Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

JUN 14 2019

ADMINISTRATIVE ORDER
No. 2019-0008

SUBJECT: **New Rules and Regulations in the Registration of Household Pesticide Products and Their Active Ingredients**

I. RATIONALE

The evaluation of the safety and efficacy of household/urban hazardous substances (HUHS), such as household pesticide products, is essential to ensure that potential health risks to the general public and its applicators are kept at a minimum or to prescribed acceptable levels.

Pursuant to Republic Act (RA) 9711, otherwise known as the "Food and Drug Administration (FDA) Act of 2009", and its Implementing Rules and Regulations (IRR), the FDA is granted the authority to regulate health products, including household pesticide products, among others.

Consistent with this Act, Administrative Order (AO) No. 2014-0038 entitled "Rules and Regulations Governing Household/Urban Pesticides Licensing of Establishments and Operators, Registration of Their Products and for Other Purposes" was issued on 27 October 2014. As there is a need to provide updated guidelines and requirements consistent with international commitments such as but not limited to Montreal Protocol, Rotterdam Convention, and/or Stockholm Convention, and related local pesticide regulations and standards, this AO shall replace AO 2014-0038 to (1) better protect public health and the environment from the risks associated with pesticide use; and (2) to ensure safety, efficacy and quality of pesticide products.

II. OBJECTIVES

This Order aims to:

1. Provide guidelines on the registration of household pesticide products; and
2. Establish guidelines for product stewardship, as applicable, in the market of household pesticide products.

III. SCOPE

These guidelines shall cover household pesticide products and their active ingredient/s 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 and/or active ingredient/s.

This AO, however, shall not cover guidelines on genetically-modified/engineered household pesticide products, and issuance of permits for experimental use to generate efficacy data for label expansion.

IV. DEFINITION OF TERMS

1. Acute Toxicity – refers to those adverse effects occurring following oral or dermal administration of a single dose of a substance, or multiple doses given within twenty-four (24) hours, or an inhalation exposure of four (4) hours.

2. Banned Pesticide – refers to a pesticide, all uses of which have been prohibited by final regulatory action to protect human health or the environment.

3. Bio-efficacy Test – refers to a scientific study conducted to show, demonstrate or substantiate a claim of efficacy against pest/s as indicated in the label or as claimed by the applicant. The data or information generated from bio-efficacy studies shall be based on actual experiment with hypotheses consistent with the mechanism of action.

4. Certificate of Product Registration (CPR) – refers to the authorization issued by FDA for a household pesticide product after evaluation of its safety, efficacy and quality that permits its manufacture, importation, exportation sale, offer for sale, distribution, transfer, and where applicable, its use, testing, promotion, advertisement, and/or sponsorship.

5. Chronic Toxicity – refers to adverse effects following chronic exposure. The term also refers to effects which persist over long period of time whether or not they occur immediately upon exposure or are delayed.

6. Emergency condition – means an urgent, non-routine situation that requires the use of a household pesticide product and shall be deemed to exist when:

   a. No effective household pesticide products are available that have labelled uses registered for control of the pest under the conditions of the emergency; and/or

   b. No economically or environmentally feasible alternative practices which provide adequate control are available; and/or

   c. The situation:

      i. Involves the introduction or dissemination of an invasive species or a pesticide new to or not theretofore known to be widely prevalent or distributed within or throughout the Philippines; or

      ii. Will present significant risks to human health; or

      iii. Will present significant risks to threatened or endangered species, beneficial organisms, to the environment; or

iv. Will cause significant economic loss due to an outbreak of a pest.

7. FPA – refers to the Fertilizer and Pesticide Authority

8. Globally Harmonized System of Classification and Labelling of Chemicals (GHS) – refers to a system for standardizing and harmonizing the classification and labelling of chemicals. It is a logical and comprehensive approach to: (a) defining health, physical and environmental hazards of chemicals; (b) creating classification processes that use available data on chemicals for comparison with the defined hazard criteria; and (c) communicating hazard information, as well as protective measures, on labels and Safety Data Sheets (SDS).

9. Household Pesticide – also known as "household/urban pesticide", refers to non-agricultural pesticides 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. but shall exclude chemicals used in commercial agricultural production. The term also refers to a product used for the control of insect pests, rodents, and weeds that are found in places of human habitation, work and recreation. Examples of insect pests are flies, mosquitoes, cockroaches, ants, termites, bedbugs, and others.

   Household pesticides shall include products such as, but not limited to, insecticides, rodenticides, herbicides, larvicides, termiticides, wood preservative, baits, and repellents.

   For the purpose of this AO, the term household pesticide shall not include disinfectants.

   Household pesticides can be classified as follows:

   a. For Professional Use – refer to household pesticide products used in the control of pests of public health significance and intended to be used or applied by a trained FDA-certified pesticide handler under the supervision of a FDA-licensed Pest Control Operator to institutions such as but not limited to schools, malls, condominiums, hospitals, buildings, manufacturing sites, warehouses, golf courses, etc. because of its higher risk/probability to cause unreasonable adverse effects to man.

   b. For General Use – refer to household pesticide products intended to control pests in the household and its surroundings which when applied in accordance with its direction for use, will generally not cause unreasonable adverse effects to man.

10. Household Pesticide Establishment – refers to sole proprietorship, partnership, corporation, institution, association or organization engaged in the manufacture, importation, exporation, distribution, transfer, promotion, advertising or sponsorship of household pesticide products. Household Pesticide Establishments shall be classified as follow:
    a. Manufacturer
    b. Trader
    c. Distributor
    d. Distributor (Active Ingredient)

11. Household Pesticide Expert Panel – refers to the recommendatory body created by FDA to provide technical expertise in the review and development of strategic policy direction and guidance on household pesticide products.

12. Household/Urban Hazardous Substances means:

    a. Any substance or mixture of substances intended for individual or limited purposes and which is toxic, corrosive, an irritant, a strong sensitizer, is flammable or combustible, generates pressure through decomposition, heat or other means, if such substance or mixture of substances may cause substantial injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable ingestion by children, but shall not include agricultural fertilizers, agricultural pesticides, and agricultural insecticides and other economic poisons, radioactive substances, or substances intended for use as fuels, coolants, refrigerants and the like;

    b. Any substance which the FDA finds to be under the categories enumerated in clause (a) of this paragraph;

    c. Any toy or other articles intended for use by children which the FDA may determine to pose an electrical, chemical, physical, or thermal hazard; and

    d. This term shall not apply to food, drugs, cosmetics, devices or to substances intended for use as fuels when stored in containers and used in the heating, cooking or refrigeration system of a house, but such term shall apply to any article which is not in itself an agricultural pesticide but which is a hazardous substance, as construed in paragraph (a), by reason of bearing or containing such harmful substances described therein.

13. Label – means a display of written, printed, or graphic matter upon the immediate container, or other materials affixed thereto, of any article. The label of the product shall include other informative materials such as, but not limited to, pamphlets, leaflets, insets, hangtags, etc.

14. License to Operate (LTO) – refers to an authorization issued by FDA to establishment(s) authorizing the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and where applicable, the use, testing, promotion, advertisement, and/or sponsorship of pesticide products.

15. Marketing Authorization (MA) – is the approval granted by the National Regulatory Authority (NRA) to market a specific product in a particular country. The NRA in the Philippines is the FDA. A CPR is a MA issued by the FDA.

16. Marketing Authorization Holder (MAH) – means the establishment or company named on the Marketing Authorization for a specific product in a particular country. The owner of the CPR issued by the FDA is the MAH.

17. Pesticide Registration – means the process whereby the FDA approves the sale and use of a household pesticide product following the evaluation of comprehensive scientific data demonstrating that the product is effective for its intended purposes and does not pose an unacceptable risk to human or animal health or the environment.

18. Safety Data Sheet (SDS) – is a document that provides important physical characteristics, ecological, safety and toxicological information on chemical substances or mixtures of ingredients used at the workplace, transported or maybe utilized by the consumer.

19. Stability Study – refers to a scientific study performed to show data, demonstrate or substantiate a claimed shelf-life of a product. Stability tests are carried out to determine the acceptable period of storage at a specified condition within which the household pesticide product still meets its established specifications or claim of efficacy.

20. Toxicity – refers to the ability of a substance to cause injury to biologic material.

21. Toxicity Study – refers to a study performed *in vivo* or on animals that is initiated by exposure to a chemical, physical or biological agent, and to determine the toxicity level, adverse effects and to show a series of events. The toxicity reports contain sets of data or information from an experiment for the purpose of risk assessment and risk analysis of the product.

V. GENERAL GUIDELINES

1. The applicant for registration of household pesticide product and the active ingredient/s for use in the formulation of a household pesticide product shall be a holder of a valid LTO as Household Pesticide Establishment issued by the FDA.

2. All household pesticide products intended to be manufactured, imported, exported, sold, offered for sale, distributed, transferred, and where applicable, used, promoted, advertised, and/or sponsored shall be registered with the FDA in a per formulation and per packaging material type basis.

3. Household pesticide product shall contain a maximum of three (3) active ingredients.

4. For a household pesticide product with dual use as agricultural pesticide, the applicant shall register such dual-use pesticide product with both the FDA and FPA.

5. All active ingredients for use in the formulation of household pesticide products shall be registered with the FDA. If such active ingredient/s has current and valid registration with the FPA, the FDA shall recognize the FPA registration of such active ingredient/s.

The applicant for registration of household pesticide product shall submit stewardship program in protecting consumer health and the environment. The FPA guidelines on product stewardship and responsible care are hereby adopted for compliance by applicants of household pesticides for registration.

7. Household pesticide product labels shall have the mandatory label elements of the Globally Harmonized System of Classification and Labeling of Chemicals.

8. The FDA shall adhere and promote the agreements such as the Montreal Protocol, Rotterdam Convention, Stockholm Convention, and other international convention/s wherein the Philippine government is one of the signatories, in the ban or restriction of ingredients used in the manufacture of household pesticide products.

9. All household pesticide products containing any banned ingredient as declared by the FDA, and/or FPA shall be prevented from entering the Philippine market.

10. Hazard Classification of the household pesticide product shall be based on GHS.

11. Only household pesticide products with GHS Acute Toxicity Categories 3, 4, and 5 shall be allowed for registration for household use. Household Pesticide products classified as GHS Acute Toxicity Category 1 and 2 shall be prohibited in household use.

12. Only household pesticide products with GHS Acute Toxicity Categories 2, 3, 4, and 5 shall be allowed for registration for professional use. Household pesticide products classified as GHS Acute Toxicity Category 2 shall be subject to the review and recommendatory action of the Household Pesticide Expert Panel.

13. FDA-registered household pesticide products for professional use shall not be allowed for over-the-counter selling.

14. FDA-registered products shall be subject to post-marketing surveillance activities including but not limited to product verification, laboratory analysis and product recall.

15. MAH shall be responsible for the continuous monitoring and evaluation of their household pesticide products, such as but not limited to periodic review of scientific evidence and market reports pertaining to the product's safety and efficacy, to ensure continuous compliance with the latest standards.

16. Variations involving changes in the product's indications of use GHS health hazard category (acute toxicity, skin corrosion/irritation, serious eye damage/ eye irritation and skin sensitization), composition, manufacturer, address of manufacturer, and/or supplier, shall warrant a new product registration. Any other changes shall only require CPR amendment.

17. MAH shall immediately notify FDA in cases of serious adverse effects associated with the use of household pesticide products. It shall be the responsibility of the MAH to ensure availability and adequate supply of antidote for their household pesticide products.

18. The FDA shall work closely with local partners and international organizations to develop and strengthen FDA regulatory standards or approaches to the sound management of household pesticide products.

19. MAH shall conform to the existing guidelines of Republic Act (RA) 6969, otherwise known as the "Toxic Substances and Hazardous and Nuclear Wastes Control Act of 1990" and its Implementing Rules and Regulations (IRR) for the storage, transport and final disposal of expired, banned, obsolete, rejected, recalled and/or out of specification formulated household pesticide products.

VI. SPECIFIC GUIDELINES

All applicants for registration of active ingredients and household pesticide products shall submit the registration requirements as specified by the FDA.

1. Application Process

a. Filing

An application for Certificate of Product Registration (CPR), whether new, renewal, or variation, is considered valid and final upon submission of complete requirements including payment of required fees and charges.

b. Evaluation

The evaluation of all applications for CPR shall be based on the completeness and accuracy of the submitted documents, compliance with appropriate standards and acceptability of the product safety and efficacy.

i. Submission of Bio-efficacy Study

a. Product claims shall be based on the pests/insects tested, spectrum of activity, mode of application and dose rate that shall be used in the bio-efficacy study/ies to be conducted.

b. The study shall be conducted locally by an independent researcher. Foreign generated data (laboratory and field trials) shall be acceptable 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.

c. The submitted bio-efficacy study shall comply with the requirements specified by the FDA in accordance with accepted protocols, if available, including but not limited to:

Product	Protocol
Insecticidal Net	WHO Guidelines for Laboratory and Field Testing of Long-Lasting Insecticidal Nets
Human Mosquito Repellent	WHO Guidelines for Efficacy Testing of Mosquito Repellents for Human Skin
Mosquito Coils, Vaporizer Mats, Liquid Vaporizersm Ambient Emanators and Aerosols	WHO Guidelines for Efficacy Testing of Household Insecticide Products

Mosquito Larvicide	WHO Guidelines for Laboratory and Field Testing of Mosquito Larvicides

d. Test insects which will be used shall be the local strain. Any other deviation from the standard protocol shall be justified.

e. The study shall be accepted if it has been conducted for not more than ten (10) years or upon proof of continued efficacy against the claimed target pest/s, unless there are reports of development of resistance, adverse effects, etc., prior to registration.

f. The treatments shall be composed of the positive control, negative control and the product being registered. In case of novel products, the positive control is allowed to be omitted from the bio-efficacy study.

g. The FDA-registered positive control and the product being registered shall have the same active ingredient/s or active ingredients from the same family of chemicals at the very least, formulated into similar product type (i.e. aerosol, repellent lotion).

h. The negative control shall simulate the concentration of the solvent used in the formulation.

i. Product efficacy of the product being registered shall be deemed acceptable if proven to be equivalent with or bether than the positive control, unless the standard protocol set a minimum limit for efficacy (≥80% mortality after 24 hours or ≥95% knock-down 60 minutes after exposure for insecticidal net).

ii. Submission of Toxicity Study

a. Toxicity study/ies shall be conducted using the household pesticide product being registered.

b. The submitted toxicity study/ies shall comply with the requirements specified by the FDA in accordance with accepted protocols such as the Organization for Economic Cooperation and Development (OECD) guidelines or any international counterpart.

In case the applicant made misrepresentations, false entries, or withheld any relevant data to the provisions the law or appropriate standards, the application shall be disapproved. In such cases, the applicant shall be investigated, and appropriate charges may be filed and penalties be imposed, if the circumstances so warrant.

2. Issuance of CPR

A CPR shall be issued to household pesticide products that comply with the documentary requirements and standards of safety, efficacy and quality based on existing FDA rules and regulations.

A registration number shall be assigned to a household pesticide product whose product registration application has passed the product registration process of the FDA.

The validity of the CPR shall be for a minimum of two (2) years or maximum of five (5) years unless recalled or banned by the FDA.

3. Cancellation of CPR

a. Automatic Cancellation

The registration of a household pesticide product that is not renewed within one hundred twenty (120) days from the date of expiration shall be automatically cancelled and deleted from the list of registered household pesticide products without prejudice to their re-application. The product shall be re-applied for registration and shall follow the new registration process and requirements and pay the corresponding fees.

b. Voluntary Cancellation

The MAH may apply for voluntary cancellation of its existing CPR by filing a formal notification with the FDA citing the reasons thereof.

c. Cancellation and/or Revocation as a Penalty

The FDA shall impose the penalty of cancellation and/or revocation of CPR as per Book II, Article I, Sec. 4. Grounds for Disapproval of Application and Suspension or Cancellation of License, Registration or Authorization of the IRR of RA 9711.

The MAH shall remain to be accountable/liable for any violations committed, and are subject to the penalties levied and administrative sanctions imposed by FDA.

4. Accessibility

The relevant forms, requirements for application, and the submission process shall be made accessible at the FDA website.

5. Responsibility of the Marketing Authorization Holder (MAH)

In case the household pesticide product has been withdrawn for health and safety reasons due to violations, the MAH shall immediately undertake the necessary measures, as well as shoulder incidental costs, in banning its sale, distribution or donation, or its immediate recall, withdrawal or seizure from the market, and its disposal in accordance with existing rules and regulations and product stewardship comitments.

6. Issuance of Off-Label Use / Emergency Exemption Permit

In emergency conditions as declared by the DOH or the respective Local Government Unit (LGU) such as pest outbreaks or disease/epidemic, an off-label permit may be applied for use by an unregistered household pesticide product or by a registered household pesticide product with use different from what has been approved by the FDA.

Application for an off-label use permit shall be evaluated on its merit based on the information submitted and shall be granted permission only for the duration of the emergency period and upon the recommendation of the Household Pesticide Expert Panel.

VII. FEES AND CHARGES

The FDA shall charge a fee for all CPR applications whether new, renewal or variation/s based on existing guidelines being implemented by the FDA.

VIII. PENALTY CLAUSE

Establishments engaged in the manufacture, importation, exportation, sale, offer for sale, distribution, donation, transfer, and where applicable, the use, testing, promotion, advertising, or sponsorship of household pesticide products including the facilities and installations needed for its activities who are found to be operating outside the rules and regulations of FDA shall be subjected to sanctions and penalties as prescribed by RA 9711.

IX. REPEALING CLAUSE

This Order effectively repeals AO 2014-0038 entitled "Rules and Regulations Governing Household/Urban Pesticides Licensing of Establishments and Operators, Registration of Their Products and for Other Purposes". All other administrative issuances, bureau circulars and memoranda and other regulations inconsistent with this Order are hereby withdrawn, repealed and/or revoked accordingly.

X. SEPARABILITY CLAUSE

If any part or term of provision of this Order shall be declared invalid or unenforceable, the validity or enforceability of the remaining portions or provisions shall not be affected and this Order shall be construed as if it did not contain the particular invalid or unenforceable part, term or provision.

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JUL 01 2019
CORAZON S. DELA CRUZ
RMITS - RECORDS SECTION
Department of Health

XI. EFFECTIVITY

This Order shall take effect fifteen (15) days following the completion of its publication in two (2) newspapers of general circulation and submission of a copy hereof to the University of the Philippines Office of the National Registry (UP-ONAR).

FRANCISCO T. DUQUE III, MD, MSc.
Secretary of Health

CERTIFIED TRUE COPY
JUL 01 2019
CORAZON S. DELA CRUZ
HMITS - RECORDS SECTION
Department of Health

ANNEX A

Data Requirements for Registration of Active Ingredients for Use in Household Pesticides

I. New Registration

A. Identity and Specifications

	Data Requirements	Remarks
A.1.	**Applicant Identity and Administrative Requirements**	
	1.1 Completely Accomplished and Notarized Integrated Application Form with Declaration	
	1.2 Copy of valid License to Operate as household pesticide manufacturer, trader or distributor	
	1.3 Payment of fee	
A.2.	**Chemical Identity**	
	2.1 Chemical Abstract Services Number	
	2.2 Name of active ingredient (proposed or accepted by ISO and synonyms)	
	2.3 Structural formula	
	2.4 Chemical name (according to internationally agreed nomenclature, preferably IUPAC)	
	2.5 Empirical formula	
	2.6 Molecular weight	
A.3.	**Physical properties of the Active Ingredient**	
	3.1 Appearance (physical state, color, odor)	
	3.2 Melting/decomposition/boiling point	
	3.3 Vapor pressure	Figures should be given at a stated temperature (preferably in the range of 20-25°C), but only when above 10^{-3} Pascal
	3.4 Flammability: liquids – flash point; solids – a statement must be made as to whether the product is flammable	
	3.5 pH	
	3.6 Solubility in water and organic solvents	At a stated temperature preferably in the range of 20-25°C
	3.7 Suspendibility/emulsifying characteristics	
	3.8 Octanol partition coefficient	Required if A.I. is organic and non-polar
	3.9 Density	For liquids only
	3.10 Hydrolysis	
	3.11 Photolysis	
	3.12 Absorption spectra	e.g. ultra-violet, visible, infra-red, etc.
	3.13 Known compatibility/incompatibility with other pesticide active ingredient	

	3.14 The minimum (and maximum) active ingredient content in g/kg	
	3.15 Identity and amount of isomers, impurities and other by-products	
	3.16 Name and address of the manufacturer / source	
	3.17 Process of manufacture	
A.4.	**Product specifications**	
A.5.	**Certificate of Analysis** • Analytical test report of impurity profile and AI content • Analytical test report of other specifications	Shall be aligned with the product specifications
A.6.	**Safety Data Sheet (SDS)**	
	6.1 Identification	
	6.2 Hazard identification	
	6.3 Composition and information of ingredients	
	6.4 First-aid measures	
	6.5 Fire-fighting measures	
	6.6 Accidental release measures	
	6.7 Handling and storage	
	6.8 Exposure controls and personal protection	
	6.9 Physical and chemical properties	
	6.10 Stability and reactivity	
	6.11 Toxicological information	
	6.12 Ecological information	
	6.13 Disposal considerations	
	6.14 Transport information	
	6.15 Regulatory information	
	6.16 Other information	
A.7.	**Proof of Manufacturer's Compliance to Good Manufacturing Practices (GMP)[1]**	
A.8.	**Submission of actual sample and reference standard**	- Min. 1 g for the reference standard - Min. 1 g for the AI sample

B. Toxicity Data [2,3]

	Data Requirements	**Remarks**
B.1.	**Acute Toxicity Tests**	
	1.1 Acute oral toxicity	LD_{50} expressed as mg/kg of body weight
	1.2 Acute dermal toxicity	LD_{50} expressed as mg/kg of body weight
	1.3 Acute inhalation toxicity	LC_{50} in mg/L
B.2.	**Corrosion/Irritation tests**	
	2.1 Primary skin corrosion/irritation	
	2.2 Serious eye damage/irritation	
B.3.	**Allergy/sensitization test**	

B.4.	**Sub-chronic toxicity tests**	Minimum 90 days, oral in rats
B.5.	**Reproduction effects studies**	Minimum two generations in rats
B.6.	**Teratogenicity studies**	In two species, one in rats and other in non-rodents
B.7.	**Neurotoxicity studies**	In hens, for organophosphates, carbamates, 2nd generation pyrethroids
B.8.	**Mutagenicity studies**	Minimum of Ames test and in vivo micronucleus test
B.9.	**Carcinogenicity tests and chronic (long term) toxicity studies in rats**	

C. Human Exposure and Safety

	Data Requirements	**Remarks**
C.1.	**Medical data/Poisoning symptoms/Antidote**	
C.2.	**Personal protective equipment**	
C.3.	**Other precautions**	

D. Environmental Data

	Data Requirements	**Remarks**
D.1.	**Evaluation of Environmental Fate and Effects**	
	1.1 Volatility	
	1.2 Data on translocation of pesticides in soil and water	
	1.3 Primary data on potential hazards (infectivity) to mammals (including humans)	
	1.4 Primary data on potential toxicity to birds and non-targeted beneficial organisms	e.g. honey bees, pollinators, etc.
	1.5 Primary data on aquatic toxicity	
	1.6 Primary data on phytotoxicity effects	
	1.7. Primary data on treatment of effluents and methods of destruction or disposal	

E. Labeling/Packaging

	Data Requirements	**Remarks**
E.1.	**Labeling**	Submit per pack size and include other information materials such as leaflets, brochure, etc.
	1.1 Product Information	
	1.1.1 Chemical Name	
	1.1.2 Trade Name	
	1.1.3 Net content	
	1.1.4 Batch/Lot number	
	1.1.5 Manufacturing date	
	1.1.6 Registration number	

	1.2 Hazard and Safety Information	
	1.2.1 GHS pictogram, signal word, hazard statement	
	1.2.2 Precautionary statement or warnings	Indicate the mandatory statement, "Keep out of Reach of Children"; include other precautionary statements recommended by GHS based on hazard category
	1.2.3 Color band based on GHS Acute Toxicity	
	1.2.4 Signs/symptoms of poisoning	
	1.2.5 First aid treatment / Antidote information	
	1.2.6 Medical advice/Note to physician	
	1.2.7 Accidental spills advice	
	1.3 Directions for Use	
	1.3.1 Field of use	If applicable
	1.3.2 Storage and disposal	
	1.4 Name, address and contact information of the marketing authorization holder (MAH)	In case the MAH is not the manufacturer, indicate the name and address of the manufacturer including country of origin
	1.5 Contact information of the national/regional poison center	
E.2.	**Packaging**	
	2.1 Specification of primary package	
	2.2 Specification of secondary packaging	Other information materials such as leaflets, brochure, etc.
	2.3 Specification of bulk package for transport	

Notes:

1 If active ingredient is sourced from a foreign country, submit any of the following documents:
- Certificate of Free Sale (CFS) issued by the National Regulatory Authority of country of origin
- Certificate of Good Manufacturing Practice (GMP) based on international manufacturing standards
- Manufacturing license
- ISO Certificate related to manufacturing

2 If allowed in GHS and if available, validated test methods based on accepted international standards may be used in lieu of *in vivo* animal testing

3 In lieu of *in vivo* and *in vitro* animal testing, GHS bridging principles may be applied as long as the hazard categories of each ingredient in concentration greater than or equal to 1% are known, unless there is evidence that the ingredients in concentration less than 1% are hazardous.

II. Variations to a CPR

A. Minor Variations

1. Change in business name of the manufacturer/ distributor
    1.1. Completely accomplished Integrated Application Form
    1.2. Letter of request
    1.3. Copy of valid LTO reflecting the variation
    1.4. Copy of the valid original CPR
    1.5. Complete labeling requirements reflecting the change (primary, secondary and inserts, if any) in English and/or Filipino language with local dialects as applicable
    1.6. Payment of fee

2. Change of address of the distributor of the product
    2.1. Completely accomplished Integrated Application Form
    2.2. Letter of request
    2.3. Copy of valid LTO reflecting the new address
    2.4. Copy of the valid original CPR
    2.5. Any valid document/s showing proof of transfer
    2.6. Complete labeling requirements reflecting the change (primary, secondary and inserts, if any) in English and/or Filipino language with local dialects as applicable
    2.7. Payment of fee

3. Addition or deletion of packaging of the product
    3.1. Completely accomplished Integrated Application Form
    3.2. Letter of request
    3.3. Copy of valid LTO reflecting the new address
    3.4. Copy of the valid original CPR
    3.5. Complete labeling requirements reflecting the change (primary, secondary and inserts, if any) in English and/or Filipino language with local dialects as applicable
    3.6. Payment of fee

B. Major Variation

1. Change in GHS category/hazard class
    1.1 Completely accomplished Integrated Application Form
    1.2 Letter of request
    1.3 Copy of valid LTO
    1.4 Copy of the valid original CPR
    1.5 Copy of SDS

1.6 Copy of complete toxicity studies, if request is for change in hazard class
1.7 Complete labeling requirements reflecting the change (primary, secondary and inserts, if any) in English and/or Filipino language with local dialects as applicable
1.8 Payment of fee

ANNEX B
Data Requirements for Registration of Formulated Household Pesticides

I. New Registration

A. Identity and Specifications

	Data Requirements	Remarks
A.1.	**Applicant Identity and Administrative Requirements**	
	1.1 Completely Accomplished and Notarized Integrated Application Form with Declaration	
	1.2 Copy of valid License to Operate as household pesticide manufacturer, trader or distributor (importer, wholesaler, exporter)	
	1.3 Payment of fee	
A.2.	**Product Identity**	
	2.1 Formulator's name and address	
	2.2 Proprietary name	
	2.3 Use category	e.g. insecticide, rodenticide, etc.
	2.4 Type of formulation	e.g. EC, SC, WP, etc.
A.3.	**Quantitative and Qualitative Composition of product**	
	3.1 Content of technical grade active ingredient(s)	Where more than one active ingredient, information should be given on each ingredient separately
	3.2 Content and nature of other components included in the formulation including water or any other solvents	
A.4.	**Technical specifications of the formulated product**	Submit whichever is applicable
	4.1 Appearance (physical state, color, odor)	
	4.2 Density	For liquids only
	4.3 Flammability: liquids – flash point; solids – a statement must be made as to whether the product is flammable	
	4.4 pH	
	4.5 Wettability	For dispersible powders
	4.6 Persistent foam	For formulations applied in water
	4.7 Suspendibility	For dispersible powders and suspension concentrates
	4.8 Wet sieve test	For dispersible powders and suspension concentrates
	4.9 Dry sieve test	For granules, dusts
	4.10 Emulsion stability	For emulsifiable concentrates
	4.11 Corrosiveness (when necessary)	
	4.12 Known incompatibilities with other products	

	4.13 Shelf life[1]	Supported by stability studies
A.5.	**Product specifications - Tolerance for the Active Ingredient/s[2]**	
A.6.	**Certificate of analysis containing the manufacturing date, batch/lot number, name and signature of the laboratory analyst and manager**	Shall be aligned with the product specifications
A.7.	**Test procedures/methods conducted on the formulated product**	Based on the technical specifications of the formulated product
A.8.	**Safety Data Sheet (SDS) of the formulated product**	
	8.1 Identification	
	8.2 Hazard identification	
	8.3 Composition and information of ingredients	
	8.4 First-aid measures	
	8.5 Fire-fighting measures	
	8.6 Accidental release measures	
	8.7 Handling and storage	
	8.8 Exposure controls and personal protection	
	8.9 Physical and chemical properties	
	8.10 Stability and reactivity	
	8.11 Toxicological information	
	8.12 Ecological information	
	8.13 Disposal considerations	
	8.14 Transport information	
	8.15 Regulatory information	
	8.16 Other information	
A.9.	**Proof of Manufacturer's Compliance to Good Manufacturing Practices (GMP)[3]**	
A.10.	**Substantiation to support special product claims**	
A.11.	**Product Stewardship Program**	
A.12.	**Submission of actual sample and reference standard**	- Min. 1 g for the reference standard - Min. 500mL/0.5kg product sample

B. Toxicity Data[4,5]

	Data Requirements	**Remarks**
B.1.	**Acute Toxicity Tests**	
	1.1 Acute oral toxicity	LD_{50} expressed as mg/kg of body weight
	1.2 Acute dermal toxicity	LD_{50} expressed as mg/kg of body weight
	1.3 Acute inhalation toxicity	LC_{50} in mg/L or ppmV
B.2.	**Corrosion/irritation tests**	
	2.1 Primary skin corrosion/irritation	
	2.2 Serious eye damage/irritation	
B.3.	**Allergy/sensitization test**	
B.4.	**Sub-chronic toxicity tests**	Minimum 90 days, oral in rats

B.5.	**Reproduction effects studies**	Minimum two generations in rats
B.6.	**Teratogenicity studies**	In two species, one in rats and other in non-rodents
B.7.	**Neurotoxicity studies**	In hens, for organophosphates, carbamates, 2nd generation pyrethroids
B.8.	**Mutagenicity studies**	Minimum of Ames test and in vivo micronucleus test
B.9.	**Carcinogenicity tests and chronic (long term) toxicity studies in rats**	

C. Bio-efficacy Data[6]

	Data Requirements	Remarks
C.1	**Report design**	
	1.1 Abstract	This section is a short summary of the whole bio-efficacy study report.
	1.2 Introduction	This section discusses the following: • Background information of the product (product classification, product owner, formulation type) including the active ingredient/s used and its concentration in the product, efficacy of the active ingredient against specific pest/s • Known or confirm acute and/or long-term toxicity of the active ingredient • Potential for the development of resistance and cross-resistance • Significance of the study • In case of innovative products, justify the need (e.g. advantages of using the product) for the product
	1.3 Objectives	This section discusses the specific purpose of the study
	1.4 Methodology	This section discusses the whole test procedures/design in view of the objectives. If the test design has been patterned after an international guideline, said guideline is cited here. In case deviations are made from the standard, these are also discussed and justified in this section. *Other information discussed in this section are the following:* • Duration of the study • Adequacy of infrastructures and location where the test is conducted (i.e. laboratory or field) • In case of field study, suitability of the location and plot size • Size and design (i.e. number of trials per replicate, minimum of three replicates) • Test organisms/species and the conditions of their handling o genus and species of the test insect o age and sex o laboratory-reared, wild collected, o rearing techniques including environmental conditions, food source o number of test insects used per trial, environmental conditions • Sampling methods and techniques used • Equipment design and dimension

		• Treatments/controls used
		  o information on the ingredient/formulation as reference product or positive control
		• Inclusion/exclusion criteria used
		• Preparations performed such as:
		  o Acclimatization
		  o Washing of area of application
		  o Weighing of test animal (rodents)
		• Application method including equipment used, dilution rate, application rate, amount of treatments per application and timing of the application, if applicable
		• Schedule of monitoring/observation

	1.5 Presentation, Analysis and Interpretation of Data	This section discusses the statistical methods used and its suitability in achieving the objectives specified in Section 3. Other information found here are the following: • Raw data • Statistical analysis results • Interpretations
	1.6 Summary of Findings, Conclusions and Recommendations	This section discusses the results of the bio-efficacy study. Recommendations for further studies are also discussed here in case the researcher deems it necessary.
	1.7 Bibliography	This section cites the list of references
	1.8 Annexes, if any	This section contains the Qualifications of the Principal Investigator/Researcher (CV, FPA Accreditation) Copy of Ethical Clearance issued by an Ethics Review Committee (ERC) duly registered with and/or accredited by the Philippine Health Ethics Research Board in case human subjects are used

D. Human Exposure and Safety

	Data Requirements	**Remarks**
D.1.	**Operators exposure data**	Dermal/inhalation exposure, biological monitoring
D.2.	**Bystanders exposure data**	Dermal/inhalation exposure, biological monitoring
D.3.	**Medical data/Poisoning symptoms/Antidote**	
D.4.	**Permissible exposure level**	For professional handlers/applicators
D.5.	**Personal protective equipment**	
D.6.	**Other precautions**	

E. Environmental Data

	Data Requirements	**Remarks**
E.1.	**Evaluation of Environmental Fate and Effects**	
	1.1 Data on translocation of pesticides in soil and water	
	1.2 Primary data on potential hazards (infectivity) to mammals (including humans)	

	1.3 Primary data on aquatic toxicity	
	1.4 Primary data on phytotoxicity effects	
	1.5. Primary data on treatment of effluents and methods of destruction or disposal	

F. Labeling/Packaging

	Data Requirements	**Remarks**
F.1.	**Labeling**	Submit per pack size and include other information materials such as leaflets, brochure, etc.
	1.1 Product Information	
	1.1.1 Brand and Product name	
	1.1.2 Product or user category	Household use or Professional Use
	1.1.3 Type of formulation	
	1.1.4 Intended use including the target pests	
	1.1.5 Active ingredient/s including percentage concentration in %w/w or %w/v	Indicate the active ingredient in the primary packaging label
	1.1.6 Net content	
	1.1.7 Batch/Lot number	
	1.1.8 Manufacturing date	
	1.1.9 Expiry date	
	1.1.10 Registration number	Specified as HSR No.XXXX
	1.2 Hazard and Safety Information	
	1.2.1 GHS pictogram, signal word, hazard statement	
	1.2.2 Precautionary statement or warnings	Indicate the mandatory statement, "Keep out of Reach of Children" " in the front panel; include other precautionary statements recommended by GHS based on hazard category
	1.2.3 Color band based on GHS Acute Toxicity	
	1.2.4 Signs/symptoms of poisoning	
	1.2.5 First aid treatment / Antidote information	
	1.2.6 Medical advice/Note to physician	
	1.2.7 Accidental spills advice	
	1.3 Directions for Use	
	1.3.1 Field of use	If applicable
	1.3.2 Dilution and application rate	If applicable
	1.3.3 Directions for use	
	1.3.4 Re-entry period	If applicable
	1.3.5 Frequency of re-application	If applicable

	1.3.6 Storage and disposal	
	1.4 Name, complete address and contact information of the marketing authorization holder (MAH)	In case the MAH is not the manufacturer, indicate the name and complete address of the manufacturer including country of origin
	1.5 Contact information of the national/regional poison center	
F.2.	**Packaging**	
	2.1 Specification of primary package	
	2.2 Specification of secondary packaging	
	2.3 Specification of bulk package for transport	
	2.4 Assessment of need of child resistant packaging	

Notes:

1 Stability studies may be accelerated or real-time. For accelerated stability study, it shall be conducted under the following conditions which shall only be equivalent to two (2) year shelf-life:
   a. 54 ± 2°C for 14 days
   b. 50 ± 2°C for 4 weeks
   c. 45 ± 2°C for 6 weeks

2 Values for the tolerance limits for the active ingredient/s shall be in accordance with the Manual on Development and use of FAO and WHO Specifications for Pesticides

3 If active ingredient is sourced from a foreign country, submit any of the following documents:
   - Certificate of Free Sale (CFS) issued by the National Regulatory Authority of country of origin
   - Certificate of Good Manufacturing Practice (GMP) based on international manufacturing standards
   - Manufacturing license
   - ISO Certificate related to manufacturing

4 If allowed in GHS and if available, validated test methods based on accepted international standards may be used in lieu of *in vivo* animal testing.

5 In lieu of *in vivo* and *in vitro* animal testing, GHS bridging principles may be applied as long as the hazard categories of each ingredient in concentration greater than or equal to 1% are known, unless there is evidence that the ingredients in concentration less than 1% are hazardous.

6 Identify the international standard where the bio-efficacy test design was patterned and justification when the design differs from the standard.

II. Renewal of Product Registration

1. Completely accomplished Integrated Application Form with Declaration
2. Post-market surveillance monitoring report
   - Determination of developed pesticide resistance
3. Unattached legible, comprehensive and indelible specimen of all labeling materials per pack size (including outer, immediate, package inserts, if any) in English and/or Filipino language with local dialects as applicable
4. Payment of fee

III. Variations to a CPR

A. Minor Variations

1. Change in business name of the manufacturer/ distributor
   - 1.1. Completely accomplished Integrated Application Form
   - 1.2. Letter of request
   - 1.3. Copy of valid LTO reflecting the variation
   - 1.4. Copy of the valid original CPR
   - 1.5. Complete labeling requirements reflecting the change (primary, secondary and inserts, if any) in English and/or Filipino language with local dialects as applicable
   - 1.6. Payment of fee

2. Change in product ownership
   - 2.1. Completely accomplished Integrated Application Form
   - 2.2. Letter of request
   - 2.3. Copy of valid LTO reflecting the variation
   - 2.4. Copy of the valid original CPR
   - 2.5. Copy of Termination Contract/Deed of Assignment
   - 2.6. Copy of the Agreement of the new MAH and manufacturer
   - 2.7. Complete labeling requirements reflecting the change (primary, secondary and inserts, if any) in English and/or Filipino language with local dialects as applicable
   - 2.8. Payment of fee

3. Change of address of the distributor of the product
   - 3.1. Completely accomplished Integrated Application Form
   - 3.2. Letter of request
   - 3.3. Copy of valid LTO reflecting the new address
   - 3.4. Copy of the valid original CPR
   - 3.5. Any valid document/s showing proof of transfer

3.6. Complete labeling requirements reflecting the change (primary, secondary and inserts, if any) in English and/or Filipino language with local dialects as applicable
3.7. Payment of fee

4. Addition or deletion of packaging of the product
   4.1. Completely accomplished Integrated Application Form
   4.2. Letter of request
   4.3. Duly notarized affidavit/declaration of no change in the formulation
   4.4. Copy of valid LTO reflecting the new address
   4.5. Copy of the valid original CPR
   4.6. Complete labeling requirements reflecting the change (primary, secondary and inserts, if any) in English and/or Filipino language with local dialects as applicable
   4.7. Payment of fee

B. <u>Major Variations</u>

1. Change in product name (brand name/ variant name)
   1.1 Completely accomplished Integrated Application Form
   1.2 Letter of request
   1.3 Duly notarized affidavit/declaration of no change in the formulation
   1.4 Copy of valid LTO
   1.5 Copy of the valid original CPR
   1.6 Extension of use or claim and new bio-efficacy study, if there is request to include additional target pests
   1.7 Complete labeling requirements reflecting the change (primary, secondary and inserts, if any) in English and/or Filipino language with local dialects as applicable
   1.8 Payment of fee

2. Change in rate, timing or frequency of application or method of application
   2.1 Completely accomplished Integrated Application Form
   2.2 Letter of request
   2.3 Copy of valid LTO
   2.4 Copy of the valid original CPR
   2.5 Extension of use or claim and new bio-efficacy study, if there is request to include additional target pests
   2.6 Study or studies that shall justify request for change in rate, timing or frequency of application, or method of application
   2.7 Complete labeling requirements reflecting the change (primary, secondary and inserts, if any) in English and/or Filipino language with local dialects as applicable

2.8 Payment of fee

3. Change in label claim/Request for additional target pest(s)
   - 3.1 Completely accomplished Integrated Application Form
   - 3.2 Letter of request
   - 3.3 Copy of valid LTO
   - 3.4 Copy of the valid original CPR
   - 3.5 Extension of use or claim and new bio-efficacy study, if there is request to include additional target pests
   - 3.6 Complete labeling requirements reflecting the change (primary, secondary and inserts, if any) in English and/or Filipino language with local dialects as applicable
   - 3.7 Payment of fee

4. Change in GHS category/hazard class
   - 4.1 Completely accomplished Integrated Application Form
   - 4.2 Letter of request
   - 4.3 Copy of valid LTO
   - 4.4 Copy of the valid original CPR
   - 4.5 Copy of SDS
   - 4.6 Copy of complete toxicity studies, if request is for change in hazard class
   - 4.7 Complete labeling requirements reflecting the change (primary, secondary and inserts, if any) in English and/or Filipino language with local dialects as applicable
   - 4.8 Payment of fee

ANNEX C
Requirements for Off-Label Use /
Public Health Emergency Exemption Permit

1. Application Form / Letter of Request

2. Information required for public health exemption:

   2.1 The scientific and common name of the pest to be controlled and, if the pest is a vector, a description of the disease it is expected to transmit;
   2.2 A discussion of the magnitude of the health problems which are expected to occur without the possible use; and
   2.3 Discussion of the availability of medical treatment for the health problem.

3. Description of the pesticide:

   3.1 Complete ingredient listing of the formulated finished product (expressed in %w/w; %w/v; %v/v)
   3.2 Complete labeling to be used in connection with the proposed exemption use.

4. Description of the proposed use:

   4.1 Sites to be treated, including their locations within the country;
   4.2 The method of application;
   4.3 The rate of application in terms of active ingredient and product;
   4.4 The maximum number of applications;
   4.5 The total area proposed to be treated;
   4.6 The total amount of household pesticide proposed to be used in terms of both active ingredient and product;
   4.7 All applicable restrictions and requirements concerning the proposed use which may not appear on labelling; and
   4.8 The duration of the proposed use.

5. Alternative methods of control:

   5.1 A detailed explanation of why the household pesticide(s) currently registered for the particular use proposed in the application is not available in adequate supplies and/or effective to the degree needed to control the emergency. If the applicant states that an available registered household pesticide is ineffective for the given situation, the statement must be supported by data which demonstrate ineffectiveness of registered household pesticides, or, if such data are unavailable, statements by qualified pesticide experts, academe or other person similarly qualified in the field of pest control; and

5.2 A detailed explanation of why alternative practices, if available, either would not provide adequate control or would not be economically or environmentally feasible.

6. Effectiveness of proposed use. (Bio-efficacy Study)

7. Discussion of risk information. (Toxicity Study)

8. Description of the proposed enforcement program.

Prior to approval, the applicant shall provide an explanation of the authority of the applicant for ensuring that use of the household pesticide under the proposed exemption would comply with any special requirements imposed by FDA and a description of the program and procedures for assuring such compliance.