

## Republic of the Philippines Department of Environment and Natural Resources ENVIRONMENTAL MANAGEMENT BUREAU

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Memorandum Circular No. \_\_\_\_\_ Series of 2019

SUBJECT: AMENDMENT TO EMB MEMORANDUM CIRCULAR 2016-011 TO

ALLOW THE ISSUANCE OF CERTIFICATION FOR CHEMICALS LISTED IN THE PHILIPPINE INVENTORY OF CHEMICALS AND

**CHEMICAL SUBSTANCES (PICCS)** 

Pursuant to Republic Act (RA) 6969 otherwise known as the Toxic Substances and Hazardous and Nuclear Wastes Control Act of 1990 and DENR Administrative Order (DAO) 1992-29: Implementing Rules and Regulations of RA 6969, the EMB Memorandum Circular (MC) 2016-011 is hereby amended to allow the issuance of Certification for chemicals listed in the Philippine Inventory of Chemicals and Chemical Substances (PICCS).

#### **Section 1.** Rationale

Despite the guidance under Section 2 of EMB MC 2014-001 that importers and manufacturers do not need to secure clearance from EMB for unregulated chemicals that are already listed in the PICCS and the instructions under Section 3 of EMB MC 2016-011 prohibiting EMB Regional Offices from issuing PICCS Certification, importers of chemicals continue to request for official confirmation from EMB for the same purpose. The volume of said requests had significantly increased following the issuance of BOC MC 2018-228 enforcing a more stringent customs verification procedure to all chemical importations for possible presence of controlled precursors and essential chemicals used to manufacture dangerous drugs. The EMB therefore deems the necessity to repeal the said prohibition, and thus allowing the issuance of the PICCS Certificate in order to mainstream the validation process.

#### Section 2. Objective

This Circular repeals the prohibition on EMB MC 2016-011, thereby allowing the issuance of the PICCS Certificate. This shall set forth the guidelines on the validation and issuance of PICCS Certificate.

#### **Section 3. Definition of Terms**

Unless otherwise specified, the following terms shall be used as defined by this Circular:

- 3.1. Article A manufactured item which: (i) is formed to a specific shape or design during manufacture, (ii) has end use function dependent in whole or in part upon its shape or design during the end use, and (iii) 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.
- 3.2. By-Product A chemical substance produced without separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture.
- 3.3. CAS Registry Index Name A name assigned to a chemical by the Chemical Abstract Service (CAS).
- 3.4. CAS Registry Number A unique identifying number by CAS to number chemicals and to assign them a running number as they are accepted in the CAS databank.
- 3.5. Chemical Substance Any organic or inorganic substance of a particular molecular identity, including: (i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature and (ii) any element or uncombined radical.

- 3.6. Impurity A chemical substance unintentionally present with another chemical substance. Impurities may be listed as by-product.
- 3.7. Mixture Any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of chemical reaction; except that such term does not include any combination which occurs, in whole or in part, as a result of a chemical reaction if none of the chemical substances comprising the mixture is a new chemical substance and if the combination could have been manufactured or imported for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined.
- 3.8. Naturally Occurring Substance Any chemical substance which is naturally occurring and: (i) is unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, or by heating solely to remove water; or (ii) is extracted from air by any means. This includes raw agricultural commodities; water, air, natural gas, and crude oil; and rocks, ores, and minerals.
- 3.9. New Chemical Any chemical substance imported into or manufactured in the country after December 31, 1993 and which is not included in the updated PICCS as published by the DENR.
- 3.10. Non-Chemical Substances Any substance that is not considered a "Chemical Substance" as defined in this Section.
- 3.11. Reaction Intermediate Any chemical substance that is consumed, in whole or in part, in chemical reactions used for the intentional manufacture of other chemical substances or mixtures, or that is intentionally present for the purpose of altering the rates of such chemical reactions.

#### Section 4. General Rules, Requirements, and Procedures

- 4.1. In accordance with DENR MC 2002-12, the function of validation and issuance of PICCS Certificate is delegated to the EMB Regional Offices.
- 4.2. The applicant shall submit the following requirements for evaluation:
  - (a) Notarized application form (Annex A);
  - (b) Copy of Business Permit;
  - (c) 100% composition with corresponding CAS Registry Index Name and Number of the chemical substance or each substance in the mixture if product is not a pure substance, duly certified by the manufacturer and updated within five (5) years;
  - (d) Safety data sheet (SDS) of the product updated within five (5) years following either GHS or ISO 16 sections format;
  - (e) Official Receipt for payment of processing fee; and
  - (f) Other documents as the circumstances and exigencies may require.
- 4.3. The following materials are not covered or exempted by the PICCS Certification:
  - (a) Non-chemical substances;
  - (b) Articles;
  - (c) Naturally occurring substances;
  - (d) Reaction intermediates;
  - (e) By-products or impurities that are less than or equal to 1.0% w/w concentration of the product mixture; or
  - (f) Radioactive substances, pesticides, drugs, foods, cosmetics, and consumer products that are regulated by other laws in the Philippines, unless the uses of the chemicals fall within the mandate of RA 6969.
- 4.4. If a material is claimed as one of the categories under Section 4.3, the EMB may require the importer to submit a written explanation or further justification for the basis for qualifying the material to such category.
- 4.5. The importer shall pay the processing fee as prescribed in DENR MC 2000-12 or revision thereof. For amendment, the importer shall pay the additional service fee as prescribed in DAO 2016-28 or revision thereof.

- 4.6. Evaluation and issuance of the PICCS Certificate shall be on the chemical substances of the product following the prescribed format in Annex B. For confidential claim on the product composition, refer to Section 5 of this Circular.
- 4.7. Issuance of the PICCS Certificate shall serve as confirmation that the chemical substances are listed in the PICCS and are not listed under the Priority Chemical List (PCL) and not regulated under Chemical Control Order (CCO) requirements.
- 4.8. If the chemicals are evaluated as new chemicals and/or regulated chemicals, the EMB shall issue a letter to the applicant denying its application for PICCS Certification and informing the required permits in accordance with EMB MC 2017-009, following the prescribed format in Annex C.

#### Section 5. Confidential Business Information

- 5.1. If the chemical composition of a product is classified by the manufacturer or supplier as Confidential Business Information (CBI), the importer shall submit the following in addition to the requirements of Section 4.2:
  - (a) Letter from the manufacturer or supplier identifying the specific information element(s) claimed as CBI and substantiating the claim including how disclosure to public would cause harm to the business's competitive position, reason for trade secrets, and confidentiality status in other countries, among others;
  - (b) Certification from the manufacturer or supplier on the validity period of the 100% composition signifying no reformulation of the product within the said duration. Should there be any reformulation of the product within the validity period that would add chemicals other than what is currently declared, the importer shall request for amendment of the Certificate for the new 100% composition; and
  - (c) Notarized Memorandum of Agreement (MOA) between the supplier and the importer indicating that the former is providing the right and accurate information to the EMB, while the latter accepts the liability in cases of injury or damage to public health and the environment and shall properly compensate the affected parties and/or restore damaged areas resulting from the handling and use of the imported product and disposal of its generated wastes.
- 5.2. Evaluation and issuance of the PICCS Certificate with CBI shall be on the product following the prescribed format in Annex D.
- 5.3. CBI documents may be disclosed by the manufacturer or supplier through either:
  - (a) Directly to the Toxic Chemical and Hazardous Waste Management Section of the EMB Regional Office with jurisdiction over the location of chemical storage or processing facility of the importer, or through its official email; or
  - (b) Directly to the Chemical Management Section of the EMB Central Office, or through its official email at chemicals@emb.gov.ph. The EMB Central Office will subsequently forward the CBI documents to the appropriate EMB Regional Office.

#### Section 6. Online Permitting and Monitoring System

The EMB shall develop and include the processing of PICCS Certificate into its Online Permitting and Monitoring System (OPMS) and shall implement the online Certification once the system becomes operational.

#### **Section 7.** Other Regulatory Requirements

The provisions in this Circular are without prejudice to other laws and regulations applicable to the applicant.

#### Section 8. Effectivity

This Circular shall take effect fifteen (15) after its publication in a newspaper of general circulation and its registration with the Office of the National Administrative Registry (ONAR).

## **Annex A. PICCS Application Form**

# PHILIPPINE INVENTORY OF CHEMICAL AND CHEMICAL SUBSTANCES (PICCS) APPLICATION FORM (Fill-out complete information, indicate if not applicable, and put check marks on tick boxes)

A.	Company Profile Company / Applicant Business Category	: (check o	ne or more categories as  Manufacturer Others, please s	
В.	- Company		refer to Section 5 require ant :nant :	ements)
	Chemical Name*	Trade / Generic Name	CAS Registry No.	% Composition in Product
		Tuille		Trouder
C.		to the best of my kn n the required docum A S F I		
SU iss	UBSCRIBED AND S'ued at	WORN to before management with the work with the work of the work with t	e, a Notary Public, in me his/her	on No
Pa Bo	oc. No. ge No. ook No. ries of			Notary Public

Code No.: PICCS-OL-Rxx-20xx-xxxx

## PICCS CERTIFICATE

By virtue of Republic A and Nuclear Wastes Control Ac 29 Series of 1992, a Certificate	t of 1990, as implemented by the	e Toxic Substances and Hazardous e DENR Administrative Order No.
Company Name: Office Address: Facility / Premise Address:		
(PICCS) requirements. This Cer	tificate hereby confirms that the CS and are NOT listed under the	nemicals and Chemical Substances following chemicals and chemical Priority Chemical List and NOT
Chemical Name	Trade / Generic Name	CAS Registry Number
Issued on invalid for causes and reasons of	, and shall remain valid unle of national interest or by the forc	ess otherwise nullified or declared e of law.
EMB Regional Director		
OR #: A	mount: P	OR Date:

#### **Annex C. Sample PICCS Application Denial Letter** (Date) (Managing Head) (Company Address) Attention: (Authorized Representative) **Denial of Application for PICCS Certificate** Subject: Dear **Mr. / Ms.** \_\_\_\_\_: This has reference to you application for Philippine Inventory of Chemicals and Chemical \_\_\_\_\_ with application no. \_ Substances (PICCS) Certification dated \_\_\_ Upon review of the documents submitted, we have the evaluation for the following chemicals: **Chemical Regulations** CAS Chemical $\overline{\text{PMPIN}}^2$ , **Registry** PICCS1 PCL<sup>4</sup> CCO<sup>5</sup> Name Requirements SQI<sup>3</sup> No. Water 7732-18-5 Not No compliance Listed Not new Not <u>regu</u>lated chemical listed needed ABC Not CAS Not listed Not Not Secure New regulated PMPIN or chemical listed registered SOI Clearance XYZ 123-45-6 Not listed New Not Not No compliance chemical listed regulated needed (confirmed impurity at $\leq 1.0\%$ Secure PCL Listed Listed Not Other Declared Not new chemical Compliance ingredients confidential regulated Certificate declared by supplier confidential by supplier Philippine Inventory of Chemicals and Chemical Substances <sup>2</sup>Pre-Manufacturing and Pre-Importation Notification <sup>3</sup>Small Quantity Importation <sup>4</sup>Priority Chemical List <sup>5</sup>Chemical Control Order In this regard, you application for PICCS Certificate is hereby denied subject to compliance of the above-mentioned EMB requirements under RA 6969.

Please be guided accordingly.

Very truly yours,

**EMB Regional Director** 

#### **CONFIDENTIAL**

Code No.: PICCS-OL-Rxx-20xx-xxxx

#### PICCS CERTIFICATE

	ntrol Act of 1990, as imp	plemented by the DENR Administrative Order to:	
Company Name: Office Address: Facility / Premise Addre	288:		_ _ _
(PICCS) requirements.	This Certificate herebated in the PICCS and ar	e Inventory of Chemicals and Chemical Substruction of Chemicals and Chemical Substruction of Chemical Substruction of Chemical Chemical Line NOT listed under the Priority Chemical Substruction of Chemicals and Chemical Substruction of Chem	of the
	(PRODU	CT NAME)	
within the validity peri	iod that would add che	manufacturer makes reformulation of the premicals substances other than what is curamendment of this Certificate for the new	rently
Issued on supplier, unless otherwork or by the force of law.	, and shall ise nullified or declared	remain valid until (validity period declar invalid for causes and reasons of national in	ed by iterest
EMB Regional Directo	r		
OR #:	Amount: P	OR Date:	