The virtual session will start at 10AM

# Virtual Consultation

Proposed issuance "*Guidelines on the Filing and Submission of Acceptable Variations on Protocols and Non-standard Protocols for the Review and Pre-Approval by the Food and Drug Administration Prior to the Conduct of Bio-efficacy Test Studies of Household Pesticides for the Purposes of Securing a Certificate of Product Registration*"

05 August 2022 | 10AM – 11:30 AM

# HOUSE RULES AND REMINDERS

1. Participants should mute their microphones when not speaking.

2. Please record your attendance using the attendance form.

3. Please be informed that the session will be recorded and the information gathered will be solely be used for improving the proposed and upcoming policies and programs of the Center.

4. Discussions should follow the meeting objectives. Practice professionalism and respect during the session.

# PRESENTATION OUTLINE

I. Opening remarks
II. Session objectives
III. Presentation of the proposed policy
   - ➢ Legal basis of the issuance
   - ➢ Objective of the issuance
   - ➢ Salient points
IV. Presentation of consolidated comments
V. Listening session for stakeholders
VI. Next steps
VII. Closing remarks

# I. Opening Remarks

**ENGR. ANA TRINIDAD F. RIVERA, MSc**
Director IV, CCHUHSRR

# II. Session objectives

1. To present the proposed policy and discuss its salient features.
2. To present feedback on the initial comments
3. To solicit comments through the conduct of listening session
4. To share the next steps in policy development

# III. Presentation of the proposed policy

# III. Presentation of the proposed policy

➢ **Legal basis of the issuance**

1. **<u>Department of Health (DOH) Administrative Order (AO) No. 2019-0008 :</u>** New Rules and Regulations in the Registration of Household Pesticide Products and their Active Ingredients

2. **<u>DOH AO No. 50 s. 2001 :</u>** Revised 2001 Schedule of Fees and Charges

3. **<u>RA 11032 :</u>** the Ease of Doing Business and Efficient Government Service Delivery Act of 2018

# III. Presentation of the proposed policy

- **Objective of the issuance**
  - This proposed circular aims to improve the regulatory compliance of pesticide registration applications and facilitate the same through the establishment of a pathway for the review and pre-approval of non-standard and modified bio-efficacy test protocols, which will be submitted in support of pesticide registration under DOH AO No. 2019-0008.

# III. Presentation of the proposed policy

## ➢ Salient features of the proposed policy

A. The applicant for pesticide registration shall be a holder of a valid License to Operate (LTO) as a Household Pesticide Establishment issued by the FDA.

A. All household pesticides shall preferably be tested in accordance with existing accepted protocols as listed in Annex A.

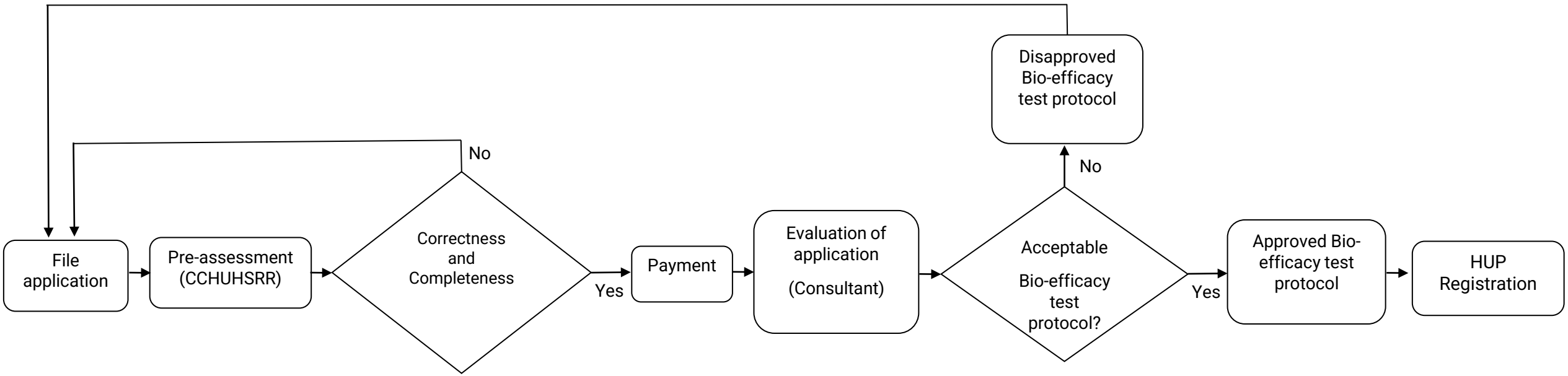
# III. Presentation of the proposed policy

C. MAH applying for a household pesticide registration utilizes a non-standard protocol or where justifiable circumstances require deviations, shall submit the said modified or non-standard test protocol to the FDA for review and approval.

D. Applications for the pre-approval of non-standard and modified bio-efficacy test protocols shall be filed following the procedure outlined in Section V.A. (Filing an application) and the requirements provided in Section V.B. (Documentary requirements).

# III. Presentation of the proposed policy

## Pathways for pre-approval of Bio-efficacy test protocols



# III. Presentation of the proposed policy

E. Re-using of pre-approved bio-efficacy protocol is allowed.

Provided, the product type, intended use and manner of use shall be similar to as the previously approved bio-efficacy protocol, and the MAH of the pesticide registration shall be the same.

# IV. Presentation of consolidated comments (29 June – 29 July 2022)

# IV. Presentation of consolidated comments

1. How will FDA view non-standard and modified Bio-efficacy test, especially for innovative formulations and claims?

When the proposed policy has been issued, FDA-CCHUHSRR intends to direct market authorization applicants to first secure a pre-approval for non-standard and modified bio-efficacy test protocols before before proceeding with the conduct of their planned bio-efficacy study and subsequently, to product registration. With the new guidelines, the aim of the FDA is to improve the efficiency of the registration process and the approval rate of HUP CPR applications ensuring that protocols were designed to support product claims.

# IV. Presentation of consolidated comments

2. Will FDA accept data from overseas labs?

Yes, provided the trials were conducted under similar environmental conditions and test animals or insects used are proven to be the same with the local species. (DOH AO No. 2019-008, Section VI.1.b.i.b)

# IV. Presentation of consolidated comments

3. The purpose I am writing this email is to confirm the covered products of this TBT notification (G_TBT_N_PHL_291). I understand that the covered product is simply a household pesticide, not an agrochemical, but am I correct in understand about it? If not, would you please show me what will be changed from the point of view of importation of agrochemical.

Please be informed that the subject notification covers Household/Urban Pesticides, refers to non-agricultural pesticides, which include insecticides, rodenticides, herbicides, larvicides, termiticides, wood preservative, baits, and repellents, used for the control of pests in homes, yards and gardens, domestic and/or commercial establishments such as schools, malls, condominiums, hospitals, buildings, manufacturing sites, warehouses, golf courses, etc. Thus, the scope of the proposed Guidelines excludes chemicals used in commercial agricultural production or agrochemicals.

# IV. Consolidated Comments (29 June – 29 July 2022)

4. Even if it passed the pre-assessment/pre-approval, the assurance of approval when re-submitted the bioefficacy dossier during the CPR application is not yet assured. As mentioned, the comprehensive evaluation for correctness and compliance to administrative and technical standards is performed in the evaluation step.

The provision where the comment is based from is the clarification of the difference between "pre-assessment" required by RA 11032, which checks completeness of the filed application, and the "evaluation" step which checks compliance to administrative and technical requirements.

It is also clarified that pre-approval of non-standard and modified test protocols is being introduced in the proposed policy, which will come before pesticide registration.

# IV. Presentation of consolidated comments

5. The duration of review is the same when applying for the CPR with completed requirements. The timeline for this pre-approval should be less than 20 working days (regular CPR evaluation), maybe 5 to 7 working days without extensions to further facilitate the pre-approval, since this is only 1set of document compared to the complete CPR deck file.

Yes, it is true that that in the current HUP registration scheme, only a portion of the 20WD processing timeline is allocated for the review of the test protocol/s used in the bio-efficacy study/ies. However, depending on the test protocol used (i.e. adherence to or deviations from accepted standards, use of unvalidated test protocols), this processing time may potentially be extended for another 20WD as allowed by law in order to evaluate the soundness of the test conducted and its reliability to generate good data. Hence, the Center believes that the 20WD currently set as the processing timeline for the pre-approval of test protocol is acceptable.0

# IV. Presentation of consolidated comments

(CONT.)

Furthermore, as this process falls within the definition of highly technical applications as defined in RA 11032, the 20WD is consistent with existing laws. However, the Center notes that though this is the specified processing timeline, it does not necessarily mean that it would always take 20WD to process a pre-approval application. This just set the maximum time frame; depending on the complexity of the submitted documents, the timeline may be shorter.

# IV. Presentation of consolidated comments

6. Only the PLAQUE test of the Malaysian Standard is listed as a residue test. From our experience this method is not appropriate as a evaluation for residue efficacy against flying insect such as mosquitoes. For example, Japan has an individual standard test method for residual efficacy against mosquitoes, which we recommend to include in Annex A.

The Center intends to regularly update Annex A once the guidelines are issued. The proposed standard (from Japan) is yet to have been reviewed for inclusion in Annex A. Should there be any requests for inclusion, proponents may submit a copy of the standard and a letter-request, which will be reviewed by the Center.

# IV. Presentation of consolidated comments

7. We request for a certificate from the FDA for non-standardized test methods upon its approval. This will avoid confusions during the CPR evaluation, and also avoid unnecessary pre-approval of the same non-standardized tests.

This comment will be incorporated into the development of the system, wherein the result of application will be a document which will be presented during pesticide registration. It is emphasized that the conditions for re-using pre-approved test protocols must follow the guidelines provided, wherein it must be for the same product type, manner and intended of use from an application of the same applicant.

# IV. Presentation of consolidated comments

8. When is the expected enforcement date, and what is the transitory period that will be given for the guideline implementation? Bioefficacy tests are time and cost consuming, and are prepared long before the CPR application, therefore a transitory period with a sufficient time frame is required, along with exceptions for bioefficacy studies that has been executed before the implementation of this guideline.

The concern is taken note of. A transitory period has been included in the draft which provides the previously-lodged applications will be reviewed in accordance to DOH AO No. 2019-0008. The Center is considering a transitory period of 6 months upon effectivity of the Guidelines, wherein prospective registration applications using data generated from bio-efficacy test studies commenced from the date of issuance of the proposed policy until the end of the transitory period, will not be required to undergo pre-approval as a precondition for product registration.

This is to allow those currently in the advanced stages of their test studies to continue filing their registration applications without the pre-approval requirement. Wherein the issuance of the guidelines is expected in the 3rd Quarter of 2022 at the earliest, the full effectivity is expected to be on the 2nd Quarter of 2023.

# IV. Presentation of consolidated comments

9. For test methods that are non-standardized, we request for the methods not to be disclosed and not to be added to Annex A. Designing a bioefficacy test method requires much technical know-hows along with time and cost, and it is an intellectual property of the inventor. We believe it should not be added to Annex A, out of respect for the applicant's confidential information.

The FDA adheres to existing laws on Intellectual Property, rest assured that proprietary and confidential information will not be unduly disclosed.

For the purposes of Annex, A, the FDA only intends to include or add published test protocols. In addition, the protocol/product developer/researcher/formulator may opt out.

# IV. Presentation of consolidated comments

10. If we refer to the Malaysian Standard as the test method, would you allow the applicant to choose to use either Philippine FDA registered product or Malaysian Standard's standard sample as a positive control? Malaysian Standard's standard sample is a benchmark sample/positive control sample in Malaysian Standard. For example, if a university in Malaysia is conducting bio-efficacy testing, there is a need to obtain an import license in order to send insecticides from the Philippines as positive control. In some cases, such as aerosols, dangerous goods may be refused to be shipped and it may be difficult to use Philippine FDA registered product as a positive control.

As per DOH AO 2019-0008, the positive control must be an FDA-registered product. Hence, in the scenario presented, the option for the researcher would be to export the product to Malaysia or have the MS reference standard registered with the FDA. If both options remain to be challenging to the applicant/researcher, the FDA encourages that the applicant/researcher to submit a position paper to be submitted on the matter so that the relevant provision providing this requirement in DOH AO 2019-0008 will be revisited for a possible amendment.

# IV. Presentation of consolidated comments

11. Would this guideline have influence on renewing CPR? Currently when renewing a product registered under AO2019-0008, applicants do not need to the submitted data. If in case a study obtained under a standard protocol is requested at the time of renewing, it is imaginable that many applicants would have to redo the study, which would be a negative impact on the industry.

This proposed Circular intends to cover only initial applications of household pesticide products pursuant to the definition and scope provided by DOH AO No. 2019-0008 and the establishments that are engaged in the manufacture, importation, exportation, sale, offer for sale, distribution, donation, transfer, and where applicable, the use, testing, promotion, advertising, or sponsorship of such household pesticide products. To clarify this, the scope of the guidelines will be improved to state as such.

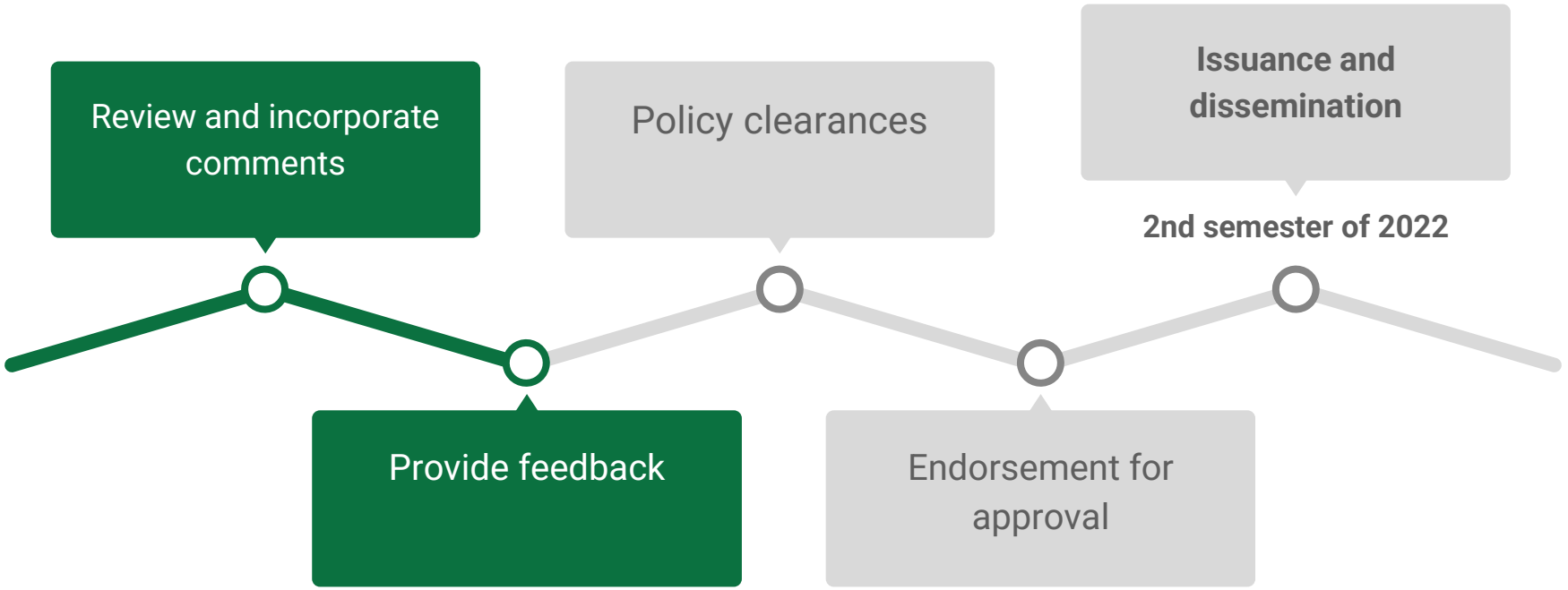
# V. Listening session for stakeholders

# Mechanics

- Pre-registered participants, who signified their intent to share their comments were included in the pool of speakers during the listening session.
- Due to time constraints, a limited number will be accommodated. (10 speakers given 3 minutes each)
- For each speaker, his/her name will be called and will be asked to unmute his/her mic. If the speaker does not respond within a minute, the next speaker will be called. The skipped speaker will then be called after the line-up.
- The speaker will be given 3 minutes, guided by a timer to share his/her comments. The speaker is requested to limit his/her comment to the topic of the proposed policy.
- When the timer ends, the mic will be automatically muted to give way for the next speaker.
- All those who were not called to speak are requested to submitted their written comments up to Monday (end of business day).
- Based on today's listening session and comments received until Monday, comments will be collated and reviewed, then feedback will be provided through e-mail or the FDA website.

03:00

# VI. Next steps



# VII. Closing remarks

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# *THANK YOU!*

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