



EMB MEMORANDUM CIRCULAR
No. 2020 **0-05**

FEB 12 2020

SUBJECT: DATA REQUIREMENTS FOR PRE-MANUFACTURE AND PRE-IMPORTATION NOTIFICATION (PMPIN) PROCEDURES

Pursuant to Republic Act 6969 otherwise known as the “Toxic Substances and Hazardous and Nuclear Wastes Control Act of 1990”, and DENR Administrative Order (DAO) No. 29, Series of 1992, the “Implementing Rules and Regulations of Republic Act 6969”, this Order is hereby issued to provide consolidated Rules and Regulations for submissions of data for new chemicals under the Pre-Manufacture and Pre-Importation Notification (PMPIN) process.

Section 1. Policy and Objectives

It is the policy of the State to regulate, restrict or prohibit the importation, manufacture, processing, sale, distribution, use and disposal of chemical substances and mixtures that present unreasonable risk and/or injury to health or the environment. Pursuant to this policy statement, this Order aims to provide the complete data requirements for assessment and evaluation of new chemicals.

Section 2. Definition of Terms

As used in this Order, the following terms are hereby defined:

- 2.1 Abbreviated Form – Form used for new chemicals that are already listed in the chemical inventories of either US, Canada, Japan, Australia, Europe, and/or Korea.
- 2.2 Article – A manufactured item: (1) which is formed to a specific shape or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design.
- 2.3 Bureau – refers to the Environmental Management Bureau of the Department of Environment and Natural Resources.
- 2.4 CAS RN – refers to the Chemical Abstract Service Registry Number, which is a unique identifying number adopted by the Chemical Abstract Service to number chemicals and to assign them a running number as accepted in the CAS databank.

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- 2.5 Department – refers to the Department of Environment and Natural Resources
- 2.6 Detailed Form – Form used for new chemicals not listed in the chemical inventories of neither US, Canada, Japan, Australia, Europe, nor Korea
- 2.7 Importer – any local juridical person or corporation that undertakes the entry of a product or substance into the country.
- 2.8 IUPAC Nomenclature – systematic method of naming organic and inorganic chemical compounds as recommended by the International Union of Pure and Applied Chemistry (IUPAC).
- 2.9 Lethal Concentration 50 (LC50) – lethal concentration required to kill 50% of the test population.
- 2.10 Lethal Dose 50 (LD50) – the lethal dose at which 50% of the test population is killed in a given period of time
- 2.11 Manufacturer – any juridical person or corporation that undertakes the physical or chemical transformation of chemical(s) already listed in the Philippine Inventory of Chemicals and Chemical Substances (PICCS) into a new chemical.
- 2.12 Material Safety Data Sheet / Safety Data Sheet (MSDS/SDS) – refers to a detailed informational document prepared by the supplier, manufacturer or importer of a chemical/product. Information in the SDS includes physicochemical, toxicological, and environmental properties of the chemical/product, as well as safety procedures, spills, leaks, storage, handling, and regulatory information.
- 2.13 Naturally-occurring substances – any chemical substance that is naturally occurring and (1) is unprocessed or processed only by manual, mechanical or gravitational means; or by dissolution in water or by flotation or by heating solely to remove water; and (2) extracted from air by any means. It includes raw agricultural commodities, water, air, natural gas, crude oil, rocks, ores and minerals.
- 2.14 New Chemical – a chemical not yet listed in the PICCS
- 2.15 Notifier – local person(s) or entities engaged in importation or manufacture of new chemicals, and whose name will be indicated on the issued permit.
- 2.16 Philippine Inventory of Chemicals and Chemical Substances (PICCS) – refers to the updated list of chemicals and chemical substances currently being imported and/or manufactured and assessed by the Department
- 2.17 Premises - shall include, but not limited to, buildings or parts of buildings, tents, stalls or other facility structures whether permanent or temporary.

Section 3. General Procedure

The following are the procedures for notification of new chemicals under the PMPIN process. New chemicals are required for notification under DENR Administrative Order (DAO) No. 29, Series of 1992, the “Implementing Rules and Regulations of Republic Act 6969”. In support to EMB Memorandum Circular 2016-003, all PMPIN applications shall be applied to the Online Permitting and Monitoring System (OPMS) website.

3.1 Abbreviated Form

The notifier shall register using the Abbreviated Form if he/she is applying for a new chemical already listed in either of the chemical inventories of US, EU, Australia, Japan, Canada and/or Korea.

- 3.1.1 The company shall submit a duly accomplished and notarized Abbreviated Form (see instructions in Annex A). The signatory should be the President/CEO/General Manager or an authorized representative of the notifying company.
- 3.1.2 The company shall submit a Material Safety Data Sheet (MSDS)/Safety Data Sheet (SDS) of the new chemical.
- 3.1.3 The company shall submit scientific literatures, reports or tests for physico-chemical, toxicological, and environmental properties compliant with Good Laboratory Practices (GLP).

3.2 Detailed Form

The notifier shall register using the Detailed Form if he/she is applying for chemicals not applicable with Section 3.1.

- 3.2.1 The company shall submit a duly accomplished and notarized Detailed Form (see instructions in Annex B). The signatory should be the President/CEO/General Manager or an authorized representative of the notifying company.
- 3.2.2 The company shall submit a Material Safety Data Sheet (MSDS)/Safety Data Sheet (SDS) of the new chemical.
- 3.2.3 The company shall submit tests for physico-chemical, toxicological, and environmental properties compliant with Good Laboratory Practices (GLP).

Section 4. Specific Requirements

The following specific requirements for each application should be written on the notarized application forms.

4.1. Application Details

- 4.1.1 Name and address of the notifier
- 4.1.2 Proper chemical name/CAS registered chemical name/IUPAC name
- 4.1.3 CAS RN (if available)
- 4.1.4 Chemical and molecular structure
- 4.1.5 Trade Name
- 4.1.6 Anticipated weight in kilograms per annum of the chemical substance being imported or manufactured by the notifier
- 4.1.7 100% composition of product with complete CAS RN; wherein the new chemical is a component of the product being imported
- 4.1.8 Intended use of the chemical

4.2. Physicochemical Properties



- 4.2.1 Appearance and color
- 4.2.2 Odor
- 4.2.3 Boiling Point/Range
- 4.2.4 Melting Point/Range
- 4.2.5 Specific Gravity/Density
- 4.2.6 Vapor Pressure
- 4.2.7 Water/octanol partition coefficient
- 4.2.8 Flammability
- 4.2.9 Solubility in water and other solvents
- 4.2.10 Known stability and incompatibilities

4.3. Toxicological and Environmental/Ecological Properties

- 4.3.1 Acute oral and dermal toxicities in terms of Lethal Dose 50 (LD50)
- 4.3.2 Acute inhalation toxicity in terms of Lethal Concentration 50 (LC50)
- 4.3.3 Chronic toxicity
- 4.3.4 Irritation on skin and eyes
- 4.3.5 Respiratory/skin sensitization
- 4.3.6 Carcinogenic, teratogenic and mutagenic properties
- 4.3.7 Acute toxicities for either fish, invertebrates and/or algae in terms of LC50/EC50
- 4.3.8 Degradability
- 4.3.9 Bioaccumulation and persistence

4.4. For Detailed applications, the Physicochemical, Toxicological and Environmental/Ecological Properties should be accompanied with laboratory tests.

Section 5. Confidential Business Information

The confidentiality of information shall be consistent with Section 40 of DAO 92-29. The following are additional procedures/information required for notifications where certain information are requested to be considered confidential by the notifier or their supplier, due to confidential information regarding trade secrets (formulations). The PMPIN Certificate to be issued shall only indicate the name of the product they will be importing.

- 5.1 In the case of importation of a new chemical in a mixture, the company shall submit an updated and adequate Material Safety Data Sheet (MSDS)/Safety Data Sheet (SDS) of the product where the new chemical is a component.
- 5.2 The company shall submit 100% composition of the product to be imported, including all the CAS RN of the components of the product. The physicochemical, toxicological and environmental properties of the new chemical shall also be submitted. In case of confidentiality of the information, the supplier or manufacturer may submit a duly accomplished Confidential Business Information Form (Annex C) along with the data subject to requirements to the Bureau by mail or email at chemicals@emb.gov.ph and corresponding justification

Section 6. Chemical Review Committee (CRC)

For applications for new chemicals under the Detailed Form, a Chemical Review Committee shall be invited to evaluate the new chemicals. This technical working group shall include but not limited to representatives of the academe and other regulatory agencies (specifically those possibly involved with the new chemical).

Section 7. Justification of Information

If the notifier is unable to supply information for application(s) due to physicochemical-based constraints of the chemical itself, the notifier shall submit a position paper on why the information on the chemical cannot possibly be supplied, with references to published and peer-reviewed articles, journals and books. This also applies to given information based on "similar substances". The validity shall be evaluated by the Chemical Review Committee (CRC), if needed.

Section 8. Issuance of Certificate

Assessment of the new chemical shall be ninety (90) working days for Abbreviated Form and one hundred and twenty (120) working days for Detailed Form.

After assessment of the new chemical, the Department shall issue a PMPIN Compliance Certificate, or a letter. A letter shall be issued on the basis of non-compliance of the notifier to the information required by the Department. After three (3) months of non-compliance, reapplication will be needed.

The company shall submit a Notice of Commencement (NOC) after the first importation of the new chemical. Submission shall include Filled-up NOC Form, Bill of Lading/Airway Bill/Seaway Bill, Import Entry Tax Declaration, signed PMPIN Certificate, and Proforma Invoice or Commercial Invoice. The product name or the new chemical must be reflected in the document of entry.

Section 9. Listing of new chemicals in the PICCS

After receipt of the Notice of Commencement, the new chemical shall be listed in the public PICCS after a year, unless requested for Confidential Business Information (CBI). Notifiers will be invited every year for clarification and updates.

Section 10. Exemption from PMPIN

The following substances are not required for reporting/nomination for inclusion in PICCS through the PMPIN:

- 10.1 Articles
- 10.2 Naturally-occurring substances
- 10.3 Radioactive substances, and finished products (pesticides, drugs, foodstuff, and cosmetics) that are regulated by other laws in the Philippines

Section 11. Capacity Building

In support to the effective implementation of this Order, continuing training and information, education and communication (IEC) efforts on notification of new chemicals for both regulated community and regulators shall be undertaken

Section 12. Revision of Requirements

The Department may amend, modify, and/or supplement the requirements and standards in this Circular after prior consultation with the stakeholders and after due notice and hearing with the public on matters to be revised. The Bureau Director may issue clarificatory guidelines, if necessary.

Section 13. Penalty Provision

Any falsification of information or violation of the requirements specified in this Order shall subject the person(s) liable thereof to the applicable administrative and criminal sanctions as provided for under Sections 41 and 43 of DAO 92-29.

Section 14. Separability Clause

All provisions in the DENR Administrative Order (DAO) No. 29, Series of 1992, and other issuances inconsistent herewith are deemed repealed, superseded and/or modified accordingly. Should any provisions or portion of this Order be declared unconstitutional or invalid, all the other provisions of this Order shall remain valid and enforceable.

Section 15. Effectivity

This Memorandum Circular shall take effect fifteen (15) days after its publication in a newspaper of general circulation and upon acknowledgment of receipt of a copy thereof by the Office of the National Administrative Register (ONAR), UP Law Center.


ENGR. WILLIAM P. CUÑADO
OIC-Director

 Department of Environment and
Natural Resources
ENVIRONMENTAL MANAGEMENT BUREAU
Office of the Director

MC No. 2020-005



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PMPIN Abbreviated Form Instruction

Confidential Business Information (CBI). Mark if you claim CBI for any of the sections. Please provide in separate page the justification for claiming CBI and attach.

Section A. Fill in the information about the premise/firm that is considered the principal submitted of this form

Section B. Provide the chemical identify information. Consult DENR if you need assistance in obtaining the information required. It will expedite the review process if synonyms or analogues to the new chemicals can be presented. Otherwise attach the results of x-ray diffraction (non-organic chemicals) or Mass spectrum (organic chemicals) analysis to enable DENR review committee for correct identification of the chemical notified.

Section C. Estimate the total quantity of new chemical to be manufactured or imported during the first 12 months of operations. Estimate how much of the intended production or import will be used in any of the four categories on an annual basis. Industrial use is defined as any use during manufacturing and process operations. Commercial use is interpreted as any use aiming at consumer services.

Section D. (not applicable to importers) Estimate the type of activities the workers will be engaged in the use and production of the new chemical. For each type of activity provide information about the maximum number of workers and minimum hours per day that the will be exposed to the new chemical

Section E. Estimate the quantity of the new chemical that will possibly be released through air, surface water, groundwater and soil. Also, provide a brief statement regarding released control measures planned.

Section F. Submission of the Abbreviated Form is primarily based on the premise that the new chemical is used in another country with similar chemical review process as the Philippines. It is important that the notifier provides all the information required in this section to expedite the review process.

Section G. Provide any document describing the physicochemical characteristics of the new chemical notified. Documented research data from other countries will be helpful. Notifiers with such information will assist DENR to expedite the review process.

Section H. Present a short description of potential toxicological effects of the new chemical (if any) and provide any document describing those effects. Documented research data and journal articles from other countries will be helpful. Health effects data may include carcinogenicity, sensitization, acute toxicity and irritation. Notifiers with such information will assist DENR to expedite the review process.

Section I. Present a short description of potential environmental effects of the new chemical (if any) and provide any document describing those effects. Documented research data and journal articles from other countries will be helpful. Environmental effects may include acute and chronic toxicity to animals (fish in particular) and terrestrial plant toxicity. Information

concerning the fate of the chemical upon release to the environment will be important. Notifiers with such information will assist DENR to expedite the review process.

Section J. Provide the list of companies requesting to apply in joint with this application. Submit the contact person and details.

The abbreviated form will be automatically printed after filling up the appropriate fields in the Online Permitting and Monitoring System. You are advised to review the printed abbreviated form prior to notarization.

PMPIN Detailed Form Instruction

Confidential Business Information (CBI). Mark if you claim CBI for any of the sections. Please provide in separate page the justification for claiming CBI and attach.

Section A. Fill in the information about the premise/firm that is considered the principal submitted of this form

Section B. Provide the chemical identify information. Consult DENR if you need assistance in obtaining the information required. It will expedite the review process if synonyms or analogues to the new chemicals can be presented. Otherwise attach the results of x-ray diffraction (non-organic chemicals) or Mass spectrum (organic chemicals) analysis to enable DENR review committee for correct identification of the chemical notified.

Section C. Estimate the total quantity of new chemical to be manufactured or imported during the first 12 months of operations. Estimate how much of the intended production or import will be used in any of the four categories on an annual basis. Industrial use is defined as any use during manufacturing and process operations. Commercial use is interpreted as any use aiming at consumer services.

Section D. (not applicable to importers) Estimate the type of activities the workers will be engaged in the use and production of the new chemical. For each type of activity provide information about the maximum number of workers and minimum hours per day that the will be exposed to the new chemical

Section E. Estimate the quantity of the new chemical that will possibly be released through air, surface water, groundwater and soil. Also, provide a brief statement regarding released control measures planned.

Section F. Submission of information concerning the regulatory status of this chemical in other countries will expedite the review process.

Section G. Provide any test results on the physicochemical characteristics of the new chemical notified. Documented research data from other countries will be helpful. Notifiers with such information will assist DENR to expedite the review process. The test results should include: Boiling Point, Vapor Pressure, Melting Point, Purity, S. Gravity, Water/Octanol partition coefficient, solubility in water, and solubility in organic compounds

Section H. Present the test results of potential toxicological effects of the new chemical and provide any document describing those effects. Submit documented research data and journal articles from Philippines or other countries. When you submit the test results, ensure that the full name and address of the laboratory which conducted the tests in the Philippines or in other countries are clearly indicated. The health effects data may include carcinogenicity, sensitization, acute toxicity and irritation. Notifiers with such information will assist DENR to expedite the review process. DENR may require full testing of the new chemical notified if it determines that the information submitted in not adequate to assess the potential risk of the new chemical.

Section I. Present the test results of potential environmental effects of the new chemical and provide any document describing those effects. Submit documented research data and journal articles from Philippines or other countries will be helpful. When you submit the test results, ensure that the full name and address of the laboratory which conducted the tests in the Philippines or in other countries are clearly indicated. Environmental effects may include acute and chronic toxicity to animals (fish in particular) and terrestrial plant toxicity. Information concerning the fate of the chemical upon release to the environment will be important and must be submitted if available. Notifiers with such information will assist DENR to expedite the review process. DENR may require full testing of the new chemical notified if it determines that the information submitted is not adequate to assess the potential risk of the new chemical.

Section J. Provide the list of companies requesting to apply in joint with this application. Submit the contact person and details.

The detailed form will be automatically printed after filling up the appropriate fields in the Online Permitting and Monitoring System. You are advised to review the printed abbreviated form prior to notarization.

Confidential Business Information (CBI) Form

Substance Information

Trade/Product Name: _____

Exporter (Manufacturer/Supplier)

Company Name: _____

Company Address: _____

Contact Person: _____

Contact Number: _____

Email Address: _____

Importer (Applicant)

Company Name: _____

Company Address : _____

Contact Number: _____

Email Address: _____

CBI Request for documents submitted

- 100% Composition of Ingredients
- Laboratory Reports
- Sections marked in the submitted PMPIN
- Others: _____

Justification(s)

Signature over Printed Name
Contact Person

President/General Manager/

Date