**Note:** This draft is only intended as a copy for comments during the stakeholder consultation period of the proposed guidelines. The content of this draft may change and does not prejudge any policy nor decision of the FDA. Citation of any text in this draft, for purposes other than the submission of comments as indicated in the issued announcement, is not recommended.

#### FDA CIRCULAR

No. \_\_\_\_\_

SUBJECT: Updates and Amendments to the List of Banned and

Restricted Pesticides and Ingredients in Household/Urban

**Pesticides** 

# I. RATIONALE

Household/urban pesticides (HUPs) as products which pose health and environmental risks are subject to the regulation of the Food and Drug Administration (FDA). Principally, the FDA ensures that only products which meet its technical standards and requirements on safety, efficacy and quality are duly-authorized prior to being placed in the market, consistent to Article 15 of Title II, Chapter I of Republic Act No. 7394 which provides that "any consumer product, the sale or use of which has been banned or withdrawn in the country of manufacture, shall not be imported into the country." To this end, the FDA continuously conducts reviews of HUPs and its components as well as assesses evidence-based local and/or international standards, policies and scientific researches to update its technical standards and requirements.

In adherence with the country's agreements on pesticides and chemicals management, including the Montreal Protocol, Stockholm Convention, Rotterdam Convention, and other international conventions, and promote regulatory alignment with the Fertilizer and Pesticides Authority (FPA), under the auspices of sound chemicals management, the list of banned and restricted pesticides by the FDA is hereby updated.

Moreover, the list hereby serves as the consolidated reference for restricted and prohibited pesticides and ingredients in HUPs, amending FDA Circular (FC) No. 2017-005, "List of Banned Pesticides" and FC No. 2017-015, "Adoption of the ASEAN Cosmetic Directive (ACD) Annexes II and VI as Standards for Household/Urban Pesticides (HUP)".

#### II. OBJECTIVE

The Circular aims to provide the list of banned and restricted pesticides and ingredients in HUPs.

# III. SCOPE

The Circular shall apply to HUPs and establishments that are engaged in the manufacture, importation, exportation, sale, offer of sale, distribution, donation, transfer, and where applicable, the use, testing, promotion, advertising, or sponsorship of such products.

#### IV. GENERAL GUIDELINES

A. The FDA shall ensure that HUPs made available in the market do not pose an unacceptable risk to human and animal health, and to the environment, under any use, directions or restrictions.

B. HUPs shall not contain any pesticides and/or ingredients banned by the DOH and FDA. For such purposes, the FDA shall issue and maintain a list of banned pesticides and ingredients in HUPs.

C. HUPs shall not contain any ingredients beyond the set restrictions, including but not limited to the maximum permitted concentration and allowable conditions for use. For such purposes, the FDA shall issue and maintain a list of restricted pesticides and ingredients in HUPs.

D. Compliance to the restrictions set in these Guidelines shall not be construed as a guarantee of an approval for any marketing authorization application filed with the FDA. Such applications, including its product dossier, shall remain to be subject to the full evaluation following the administrative and technical standards and requirements under the product registration procedure provided in Department of Health (DOH) Administrative Order (AO) No. 2019-0008 and its future amendments.

E. All pending and new applications filed with the FDA containing ingredients included in Annexes A and B shall be evaluated in accordance with these Guidelines upon the effectivity of this Circular.

F. All HUPs with a valid CPR prior the issuance of this Circular which are not in conformance to these Guidelines shall be given a three (3)-month non-extendible grace period for phase out and are further subject to a Class I Recall upon effectivity of this Circular. Marketing authorization holders (MAH) are hereby directed to initiate and complete the recall of such products following these Guidelines.

G. This order shall not preclude the FDA from disapproving applications where the technical evaluation of the submission received indicate non-compliance to adopted standards and regulations, including failure to display safety, quality, and efficacy.

H. All FDA-licensed establishments holding valid CPRs for products which do not contain any banned and restricted pesticides and ingredients beyond the restrictions as specified in this Circular shall submit a notarized letter and declaration statement of such fact, within sixty (60) days upon the effectivity of this Circular.

#### V. SPECIFIC GUIDELINES

A. List of Banned and Restricted Ingredients and Mixtures in HUPs

- 1. The banned ingredients and mixtures listed on Annex A shall not be allowed to form part of any HUP.
- 2. The ingredients and mixtures listed on Annex B shall not be allowed to form part of any HUP, unless it adheres to the set restrictions therein.

# B. Review of the list of banned/restricted pesticides and ingredients in HUPs.

The review shall be conducted by the FDA and said list shall be kept updated accordingly. Such review shall be undertaken when HUP ingredients and mixtures are banned and/or severely restricted in international conventions, treaties and protocols, internationally-acceptable standards, and local regulatory authorities, due to health and/or environmental risks, or may be triggered by health and environmental concerns based on information collected during the registration process as well as post-marketing surveillance data, including reported cases of poisoning and adverse events.

- **C. Product Recall.** This section reiterates the roles of the MAH and the FDA and provides the guidelines on the recall of products which fall under Section IV.F. of this Circular. The "Guidelines on Product Recall" under FC No. 2016-012 shall apply. However, specifically on recall strategy and communication activities for products affected by this Circular, the following shall apply:
  - 1. **Role of the MAH and the FDA.** Upon effectivity of this Circular, the MAH shall bear the overall responsibility in the initiation, implementation and completion of a product recall strategy.

The FDA shall closely monitor and supervise the conduct of the product recall of the MAH. Further, the FDA shall not be precluded from intervening and enforcing any regulatory action and providing scientific, technical and operational advice.

- 2. **Recall Strategy.** A recall strategy shall be implemented by the MAH consistent with the Risk Management Plan of the HUP establishment, Republic Act (RA) No. 6969, otherwise known as the "Toxic Substances and Hazardous and Nuclear Wastes Control Act of 1999", and its implementing rules and regulations on the storage, transport and final disposal of expired, banned, obsolete, rejected, recalled and/or out of specification/s formulated HUPs and active ingredients. The strategy shall contain the following elements:
  - a. Depth of Recall, including distribution level
  - b. Recall Communications containing the identified list of establishments as per distribution records to be contacted and contents of communications
  - c. Recall operation instructions and corresponding timelines of completion
  - d. Recall status reporting of MAH to FDA, specifying the frequency of submission
  - e. Disposal strategy

- 3. **Communication Activities.** Communication activities shall be undertaken by the FDA and the MAH to protect the public.
  - a. The MAH shall issue a notice within thirty (30) days upon effectivity of the issuance to all concerned parties, including but not limited to establishments involved in the supply chain, pest control operators, and the general public. A shorter period may be determined upon the order of the FDA. For the recall of HUPs for consumer use, a notice to the general public shall be required.

Notices shall be written in clear and easy-to-understand language, and in a manner which urges a consumer to act on or participate in the recall. Notices shall not be written in any manner whatsoever which downplays the hazards associated with the recall. The minimum information required for communications shall follow Annex B of FC No. 2016-012 and its future amendments.

- b. A copy of the notice and the communication plan shall be furnished by the MAH to the FDA no later than three (3) days from its publication. The FDA, based on its review, may order the MAH to improve the communication plan and its implementation.
- c. The FDA shall not be precluded from issuing public health warnings or advisories on products subject for recall and for products and establishments found to be in violation of these Guidelines.

The FDA may likewise share the notice issued by the MAH as product recall alerts or advisories, as appropriate.

- i. For the recall of HUPs for consumer use, the FDA shall share the notice to the public in its website and other social media platforms and, as far as practicable, through media alerts.
- ii. For the recall of HUPs for professional use, the FDA shall share the notice to licensed pest control operators.
- iii. Other channels may be utilized by the FDA to extend the dissemination of the safety information to consumers, applicators, other handlers, and the public.
- d. Should the MAH fail to issue a notice to concerned parties within thirty (30) days of the effectivity of the issuance of the updated list of banned and/or restricted pesticides and ingredients in HUPs, the FDA shall issue an Advisory to the general public for affected products existing in its registry.
- **D. Prohibited Acts.** The following activities shall be prohibited:

- 1. The manufacture, trade, distribution, sale, offer for sale, advertisement, and promotion of an HUP which contains a banned pesticide or ingredient in HUP.
- 2. The manufacture, trade, distribution, sale, offer for sale, advertisement, and promotion of an HUP which contains a restricted pesticide or ingredient in HUP beyond its allowable restrictions or conditions of use.
- 3. Failure to conduct and completely implement the product recall strategy within the timelines prescribed for products under Section IV.F. and Section V.C. of this Circular.
- 4. The over- the-counter sale and/or offer for sale to the general public of HUPs which are solely intended for Professional use.
- 5. Failure to submit a notarized letter and declaration statement under Section IV. H.

#### VI. PENALTY CLAUSE

Any person found in violation of this Circular shall be deemed a violation of Republic Act No. 3720 as amended by Republic Act No. 9711 and shall be penalized accordingly following the Uniform Rules of Procedures laid down under Book III of the Implementing Rules and Regulations of Republic Act No. 9711.

#### VII. REPEALING CLAUSE

This Circular effectively repeals FC No. 2017-005, entitled, "List of Banned Pesticides" and FC No. 2017-015, "Adoption of the ASEAN Cosmetic Directive (ACD) Annexes II and VI as Standards for Household/Urban Pesticides (HUP)". Further, FC No. 2016-012, entitled, "Guidelines on Product Recall", as it applies for the affected products of this Circular, is hereby amended. All other administrative issuances, circulars and memoranda and other regulations inconsistent with this Circular are hereby withdrawn, repealed and/or revoked accordingly.

#### VIII. SEPARABILITY CLAUSE

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

#### IX. EFFECTIVITY

This Circular shall take effect fifteen (15) days after its publication in a newspaper of general circulation and filing with the University of the Philippines Law Center Office of the National Administrative Register.

DR. SAMUEL A. ZACATE

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# ANNEX A List of ingredients and mixtures not allowed to form part of HUPs (Banned Pesticides and Ingredients in HUPs)

Name of Ingredient/Mixture	Standard/Reference
I. Pesticide	NAME OF STATE OF STAT
1. 1-Naphthylthiourea (ANTU)	FPA Pesticide Circular No. 04 s. 1989
2. 2,4,5-T	FPA Pesticide Circular No. 04 s. 1989
3. 2-Fluoroacetamide (1081)*	FPA Pesticide Circular No. 04 s. 1989
4. Aldrin	FPA Pesticide Circular No. 04 s. 1989
5. Brestan Organotin	FPA Pesticide Circular No. 04 s. 1989
6. Azinphos Ethyl	FPA Pesticide Circular No. 04 s. 1989
7. Chlordane	FPA Pesticide Resolution No. 01 s.
	1999
8. Chlorodimeform	FPA Pesticide Circular No. 04 s. 1989
9. Copper (II) Acetoaresenite (Paris	FPA Pesticide Circular No. 04 s. 1989
Green)	
10. Dibromochloropropane (DBCP)	FPA Pesticide Circular No. 04 s. 1989
11. Dichlorodiphenyltrichloroethane	FPA Board Resolution No. 04 s. 2005
(DDT)	
12. Dieldrin	FPA Pesticide Circular No. 04 s. 1989
13. Elemental Phosphorus	FPA Pesticide Circular No. 04 s. 1989
14. (White & Yellow)	
15. Endosulfan*	FPA Board Resolution No. 01, s. 2015
16. Endrin	FPA Pesticide Circular No. 04 s. 1989
17. EPN	FPA Pesticide Circular No. 04 s. 1989
18. Ethylene Bromide (EDB)	FPA Pesticide Circular No. 04 s. 1989
19. Gophacide	FPA Pesticide Circular No. 04 s. 1989
20. Hexachlorocyclohexane (HCH)/ Beta-	FPA Pesticide Circular No. 04 s. 1989
hexachlorocyclohexane (BHC)	FD4 D 1111 G1 1 N 04 1000
21. Heptachlor	FPA Pesticide Circular No. 04 s. 1989
22. Leptophos	FPA Pesticide Circular No. 04 s. 1989
23. Mercuric Fungicides	FPA Pesticide Circular No. 04 s. 1989
24. Nitrofen	FPA Pesticide Circular No. 04 s. 1989
25. Organotin Compounds	FPA Posticide Circular No. 04 s. 1989
26. Parathion-Ethyl	FPA Pesticide Circular No. 04 s. 1989 FPA Pesticide Circular No. 04 s. 1989
27. Parathion-Methyl 28. Sodium fluoroacetate	
	FPA Pesticide Circular No. 04 s. 1989 FPA Pesticide Circular No. 04 s. 1989
29. Strychnine 30. Thalium Sulfate	FPA Pesticide Circular No. 04 s. 1989  FPA Pesticide Circular No. 04 s. 1989
31. Toxaphene/Campechlor	FPA Pesticide Circular No. 04 s. 1989  FPA Pesticide Circular No. 04 s. 1989
32. Triphenyltin	FPA Pesticide Circular No. 04 s. 1989  FPA Pesticide Circular No. 04 s. 1989
33. Actinolite asbestos*	Rotterdam Treaty
34. Alachlor*	Rotterdam Treaty  Rotterdam Treaty
35. Aldicarb*	Rotterdam Treaty  Rotterdam Treaty
36. Anthophyllite asbestos*	Rotterdam Treaty  Rotterdam Treaty
37. Azinphos-methyl*	Rotterdam Treaty  Rotterdam Treaty
38. Binapacryl	Rotterdam Treaty  Rotterdam Treaty
39. Captafol	Rotterdam Treaty  Rotterdam Treaty
40. Carbofuran*	Rotterdam Treaty  Rotterdam Treaty
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41. Chlorobenzilate*	Rotterdam Treaty
42. Commercial octabromodiphenyl ether	Rotterdam Treaty
(including Hexabromodiphenyl ether	
and Heptabromodiphenyl ether)*	
43. Commercial pentabromodiphenyl ether	Rotterdam Treaty
(including tetrabromodiphenyl ether	
and pentabromodiphenyl ether)*	
44. Crocidolite asbestos*	Rotterdam Treaty
45. Decabromodiphenyl ether (decaBDE)*	Rotterdam Treaty
46. Dinitro-ortho-cresol (DNOC) and its	Rotterdam Treaty
salts (such as ammonmm salt,	
potassium salt and sodium salt)*	
47. Dinoseb and its salts and esters	Rotterdam Treaty
48. Dustable powder formulations	Rotterdam Treaty
containing a combination of benomyl	
at or above 7%, carbofuran at or above	
10% and thiram at or above 15%	
49. Ethylene dichloride	Rotterdam Treaty
50. Ethylene oxide*	Rotterdam Treaty
51. Fluoroacetamide*	Rotterdam Treaty
52. HCH (mixed isomers)*	Rotterdam Treaty
53. Hexabromocyclododecane*	Rotterdam Treaty
54. Hexachlorobenzene*	Rotterdam Treaty
55. Mercury compounds, including	Rotterdam Treaty
inorganic mercury compounds, alkyl	
mercury compounds and alkyloxyalkyl	
and aryl mercury compounds*	
56. Methamidophos*	Rotterdam Treaty
57. Methyl-Parathion (emulsifiable	Rotterdam Treaty
concentrates at or above 19.5% active	
ingredient and dusts at or above (EC)	
at or above 1.5% active ingredient)	
58. Monocrotophos*	Rotterdam Treaty
59. Pentachlorophenol and its salts and	Rotterdam Treaty
esters*	
60. Perfluorooctane sulfonic acid,	Rotterdam Treaty
perfluorooctane sulfonates,	
perfluorooctane sulfonamides and	
perfluorooctane sulfonyls*	
61. Perfluorooctanoic acid (PFOA), its	Rotterdam Treaty
salts and PFOA-related compounds*	
62. Phorate*	Rotterdam Treaty
63. Phosphamidon (Soluble liquid	Rotterdam Treaty
formulations of the substance that	
exceed 1000 g active ingredient/l)	
64. Polybrominated Biphenyls (PBBs)*	Rotterdam Treaty
65. Polychlorinated Biphenyls (PCBs)*	Rotterdam Treaty
66. Polychlorinated Terphenyls (PCTs)*	Rotterdam Treaty
67. Short-chain chlorinated paraffins	Rotterdam Treaty
(SCCP)*	1 Tottordam Troaty
(BCCI)	

68. Tetraethyl lead*	Rotterdam Treaty
69. Tetramethyl lead*	Rotterdam Treaty
70. Tremolite asbestos*	Rotterdam Treaty
71. Tributyl tin compounds*	Rotterdam Treaty
72. Trichlorfon*	Rotterdam Treaty
73. Tris(2,3-dibromopropyl) phosphate*	Rotterdam Treaty
74. Alpha hexachlorocyclohexane*	Stockholm Treaty
75. Beta hexachlorocyclohexane*	-
76. Chlordecone	Stockholm Treaty
77. Decabromodiphenyl ether (commercial	Stockholm Treaty Stockholm Treaty
1 ,	Stockholli Treaty
mixture, c-decaBDE)*	Cto alth also Tracety
78. Dicofol*	Stockholm Treaty
79. Hexabromobiphenyl*	Stockholm Treaty
80. Hexabromodiphenyl ether and	Stockholm Treaty
heptabromodiphenyl ether*	G. 11 1 T
81. Hexabromocyclododecane (HBCDD)*	Stockholm Treaty
82. Hexachlorobenzene (HCB)*	Stockholm Treaty
83. Hexachlorobutadiene*	Stockholm Treaty
84. Lindane	Stockholm Treaty
85. Mirex	Stockholm Treaty
86. Octabromodiphenyl ether	Stockholm Treaty
87. Pentachlorobenzene*	Stockholm Treaty
88. Perfluorohexane sulfonic acid	Stockholm Treaty
(PFHxS), its salts and PFHxS-related	
compounds*	
89. Perfluorooctane sulfonic acid (PFOS),	Stockholm Treaty
	Stockholm Treaty
its salts and perfluorooctane sulfonyl	Stockholm Ficaty
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its salts and perfluorooctane sulfonyl fluoride (PFOSF)  90. Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds*  91. Polychlorinated biphenyls (PCB)*  92. Polychlorinated dibenzo-p-dioxins	Stockholm Treaty
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its salts and perfluorooctane sulfonyl fluoride (PFOSF)  90. Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds*  91. Polychlorinated biphenyls (PCB)*  92. Polychlorinated dibenzo-p-dioxins (PCDD)*  93. Polychlorinated dibenzofurans (PCDF)*  94. Polychlorinated naphthalenes*  95. Short-chain chlorinated paraffins	Stockholm Treaty Stockholm Treaty Stockholm Treaty Stockholm Treaty Stockholm Treaty
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its salts and perfluorooctane sulfonyl fluoride (PFOSF)  90. Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds*  91. Polychlorinated biphenyls (PCB)*  92. Polychlorinated dibenzo-p-dioxins (PCDD)*  93. Polychlorinated dibenzofurans (PCDF)*  94. Polychlorinated naphthalenes*  95. Short-chain chlorinated paraffins (SCCPs)*  96. Technical endosulfan and its related isomers*  97. Tetrabromodiphenyl ether and	Stockholm Treaty
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106. Methyl bromide*	Montreal Treaty
107. Other fully halogenated CFCs*	Montreal Treaty
108. Chlorpyrifos*	FDA Circular No. 2018-008
109. Dichlorvos*	FDA Circular No. 2018-008
110. Substances included in Annex II of	FDA Circular No. 2017-015
the ASEAN Cosmetic Directive except	
substances intended to be the AI of the	
HUP formulation subject to existing	
restrictions indicated in Annex B of this	
Circular, if any*	

\*New additions to the previous "List of Banned Pesticides" based on FDA Circular No. 2017-005

# ANNEX B

# List of ingredients and mixtures not allowed to form part of HUPs unless under the permitted restrictions and/or allowable conditions of use (Restricted Pesticides and Ingredients in HUPs)

Name of Ingredient/Mixture Pesticide	Conditions for Use	Standard/ Reference
Brodifacoum	1. The product shall be sold with	
Difethialone	tamper-resistant bait stations and labelled as "indoors; or indoors and	Protection Agency, DOH AO No. 2019- 0010
Bromadiolone	outdoors within 50 feet or 15 meters of buildings".	
Difenacoum	2. The rodenticide shall be in a form of block or paste. Mouse and rat poisons in pellet form are banned.  3. Products may contain no more than 1 pound or 0.5 kilogram of rodenticide bait.  4. The product shall only be distributed to or sold directly to pest control operators (PCOs) and not to be sold in "consumer" stores, including drug stores, grocery stores, hardware stores, club stores, and similar retail outlets.  5. Products containing these active ingredients shall only be available for commercial use and for residential use by PCO.	
Naphthalene	Mothball shall be: 1. Sold in sachets with a tear- and moisture-resistant wrapping material 2. Packaged in plastic containers that allow for volatilization, but which would prohibit direct contact with naphthalene. 3. Formulated into larger sized cake or block products (minimum of 2.5 inches in diameter). This must also be enclosed in plastic, metal or cardboard packaging while in use.	US Environmental Protection Agency
Active Ingredient included in Annex II of the ASEAN Cosmetic Directive	May be allowed subject to the submission of a risk assessment or its resubmission if any changes/updates were identified, subject to evaluation during product registration	ASEAN Cosmetic Directive

Substances included in Annex III of the ASEAN Cosmetic Directive	Restrictions indicated on the maximum concentration, limitations and requirements, and conditions of use and warnings which must be	ASEAN Cosmetic Directive
Colorants included in Annex IV of the ASEAN Cosmetic Directive	printed on the label shall apply	ASEAN Cosmetic Directive
Preservatives included in Annex VI of the ASEAN Cosmetic Directive		ASEAN Cosmetic Directive
Chemicals restricted under Annex XVII to REACH Regulation	Restrictions indicated in the annex to REACH regulation shall apply.	Regulation (EC) No 1907/2006

1	ANNEX C
2	List of Treaties, Conventions and Protocols, Internationally-accepted Standards, and
3	Local Regulatory Agencies Recognized by the FDA
4	
5	
6	1. Montreal Protocol on Substances That Deplete the Ozone Layer
7	2. Rotterdam Convention on the Prior Informed Consent Procedure for Certain
8	3. Hazardous Chemicals and Pesticides in International Trade
9	4. Stockholm Convention on Persistent Organic Pollutants
10	5. Fertilizer and Pesticide Authority (FPA)
11	6. World Health Organization (WHO)
12	7. Food and Agriculture Organization of the United Nations (FAO)
13	8. U.S. Environmental Protection Agency (EPA)
14	9. ASEAN Cosmetic Directive (ACD)
15	10. European Union (EU)
16	11. International Agency for Research on Cancer (IARC)
17	12. International Organization for Standardization (ISO)
18	13. Organization for Economic Co-operation and Development (OECD)
19	14. Basel Convention on the Control of Transboundary Movements of Hazardous Wastes
20	and Their Disposal

1	Information Sheet on the Banned and Restricted Pesticides
2	and Ingredients in HUPs
3	
4 5 6 7	This document was prepared to provide context on recommendations and decisions made on pesticides and ingredients in HUPs listed in Annexes A and B, intended for the information of all concerned stakeholders. Please note that this information sheet does not form part of the FDA Circular.
8	
9	A. Banned Pesticides
10	
11	1. Fertilizer and Pesticide Authority (FPA)
12	Consistent with FPA Board Resolution No. 01, s. 2015, the Board resolved to ban <i>Endosulfan</i>
13	and its related isomers after due consideration and appreciation of its risks to human health and
14	the environment.
15	
16	2. Rotterdam Convention
17	The following chemicals listed in Annex III categorized as Pesticide in the Rotterdam
18	Convention for health and environmental reasons are have been included following updates to
19	the Convention. These will be in addition to the chemicals included in FDA Circular No. 2017-
20	005:
21	2.1 Alachlor
22	2.2 Aldicarb
23	2.3 Anthophyllite asbestos
24	2.4 Azinphos-methyl
25	2.5 Carbofuran
26	2.6 Chlorobenzilate
27	2.7 Commercial octabromodiphenyl ether (including Hexabromodiphenyl ether
28	and Heptabromodiphenyl ether)
29	2.8 Commercial pentabromodiphenyl ether (including tetrabromodiphenyl ether
30	and pentabromodiphenyl ether) 2.9 Crocidolite asbestos
31 32	
32 33	2.10 Decabromodiphenyl ether (decaBDE)
33	2.11 Dinitro-ortho-cresol (DNOC) and its salts (such as ammonmm salt,
3 <del>4</del>	potassium salt and sodium salt) 2.12 Ethylene oxide
36	2.13 Fluoroacetamide
37	2.14 HCH (mixed isomers)
38	2.15 Hexabromocyclododecane
39	2.16 Hexachlorobenzene
40	2.17 Mercury compounds, including inorganic mercury compounds, alkyl mercury
41	compounds and alkyloxyalkyl and aryl mercury compounds
42	2.18 Methamidophos
43	2.19 Monocrotophos
44	2.20 Pentachlorophenol and its salts and esters
45	2.21 Perfluorooctane sulfonic acid, perfluorooctane sulfonates, perfluorooctane
46	sulfonamides and perfluorooctane sulfonyls
47	2.22 Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds
48	2.23 Phorate
49	2.24 Polybrominated Biphenyls (PBBs)
50	2.25 Polychlorinated Biphenyls (PCBs)
51	2.26 Polychlorinated Terphenyls (PCTs)

1	2.27 Short-chain chlorinated paraffins (SCCP)
2	2.28 Tetraethyl lead
3	2.29 Tetramethyl lead
4	2.30 Tremolite asbestos
5	2.30 Tributyl tin compounds
6	2.31 Trichlorfon
7	2.32 Tris(2,3-dibromopropyl) phosphate
8	
9	3. Stockholm Convention
10	The following chemicals listed as Persistent Organic Pollutants (POPs) under the Stockholm
11	Convention have been recognized as causing adverse effects on humans and the ecosystem:
12	convention have been recognized as eadsing daverse effects on named and the ecosystem.
13	3.1 Alpha hexachlorocyclohexane
14	3.2 Beta hexachlorocyclohexane
15	3.3 Decabromodiphenyl ether (commercial mixture, c-decaBDE)
16	3.4 Dicofol
17	3.5 Hexabromobiphenyl
18	3.6 Hexabromodiphenyl ether and heptabromodiphenyl ether
19	3.7 Hexabromocyclododecane (HBCDD)
20	3.8 Hexachlorobutadiene (HCBD)
21	3.9 Hexachlorobutadiene
22	3.10 Pentachlorobenzene
23	3.11 Perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds
23 24	3.12 Perfluorooctane sulfonic acid (PFOS), its salts and
25	perfluorooctane sulfonyl fluoride (PFOSF)
26	3.13 Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds
27	3.14 Polychlorinated biphenyls (PCB)*
28	3.14 Polychlorinated dibenzo-p-dioxins (PCDD)
20 29	3.16 Polychlorinated dibenzofurans (PCDF)
30	3.17 Polychlorinated naphthalenes
31	3.18 Short-chain chlorinated paraffins (SCCPs)
32	3.19 Technical endosulfan and its related isomers
	3.19 Technical endosuyan and its retaled isomers 3.20 Tetrabromodiphenyl ether and pentabromodiphenyl ether
33	5.20 Tetrabromoatphenyt einer ana pentabromoatphenyt einer
34	4. Montreal Protocol
35	
36	On 1987, an agreement through the Montreal Protocol was signed and enforced in 1989 to protect
37 38	the Earth's ozone layer through a phase-out plan which includes both the production and
39	consumption of ozone-depleting substances. Below were the identified substances correspondingly banned:
39 40	4.1 1,1,1-Trichloroethane
	4.1 1,1,1-1 nemorbethane 4.2 Bromochloromethane
41	4.2 Bromochtoromethane 4.3 Carbon tetrachloride
42	
43	4.4 Chlorofluorocarbons
44 45	4.5 Halons
45 46	4.6 Hydrobromofluorocarbons (HBFCs)
46 47	4.7 Hydrochlorofluorocarbons (HCFCs)
47	4.8 Hydrofluorocarbons
48	4.9 Methyl bromide
49	4.10 Other fully halogenated CFCs
50	

B. Other pesticides previously banned by the FDA

On 2018, FDA Circular 2018-008 entitled "Ban of Chlorpyrifos and Dichlorvos for Use in Household/Urban Pesticide Products, and Household/Urban Pesticide Products Containing Chlorpyrifos and Dichlorvos as Active Ingredients" was issued to impose a ban on Chlorpyrifos and Dichlorvos which were linked to cause damaging effects to humans, animals and the environment.

# C. Restricted pesticides

# 1. Second-Generation Anticoagulants

While second-generation anticoagulants are more likely to be toxic in a single feeding than other products, time-to-death takes several days. Thus, this allows rodents to feed multiple times before death, resulting in carcasses which contain residues that may be more than the lethal dose. Predators and scavengers that feed on such carcasses may be in turn poisoned. Hence, US EPA made several announcements<sup>1-3</sup> on the banning of mouse and rat poisons in pellet form and provided guidelines to ensure that safer rodenticide products are available to consumers for use.

In view of this, products containing the following active ingredients will hence adhere to the set restrictions specified below:

1.1 Brodifacoum

1.2 Difethialone

1.3 Bromadiolone

1.4 Difenacoum

#### **Restrictions:**

1. The product shall be sold with tamper-resistant<sup>4</sup> bait stations and labelled as "indoors; or indoors and outdoors within 50 feet or 15 meters of buildings".

*1*  2. The rodenticide shall be in a form of block or paste. Mouse and rat poisons in pellet form are banned.

 3. Products may contain no more than 1 pound or 0.5 kilogram of rodenticide bait.

 4. The product shall only be distributed to or sold to pest control operators (PCOs) and not to be sold in "consumer" stores, including drug stores, grocery stores, hardware stores, club stores, and similar retail outlets.

5. Products containing these active ingredients shall only be available for commercial use and for residential use by PCOs.

# 2. Naphthalene

Naphthalene is a white, crystalline solid with a characteristic odor. It is used indoors as a moth repellent, and placed in closed drawers, closets, and other storage areas.

In humans, hemolytic anemia is the most common manifestation of naphthalene toxicity. Prominently, individuals deficient in Glucose-6-phosphate dehydrogenase (G6PD) are more susceptible to the effects of naphthalene. In the US, the EPA does not permit the marketing of loose mothballs, thus requiring the containerisation of flakes and loose mothballs to reduce the risk of ingestion by children.

Locally, the National Poison Management and Control Center had recorded fifteen (15) cases on moth ball poisoning referred via hotline and two (2) cases admitted at Philippine General Hospital for the year 2019-2023. In order to prevent further incidents, companies should take product stewardship steps (US EPA RED)<sup>5</sup> to ensure that products are packaged in a way that

would discourage children from eating the product. Other formulation and packaging types may be considered. The following restrictions will apply for this product:

Restrictions:

- 5 The products shall be -
- 6 1. Sold in sachets with a tear- and moisture-resistant wrapping material
- 7 2. Packaged in plastic containers that allow for volatilization, but which would prohibit direct contact with naphthalene.
  - 3. Formulated into larger sized cake or block products (minimum of 2.5 inches in diameter). This must also be enclosed in plastic, metal or cardboard packaging while in use.

### D. Adoption of ASEAN Cosmetic Directive (ACD)

The FDA decision to include the ingredients and their restriction in ACD Annexes II and VI through the FDA Circular No. 2017-015 was made after careful evaluation of their toxicological data and in consideration of the aggregate exposures of consumers to the identified ingredients.

Upon further review of the said adoption, the ban imposed on ingredients included Annex II is retained, while substances intended to be the AI of HUP formulations may be allowed subject to existing restrictions and evaluation during registration. Meanwhile, ingredients included in Annexes III, IV and VI are recommended to be re-categorized as restricted ingredients in the "List of Banned and Restricted Pesticides and Ingredients in HUPs" which shall be used in accordance with the identified conditions set in the respective annexes.

#### **References:**

1 2

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- 3 1. US EPA. Restrictions Rodenticide on Products, 4 https://www.epa.gov/rodenticides/restrictions-rodenticide-5 products#:~:text=Second%2Dgeneration%20anticoagulants%20registered%20in,is%20toxi c%20in%20other%20ways. 6
- 2. US EPA. Rodent Control Pesticide Safety Review, https://www.epa.gov/rodenticides/rodent-control-pesticide-safety-review 8
- "Mouse 9 poisons EPA. and rat in pellet form banned", https://www.epa.gov/safepestcontrol/mouse-and-rat-poisons-pellet-form-10 banned#:~:text=Products%20marketed%20to%20residential%20consumers%20may%20co 11 ntain%20no%20more%20than,bromadiolone%2C%20difenacoum%2C%20and%20difethi 12 alone. 13
  - 4. US EPA. PRN 94-7: Label Improvement Program for the Revision of Use Directions for Commensal Rodenticides and Statement of the Agency's Policies on the Use of Rodenticide Stations. https://www.epa.gov/pesticide-registration/prn-94-7-label-improvementprogram-revision-use-directions-commensal
  - 5. US EPA (2008) Reregistration Eligibility Decision (RED) for Naphthalene

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