

**Extraordinary**



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**NAFDAC (CHEMICAL AND CHEMICAL PRODUCT)  
REGULATIONS, 2024**



**ARRANGEMENT OF REGULATIONS**

*Regulation :*

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**NAFDAC (CHEMICAL AND CHEMICAL PRODUCT)  
REGULATIONS, 2024**

[16th Day of October, 2024]

Commence-  
ment

In exercise of the powers conferred on the Governing Council of the National Agency for Food and Drug Administration and Control ("the Governing Council") by section 30 of the National Agency for Food and Drug Administration and Control Act, Cap. N1, LFN, 2004 and section 12 of the Food, Drugs and Related Products (Registration, Etc.) Act, Cap. F33. LFN, 2004 and all other powers enabling it in that behalf, the Governing Council, with the approval of the Minister, makes the following Regulations —

**PART I — OBJECTIVE AND APPLICATION**

1. The objective of these Regulations is to provide regulatory framework for the regulation of the chemical and chemical products manufactured, imported, distributed, sold or used in Nigeria.

Objective

2. These Regulations shall apply to the regulation and control of chemical and chemical products manufactured, imported, exported, advertised, sold, distributed or used in Nigeria.

Application

**PART II — CLASSIFICATION OF CHEMICAL AND CHEMICAL PRODUCTS, LABELLING,  
PACKAGING, HANDLING, STORAGE, DISTRIBUTION, DOCUMENTATION, ETC.**

3.—(1) Chemical and chemical products shall be classified into —

Classification  
of chemical  
and chemical  
products

(a) general chemical;

(b) restricted chemical;

(c) controlled chemical;

(d) agrochemical;

(e) chemical products; and

(f) any other classification as may be prescribed by the Agency.

(2) These Regulations takes into consideration various categories of chemical that falls under international chemical convention, protocol and treaty to which Nigeria is a signatory, as specified in the First Schedule to these Regulations.

4.—(1) A chemical manufacturer, importer or downstream user of any substance or mixture shall classify, label and package hazardous chemical before placing them on the market.

Classification,  
labelling and  
packaging  
(CLP)

(2) Any chemical and chemical product imported, distributed, manufactured, transported, sold or stored shall be labelled in accordance with these Regulations.

(3) A chemical and chemical product label shall not be described or presented —

(a) in a manner that is false, misleading, deceptive or likely to create an erroneous impression regarding its character, quality, quantity and origin; or

(b) by words, pictorial or any other means, which refer to any other product or suggest directly or indirectly that the chemical is connected with any other product.

(4) The label of a chemical and chemical product shall —

(a) be clear and legible in line with the six elements of United Nations Globally Harmonised System (GHS), written in English Language and may include any other language; and

(b) include the following requirements —

(i) product name or identifiers,

(ii) GHS symbols (hazard pictograms),

(iii) signal word,

(iv) manufacturer information,

(v) precautionary statements or first aid,

(vi) hazard statements,

(vii) date of manufacture,

(viii) expiry date, as appropriate,

(ix) batch number,

(x) net content, and

(xi) any other information as may be prescribed by the Agency.

(5) The design of packaging material of chemical and chemical product shall be made in a manner to minimise any risk or hazard that may likely occur during transportation and storage.

(6) A person shall not package chemical or chemical product except the packaging facility is approved by the Agency.

General  
requirements  
for dealing  
and handling  
chemical

5.—(1) Application for manufacturing, warehousing, exporting, importing, transporting or sales of chemical, shall contain the —

(a) description of the premises where the chemical is to be stored, produced and marketed;

(b) information on the equipment and facility to distribute, handle, process, and transport the chemical from the premises;

(c) qualification of the personnel who shall supervise the operations carried out; and

(d) contingency plans for chemical safety, chemical security, and procedures to deal with emergency as prescribed by the Agency.

(2) A health and safety management plan shall be put in place with the approval of the Agency.

(3) The chemical and chemical product shall be handled in a manner as to minimise any risk or hazard that may occur while handling it.

6. A facility used for the manufacture, storage, sale or distribution of chemical and chemical product shall —

- (a) be subject to GMP inspection by the Agency;
- (b) not be in a residential area, a densely populated area, airport or any other place as may be considered as unsuitable by the Agency;
- (c) have adequate production and safety facility; and
- (d) be supervised by personnel with requisite knowledge and qualification on manufacturing, safe handling and storage of the product.

Good  
Manufacturing  
Practice  
(GMP)

7.—(1) A person who manufactures, imports, exports, sells or distributes a chemical and chemical product shall keep up-to-date records of the product.

Documentation

(2) Safety Data Sheet of the chemical and chemical product shall be as specified in the Second Schedule to these Regulations.

8.—(1) Risk management plan for chemical and chemical product shall be established and compiled in line with these Regulations.

Risk  
assessment

(2) A person who manufactures chemical and chemical product in quantities greater than 1,000 tonnes per year shall submit to the Agency an annual report on Chemical Safety Assessment (CSA), to assess the hazards, risks to human health or environment and determine how to control the product by applying suitable risk management measures.

9. Chemical and chemical products shall be clearly and conspicuously labelled with precautionary statements written legibly and indelibly —

Precautionary  
statement

(a) directing the user to read the label before the use of the product, such as “READ THE LABEL BEFORE USE”;

(b) indicating —

- (i) that the chemical and chemical product shall not be ingested,
- (ii) that a person shall wear appropriate Personal Protective Equipment (PPE) while handling the chemical and chemical products,
- (iii) that the chemical and chemical product shall be kept out of reach of children, and
- (iv) warning or cautions, hazard statements and coloured band.

10.—(1) A chemical and chemical product shall be stored in accordance with the condition prescribed by the manufacturer in the Safety Data Sheet (SDS).

Storage and  
distribution

(2) Standard Operating Procedure for the distribution of chemical and chemical products shall be established, followed, and include a —

(a) procedure where the First Expired First Out (FEFO) rule is applied; and

(b) track and trace system where each of the chemical product is traceable to the manufacturer.

Adverse  
effect  
reporting

**11.** A person who manufactures, stores, sells or distributes any chemical and chemical product shall submit preliminary and final reports of any adverse effect associated with the chemical and chemical product, which occurs in Nigeria or elsewhere, to the Agency.

Revalidation

**12.** A person shall not carry out revalidation of any chemical and chemical product without the approval of the Agency.

Disposal

**13.** A manufacturer or user of chemical and chemical product shall ensure that disposal of expired, degraded or obsolete chemical and chemical product is carried out as prescribed by the competent authority designated for the purpose and in the presence of staff of the Agency.

Prohibition

**14.—(1)** Chemical and chemical products shall not be manufactured, imported, exported, stored, advertised, distributed except with a permit granted by the Agency.

(2) A person shall not manufacture, import, export, sell or distribute a chemical and chemical product except it is accompanied by a Safety Data Sheet (SDS) and the Globally Harmonized System of Classification (GHS) label, where applicable.

(3) A person shall not obstruct an officer of the Agency from accessing any facility where a chemical or chemical product is manufactured, stored, sold or distributed.

### PART III — OFFENCES AND PENALTIES

Offences and  
penalties

**15.—(1)** A person who contravenes any of the provisions of these Regulations commits an offence and is liable on conviction, in the case of —

(a) an individual, to imprisonment for a term not exceeding one year or to a fine not exceeding ₦800,000 or both; and

(b) a body corporate, to a fine not exceeding ₦5,000,000.

(2) Where an offence under these Regulations is committed by a body corporate, firm or any other association of individuals, every —

(a) director, manager, secretary or other similar officer of the body corporate;

(b) partner or officer of the firm;

(c) trustee of the body concerned;

(d) person concerned in the management of the affairs of the association; or

(e) person who purports to act in a capacity referred to in paragraphs (a) to (d) of this regulation,

is liable to be proceeded against and be punished for the offence and in the same manner as if the person committed the offence, unless the person proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

16.—(1) A person convicted of an offence under these Regulations shall forfeit to the Federal Government —

Forfeiture  
after  
conviction

(a) asset or property constituting proceeds derived from or obtained, directly or indirectly, as a result of the offence; and

(b) any of the person's property or instrument used in any manner to commit or to facilitate the commission of the offence.

(2) In this section, "proceeds" means any property derived or obtained, directly or indirectly, through the commission of the offence.

17. The Agency shall be responsible for the enforcement of these Regulations.

Enforcement  
of these  
Regulations

18. In these Regulations —

Interpretations

"Agency" means National Agency for Food and Drug Administration and Control (NAFDAC);

"chemical" means any substance, mixture of substances prepared, element in its pure form or a substance in an article sold or in any form whether by itself or in a mixture or preparation, whether manufactured or obtained naturally or represented for domestic or industrial use such as raw material, finished or semi-finished product, laboratory reagent, industrial chemicals, diagnostic reagent, ink, cleaning chemicals, construction chemicals, oil servicing and drilling chemicals, adhesive, wood polishers and preservatives and excludes medicines, radioactives, food additives and any other substance with therapeutic effects;

"chemical product" means a substance that is formed as a result of a chemical reaction to yield one or more products such as cleaning chemical, paint, adhesive, wood preservative and polisher, photographic chemical, agrochemical, biocide, fertilizer or car care chemical;

"controlled chemical" means any precursor chemical and solvent listed under the 1988 UN Convention Against Illicit Traffic of Narcotic drugs and Psychotropic Substances and any other nationally controlled chemical;

"general chemical" means industrial and laboratory chemical and reagents;

“GHS” means Globally Harmonized System of Classification and Labelling of Chemicals developed by the United Nations;

“Good Manufacturing Practice (GMP)” means the part of quality assurance which ensures that any product is consistently produced and controlled to the quality standard appropriate to the intended use and as required by the Certificate of Registration;

“label” includes any written, printed, tag, mark, pictorial, other descriptive matter, embossed or impressed on, or attached to a container of chemical or chemical product;

“labelling” includes any written, printed or graphic matter that is present on the label, accompanying chemical and chemical product, including that for the purpose of promoting its sale or disposal;

“package” means any form of suitable container (packaging material) in which any chemical and chemical product is packed for sale as a single item;

“proceeds” means any property derived or obtained, directly or indirectly, through the commission of an offence;

“restricted chemical” means any chemical listed under 1987; Chemical Weapons Convention, 2004; Stockholm Convention on POPs, 1989; Montreal Protocol on Ozone Depleting Substances (ODS), 2004; Rotterdam Convention on Prior Informed Consent (PIC), Minamata Convention on Mercury, Basel Convention on the control of Transboundary Movements of Hazardous Wastes and their Disposal and any other restricted chemical; and

“signal word” means hazard level (danger or warning).

Citation

19. These Regulations may be cited as the Chemical and Chemical Product Regulations, 2024.

## FIRST SCHEDULE

[regulation, 3(2)]

INTERNATIONAL CHEMICAL CONVENTIONS,  
TREATIES AND PROTOCOLS

1. The Chemical Weapons Convention (CWC) is a convention on the prohibition of the development, production, stockpiling and use of chemical weapons and on their destruction, adopted on 13th January, 1993.

2. The Basel Convention is a convention on the control of trans boundary movements of hazardous waste and their disposal, signed on 22nd March, 1989.

3. The Bamako Convention is a treaty of African nations prohibiting the import of any hazardous waste, adopted in January 1991.

4. Rotterdam Convention is a multilateral treaty to promote shared responsibilities in relation to importation of hazardous chemical, signed on 10th September, 1988.

5. Stockholm Convention on Persistent Organic Pollutants is an international environmental treaty, signed on 22nd May, 2001 in Stockholm.

6. The Montreal Protocol is an international treaty designed to protect the ozone layer by phasing out the production of numerous substances that are responsible for ozone depletion, adopted on 16th September, 1987.

7. Vienna Convention for the Protection of the Ozone Layer signed on 22nd March, 1985.

8. The Minamata Convention on Mercury is an international treaty designed to protect human health and the environment from anthropogenic emissions and release of mercury and mercury compounds, adopted on 19th January, 2013.

## BRIEF DESCRIPTION OF THE CONVENTIONS

9.—(1) The Chemical Weapons Convention (CWC) —

(a) is officially the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction, and an arms control treaty administered by the Organization for the Prohibition of Chemical Weapons (OPCW), an intergovernmental organization based in the Hague, Netherlands;

(b) commenced on 29 April 1997, and prohibits the large-scale use, development, production, stockpiling and transfer of chemical weapons and their precursors; and

(c) substances under the convention include —

- (i) DEA (Diethanolamine),
- (ii) TEA (Triethanolamine),
- (iii) MEA (Monoethanolamine), and
- (iv) Enriched OASE White.

(2) The Basel Convention on the Control of Trans boundary Movements of Hazardous Wastes and their Disposal —

(a) adopted on 22 March, 1989 by the Conference of Plenipotentiaries in Basel, Switzerland, in response to a public outcry following the discovery, in the 1980s, in Africa and other parts of the developing world of deposits of toxic wastes imported from abroad and commenced on 5th May, 1992; and

(b) substances covered under the conventions include —

- (i) hazardous wastes that are explosive,
- (ii) flammable,
- (iii) poisonous,
- (iv) infectious,
- (v) corrosive, and
- (vi) toxic, or ecotoxic.

(3) The Bamako Convention is a treaty of African nations prohibiting the import of any hazardous waste, negotiated by twelve nations of the Organisation of African Unity at Bamako, Mali in January 1991, and commenced in 1998.

(4) Rotterdam Convention —

(a) is a multilateral treaty to promote shared responsibilities in relation to importation of hazardous chemical;

(b) promotes open exchange of information and calls on exporters of hazardous chemical to use proper labeling, include directions on safe handling and inform purchasers of any known restriction or ban and signed in Rotterdam, the Netherlands on 10th September 1988 and commenced on 24th February, 2004; and

(c) substances covered under the convention include —

- (i) Alachlor,
- (ii) DDT,
- (iii) Polybrominated biphenyls (PBB),
- (iv) Polychlorinated biphenyls (PCB),
- (v) Polychlorinated terphenyls (PCT),
- (vi) Tetraethyl lead, and
- (vii) Tetramethyl lead.

(5) Stockholm Convention on Persistent Organic Pollutants —

(a) is an international environmental treaty, signed on 22nd May, 2001 in Stockholm and commenced on 17th May, 2004, to eliminate or restrict the production and use of persistent organic pollutants; and

(b) substances under the conventions are —

(i) pesticides such as aldrin, chlordane, DDT, dieldrin, endrin, heptachlor, hexachlorobenzene, mirex, toxaphene,

(ii) industrial chemicals such as hexachlorobenzene, Polychlorinated Biphenyls (PCBS), and

(iii) by-products such as dibenzo-p-dioxins and Polychlorinated Dibenzofurans (PCDD or PCDF), and PCBs.

(6) The Montreal Protocol —

(a) is an international treaty designed to protect the ozone layer by phasing out the production of numerous substances that are responsible for ozone depletion;

(b) agreed on 16th September, 1987 in Montreal, Canada and commenced on 1st January, 1989; and

(c) substances under the treaty include —

(i) Chlorofluorocarbons (CFCs),

(ii) Halons,

(iii)  $\text{CCl}_4$  (Carbon tetrachloride),

(iv)  $\text{CH}_3\text{CCl}_3$  (Methyl chloroform),

(v) Hydrochlorofluorocarbons (HCFCs),

(vi) Hydrobromofluorocarbons (HBFCs), and

(vii) Methyl bromide ( $\text{CH}_3\text{Br}$ ) (horticultural uses).

(7) Vienna Convention for the Protection of the Ozone Layer is a multilateral environmental agreement signed on 22nd March, 1985 in Vienna, that provides framework for international reduction in the production of chlorofluorocarbons due to their contribution to the destruction of the ozone layer, resulting in an increased threat of skin cancer.

(8) The Minamata Convention on Mercury is an international treaty designed to protect human health and the environment from anthropogenic emissions and release of mercury and mercury compounds, approved by delegates representing close to 140 countries on 19th January, 2013 in Geneva and adopted and signed on 10th October, 2013.

SECOND SCHEDULE

[regulation, 7]

SAFETY DATA SHEET INFORMATION

- Section 1 : Identification or Name
- Section 2 : Hazard Identification
- Section 3 : Composition or Information on Ingredients
- Section 4 : First-Aid Measures
- Section 5 : Fire-Fighting Measures
- Section 6 : Accidental Release Measures
- Section 7 : Handling and Storage
- Section 8 : Exposure Controls and Personal Protection
- Section 9 : Physical and Chemical Properties
- Section 10 : Stability and Reactivity
- Section 11 : Toxicological Information
- Section 12 : Ecological Information
- Section 13 : Disposal Considerations
- Section 14 : Transport Information
- Section 15 : Regulatory Information
- Section 16 : Other Information

MADE at Abuja this 16th day of October, 2024.

MUHAMMAD ALI PATE, CON  
*Coordinating Minister of Health  
and Social Welfare*