



**NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND
CONTROL (NAFDAC)**

CHEMICAL AND CHEMICAL PRODUCTS REGULATIONS, 2020

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(ending 2nd February, 2021).**

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CHEMICAL AND CHEMICAL PRODUCTS REGULATIONS, 2020

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CHEMICAL AND CHEMICAL PRODUCTS REGULATIONS, 2020

[] Commencement

In exercise of the powers conferred on it Sections 5 and 30 of the National Agency for Food and Drugs Administration and Control Act Cap N1 Laws of the Federation of Nigeria (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 of the National Agency for Food and Drug Administration and Control with the approval of the Honorable Minister of Health makes the following Regulations –

1. Scope of Application

These Regulations prescribe the minimum requirements for importation, exportation, manufacture, advertisement, storage, sale or distribution of chemicals and chemical products.

2. Prohibition

- (1) No chemical or chemical product shall be manufactured, imported, exported, stored, advertised, distributed unless permit has been granted as appropriate in accordance with the provisions of these Regulations except as provided in these Regulations .
- (2) A person shall not manufacture, import, export, sale or distribute a chemical or chemical Products unless it is accompanied by a Safety Data Sheet (SDS) and Globally Harmonized System of Classification (GHS) label.
- (3) No person shall obstruct officers of the Agency the access to facilities where chemical or chemical products are manufactured, stored, sold or distributed.

3. Classification of Chemical and Chemical product

Chemical and chemical products shall be classified as appropriate into:

- (a) general chemicals
- (b) restricted chemicals
- (c) controlled chemicals
- (d) chemical products
- (e) and any other classification as may be prescribed by the Agency

4. Chemical Conventions, Protocols and Treaties

These Regulations takes cognizance of all categories of chemicals that falls under international Chemical Conventions, Protocols and Treaties that Nigeria is a signatory.

5. Classification, Labelling and Packaging (CLP)

CLP is applicable to all chemical manufacturers, importers or downstream users of substances or mixtures to classify, label and package their hazardous chemicals appropriately before placing them on the market.

6. Labeling

- (1) All chemicals and chemical products imported, distributed, manufactured, transported, sold, stored shall be labelled.
- (2) Chemicals and chemical products labels shall not be described or presented
 - (a) in a manner which is false, misleading, deceptive or is likely to create an erroneous impression regarding its character, quality, quantity and origin;
 - (b) by words, pictorial or other means which refer to any other product or suggest either directly or indirectly that the chemical is connected with such other products.
- (3) The label of a chemical substance shall be legible in line with the six elements of United Nations Globally Harmonized System (GHS) label written in English Language and may include Nigerian language(s) and shall include the following requirements.
 - (a) product Name or Identifiers
 - (b) GHS symbols (hazard pictograms)
 - (c) Signal Word
 - (d) manufacturer information
 - (e) precautionary statements/first aid
 - (f) hazard statements
 - (g) date of manufacture
 - (h) expiry date (as appropriate)
 - (i) batch number
 - (j) net content
 - (k) and any other information as may be prescribed by the Agency.

7. Packaging

- (1) The design of packaging material for chemicals and chemical products shall be made in a manner to minimize any risk or hazards that may occur during transportation and storage.
- (2) A person shall not engage in packaging of any chemicals or chemical products unless the packaging facility is approved by the Agency.

8. General requirements for dealers and handlers of chemicals

The application for manufacturing, warehousing, exporting, importing, transporting or sales of chemicals, shall contain

- (a) the description of premises on which the chemicals will be stored, produced and marketed;
- (b) the equipment and facilities for distributing, handling, processing, and transporting chemicals from the premises;
- (c) the qualifications of the personnel under whose direct supervision those operations will be carried out;
- (d) contingency plans for chemical safety, chemical security, and procedures for dealing with emergency in a format as prescribed by the Agency; and

9. Good Manufacturing Practice (GMP)

- (1) All facilities used for the manufacture, storage, sale or distribution of chemicals and chemical products shall
 - (a) be subjected to GMP inspection by the Agency for the purpose of approval.
 - (b) not be in a residential area.
 - (c) have adequate production and safety facilities are provided.
 - (d) be supervised by personnel with adequate knowledge of the science of manufacture and safe handling and storage of such products.

10. Documentation

- (1) All persons engaged in the manufacture, importation, exportation, Sale, distribution, of chemical and chemical products shall maintain adequate records.

- (2) Safety Data Sheet of the chemical and chemical product which shall bear the following 16 Section.
 - Section 1: Identification/Name
 - Section 2: Hazard Identification
 - Section 3: Composition/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

11. Risk Assessment

- (a) A risk Management Plan for Chemical and Chemical Products shall be established and complied in line with these Regulations.
- (b) Chemical substances manufacture in quantities greater than 1,000 tonnes per year shall submit annual report on Chemical Safety Assessment (CSA) to assess the hazards, risks to human health, environment and to determine how to control them by applying suitable risk management measures.

12. Storage and Distribution

- (1) Chemical and chemical products shall be stored under conditions indicated by manufacturer as specified in the SDS.
- (2) Standard Operating Procedures for the distribution of chemicals and Chemical Products shall be established, followed and include:
 - (i) a procedure whereby the First Expired First Out (FEFO) rule is applied.
 - (ii) a track and trace system whereby each of the chemical products can be traceable to the manufacturer.

13. Mandatory Problem reporting (Adverse effect reporting)

All facilities engaged in the manufacture, importation, exportation or distribution of chemical and chemical products shall submit preliminary and final reports to the Agency of any adverse effect associated with the chemical and chemical product occurring in Nigeria and elsewhere.

14. Revalidation

A person shall not carry out the revalidation of any chemical and chemical products without the Agency's approval.

15. Disposal

Disposal of any expired, degraded and obsolete chemical and chemical products shall be carried out by an approved government body in presence of a staff of the Agency.

16. Offences and Penalties

- (1) Any person who contravenes any of the provisions of these Regulations, commits an offence and shall be liable on conviction, in case of -
 - (a) an individual, to imprisonment for a term not exceeding one year or to a fine not exceeding N800,000.00 or to both; and
 - (b) a body corporate, to a fine not exceeding N5,000,000.00.
- (2) Where an offence under these Regulations is committed by a body corporate, firm or 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 sub-regulation, is severally liable to be proceeded against and punished for that offence in the same manner as if he had himself committed the offence, unless he proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

17. Forfeiture after conviction

Any person convicted of an offence under these Regulations shall forfeit to the Federal Government-

- (a) any 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 instrumentalities used in any manner to commit or to facilitate the commission of the offence.

18. Interpretations

In these Regulations unless the context otherwise requires:

Agency means a substance National Agency for Food and Drug Administration and Control;

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/semi-finished product, laboratory reagent, industrial chemicals, diagnostic reagent, ink, cleaning chemicals, construction chemicals, oil servicing and drilling chemicals, adhesive, wood polishers and preservatives but excludes medicines, radioactives, food additives and any other substance that has 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 chemicals, paint, adhesives, wood preservatives & polishers, photographic chemicals, agrochemicals, biocides, fertilizers, car care chemicals.

Controlled Chemicals means precursor chemicals and solvents listed under the 1988 UN Convention against illicit traffic of Narcotic drugs and Psychotropic substances and other nationally controlled chemicals.

General Chemicals means industrial and laboratory chemical and reagents.

GHS means Globally Harmonized System of Classification and Labelling of Chemicals (GHS) developed by the United Nations.

Good Manufacturing Practice (GMP) means that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the Certificate of Registration.

Label includes any written, printed, tag, or 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 chemicals and chemical products, including that for the purpose of promoting its sale or disposal.

Package means any form of suitable container (packaging material) in which chemicals and chemical products are packed for sale as a single item.

Proceeds means any property derived or obtained, directly or indirectly, through the commission of the offence.

Restricted Chemicals are chemicals 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 other restricted chemicals.

Signal word means hazard level (Danger or Warning) ;

19. Citation

This Regulations shall be cited as the Chemical and Chemical Products Regulations, 2020

MADE at Abuja this day of 2020.

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