered by the Administrative Circular. Please format the list in a manner that allows everyone to understand which type of authorization and recognition is being covered by the regulations.<i>(Philippine Veterinary Drugs Association)</i>.</p>	<p>Section 5 already lists entities, persons, activities and products covered by the issuance.</p> <p>Further, agencies include the same information in the FAQ page of their respective website.</p>
<p>9. Include a provision for regulatory agencies to review their own regulatory authorizations/recognitions to check for necessity or relevance of the same <i>(Philippine Veterinary Drugs Association)</i>.</p>	<p>This suggestion is adopted. A paragraph has been incorporated as (a) in Section 72.</p>

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<p>10. Intensify strong coordination/streamlining efforts with other government agencies to reduce red tapes. DA should intensify its close coordination with the Food and Drugs Administration who is co-implementer of the Republic Act No. 10611: Food Safety Act, and with Bureau of Customs to effectively implement Republic Act No. 10845: Anti Agricultural Smuggling Act of 2016 to curb agricultural smuggling.</p> <p>11. The Food Safety Act is also being implemented by different non-DA agencies and other Departments. It is suggested to collaborate with the other non-DA implementing agencies to ensure the harmonization of all regulatory terms and definitions (<i>Philippine Veterinary Drugs Association and Philippine Sugar Millers Association</i>).</p>	<p>As a side endeavor, DA continues to coordinate with BOC and FDA to pursue streamlining/harmonization efforts.</p>
<p>12. Concern on non-use of the term “permit” under the draft AC. Reading the provisions of CAO 2-2017, close coordination of DA agencies and BOC is necessary (<i>Philippine Sugar Millers Association</i>).</p>	<p>Once the administrative circular is approved and issued, the change in terminologies will be officially communicated to BOC.</p>
<p>13. Expedite the implementation of DTI-DA-DOH-DENR-IPO-NPC Joint Administrative Order No. 22-01, Series of 2022 Guidelines for Online Businesses Reiterating the Laws and Regulations Applicable to Online Businesses and Consumers. Digitalization of processing, tracking, and data security on registration documentation to improve data transparency, security/privacy of data, and other benefits that will bring huge efficiency improvement.</p> <p>Online selling is a business model that will require a new way to regulate and ensure products and services are registered and technically qualified for use by our local farmers (<i>Crop Life Philippines</i>).</p>	<p>This comment was forwarded to appropriate DA offices on July 27, 2022.</p>
<p>14. Make registration of farms, farmers, and fishers mandatory. The purpose of registration is not just to identify “beneficiaries” for programs. It is also an important and necessary component to strengthen bio security and would also help to provide an accurate census of livestock and number of people who actually depend on agriculture for livelihood. <u>This information can then be used to better craft disease response measures.</u> To encourage registration,</p>	<p>Article IV on the national registration of farms, farmers and fishers states the same purposes. Section 9 of the Article has been improved to include the suggestion on efficiency and simplification. The suggestion on transparency is already reflected in the Article as well as in Section 3 under the article on General Provisions.</p>

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<p>however, the DA should make the process as simple and transparent as possible. Many involved in livestock and crop production operate without any oversight from Government (<i>Meat Importer's and Trader's Association</i>).</p>	
<p>15. Query whether frozen meat will be considered to undergo product registration. While “product registration” might be necessary for certain farm inputs like veterinary drugs, fertilizers, etc., we do not see any need to register frozen meat that is not considered a dangerous (i.e., Poisonous) substance. On the other hand, processed meat products intended for retail are under the supervision of FDA (<i>Meat Importer's and Trader's Association</i>).</p>	<p>Product Registration of frozen meat is not required.</p>
<p>16. Limit HS code to four digits only. We are suggesting that should there be a need to specify the import commodity in certain accreditations/clearances/registrations, that we limit the information required to the four-digit HS Code. Import requirements change based on market demand, price, and supply availability such that it would be impractical to write all of them down in a detailed manner that might only "box in" the importer. We can, however, use the 6-digit HS code when applying for SPS for specific commodities (<i>Meat Importer's & Trader's Association</i>).</p>	<p>The information requirement in the application for a license has been limited to chapter classification; however, applicants for other types of authorization and recognition (i.e., clearance, product registration, and commodity certification), e.g., SPSIC, must indicate the HS Code/AHTN Code.</p>
<p>17. Comments on various requirements in Article 5 Section 13. It is not stipulated in this section that every Bureau has different requirements. Centralization of all requirements of each agencies and offices is recommended (<i>Jentec Storage Incorporated</i>).</p>	<p>Section 72 requires regulatory agencies to review and revise their respective citizen's charter to comply with the provisions of the AC (once signed). Should there be additional requirements in a certain authorization/recognition, DA Administrative Circular 08/2022 directs regulatory agencies to conduct regulatory impact assessment in the modification, repeal or formulation of existing or new regulations within the regulatory jurisdiction of DA.</p>
<p>18. Harmonize processing of permits issued by PCSD and BFAR. Please consider the aquaculture corporations in Palawan to streamline the processing of permits needed for the accreditation and operationalization of hatcheries. It is recommended for PCSD and BFAR to coordinate to possibly agree to issue one certification for aquaculture hatcheries (<i>Palawan Aquaculture Corporation</i>).</p>	<p>PCSD's technical requirement imposed on hatcheries intends to regulate direct trade/commercial use of indigenous species in Palawan pursuant to Republic Act 7611, s. 1992. Furthermore, the Philippine Fisheries Code of 1998 requires that all fish hatcheries, fish breeding facilities, and private fishponds must be registered with the LGUs which shall prescribe minimum standards for such facilities in consultation with the Department of the Agriculture. The DA-BFAR issues regulations on the registration and operation of such facilities pursuant to the Fisheries Code and the Food Safety Act of 2013.</p>

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<p>19. General and technical requirements are not aligned with the intention of the Draft Administrative Circular. Section 13 and Section 23 is observed no to be aligned with the intention to streamline the procedures and simplify requirements. It rather adds more requirements to an already streamlined procedures and requirements being implemented by SRA. This additional requirement may impact the availability of sugar in the market. Some requirements mentioned in Section 13 and 23 are outside the jurisdiction of SRA and contrary to the right to due process of mills and refineries (<i>Philippine Sugar Millers Association</i>).</p>	<p>The draft AC harmonizes the general documentary requirements for licensing across all DA regulatory agencies to include only the following:</p> <ol style="list-style-type: none"> 1. Accomplished application form 2. Proof of Business Registration 3. Up-to-date Mayor's/Business Permit 4. Company Profile, including officers, office and establishment location map with geotagged photos 5. (For international traders only) proof of authorization or recognition by the Bureau of Customs <p>Section 13 (and 23) pertains to technical information/documentary requirements specific to the individual mandates of DA regulatory agencies pursuant to existing legislations. The enumerated purposes of specific technical requirements are closely connected to the individual agency's legal mandates, such as those stipulated under the Food Safety Act, Fisheries Code, Meat Inspection Code, etc. For instance, BFAR has a mandate related to the conservation of fisheries resources under the Fisheries Code. Not all of the enumerated purposes are applicable to all types of licensing applicants. For greater clarity, all relevant sections on specific technical requirements are refined to include the phrase: "as appropriate".</p>
<p>20. Maximize number of initial evaluations should be up to two notices only to address the repetitive issue of notice of deficiencies on submitted application by technical evaluators. Once the compliance satisfied the said noted deficiency, evaluation should now be endorsed for inspection (<i>Cargill Philippines</i>).</p>	<p>The suggestion is adopted for licensing, clearance, certification, and official accreditation.</p> <p>As for product registration, the suggestion is adopted with modification: "unless the product which is the subject of application has specific safety concerns." In the conduct of highly technical assessment, evaluators may need further scientific data from applicants to supplement previously submitted documents and prove the safety and quality of the products.</p>
<p>21. Include the technical requirements that can suffice the products compliance with safety & quality (<i>Cargill Philippines</i>).</p>	<p>The draft AC harmonizes the general documentary requirements across all DA regulatory agencies as well as authorization and recognition types. However,</p>

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	<p>harmonizing all technical requirements across all agencies under DA for all types of authorization and recognition would be tedious and too long for the AC. This is due to the various legal mandates of specific agencies. Instead, the AC prescribes a blanket directive that regulatory agencies must limit technical requirements to what is necessary to conduct an objective assessment.</p>
<p>22. Query on the harmonized terms of following documents (<i>Cargill Philippines</i>) NMIS – Meat Inspection Certificate (MIC) BAI – Veterinary Health Certificate (VHC) BAI – Shipping Permit (SP)</p>	<p>No change for MIC and VHC. On the other hand, BAI’s Shipping Permit will be called as “Shipping Clearance” upon effectivity of the AC.</p>
<p>23. Request to review the additional requirement of BAI-AFVDBCD on submission of 3rd party certificate of analysis (COA). This is an additional financial burden to importers because this is not an original requirement in the checklist prescribed by DA Administrative Order 12. Previously, AFVDBCD revalidates the product registration every five (5) years (CoA is required) for a yearly renewal (<i>Vet Specialists Inc.</i>).</p>	<p>This request will be covered by Section 72 of the draft AC.</p>
<p>24. Query whether sugar will be subject to product registration under the draft AC. Refined/white sugar are registered with the Philippine Food and Drug Administration pursuant to RA 10611 (Food Safety Act of 2013). As a food product, it falls outside the regulatory jurisdiction of SRA (<i>Philippine Sugar Millers Association</i>).</p>	<p>Republic Act No. 10659: Sugar Industry Development Act does not require sugar to be registered by SRA.</p>
<p>25. Harmonize pesticide regulations. The FPA and FDA statutory requirements for the registration of the pesticide products should be harmonized based on international reference standards. All pesticide regulatory agencies should be integrated under one office whether the product is considered as synthetic/agricultural biocide or household pesticide.</p> <p>There should be a review on what standard (US, EU, JPN) we will benchmark our regulatory requirements such as shelf life, labeling, and other standards applied throughout the department. Currently, FDA and FPA have different shelf life for the same active ingredients. Harmonizing with ASEAN countries is also a way to reduce registration cycle time.</p>	<p>The request of the industry to have a single office regulating such products is well understood. However, the request cannot be addressed by the draft AC as the issue requires legislative intervention. Each agency mentioned (DA-FPA, DA-BAFS, and DOH-FDA) has specific regulatory functions pursuant to the mandates under existing laws. Nevertheless, harmonized and streamlined requirements and procedures are the objectives of the draft AC.</p> <p>FPA harmonizes with ASEAN countries and adopts standards of other international bodies, such as APEC, FAO-WHO, etc. It must be noted that FDA and FPA have different mandates. Thus, the basis and considerations of regulatory requirements also vary.</p>

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<p>Redundancy of functions should be rationalized that may exist between regulatory bodies.</p> <p>The submission of market surveillance should be conducted for new/renewal of registration to improve the timeliness of bringing the technology to the market (Example: possible harmonizes between BPI and FPA on conducting GM field and EUP trials) (<i>CropLife Philippines</i>).</p>	<p>FPA and BPI already formed a Technical Working Group to formulate the guidelines on the conduct of joint trials involving GM crops.</p>
<p>26. Good governance should prevail in requirements and prescribed procedures for granting clearances of animal and animal by-products (<i>WCL Cold Storage Solutions, Inc.</i>).</p>	<p>The draft AC outlines the prescribed procedures, harmonizes the general documentary requirements, and provides a blanket guideline for specific technical requirements in its intention to provide a predictable system of authorization and recognition. Adherence to the transparency principle is included in the provisions.</p> <p>AFVDBCD now employs online processes in licensing and registration while other divisions of BAI are working on establishing an online system. Transparency is adhered to as clients can check the status of their applications on the system anytime they wish.</p>
<p>27. Suggestions to increase the production of Pineapple Fiber as this can be an alternative raw material for the world. Ban the exportation of Raw Pineapple Fiber abroad because there are numerous processes under the Philippine textile supply chain that can add value to the pineapple fiber. Start defining price and quality standard of the Pineapple fiber (<i>Ananas Anam</i>).</p>	<p>The concerns raised are beyond the scope of the draft AC. However, this concern is duly acknowledged, and PhilFIDA will look into the matter.</p> <p>The Philippine National Standards for Pineapple fiber has been completed.</p>
<p>28. Use consistent terms in the draft AC (e.g., use of subsisting and existing). The draft AC needs to be consistent in the terms used in the draft Administrative Circular (<i>Vet Specialists, Inc./ Philippine Association of Pharmacists in Veterinary Industry</i>).</p>	<p>The suggestion is adopted.</p>