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Republic of the Philippines  
Department of Health  
**OFFICE OF THE SECRETARY**

**1<sup>ST</sup> DRAFT**

November 04, 2012

**ADMINISTRATIVE ORDER**  
No. \_\_\_\_\_ S. 2012

**SUBJECT:** Procedural Rules and Regulations Implementing the Globally Harmonized System (GHS) for Classification and Labeling of Household Hazardous Chemicals and Consumer Products Regulated by the Department of Health

Consumers are exposed to a wide variety of hazardous chemicals such as paints, dyes, cleaning products, ornamental plant and household pesticides, among others. Vulnerable groups which includes children, the elderly, pregnant and lactating women may also be exposed to chemical hazards through consumer products used in the home. Ensuring the provision of comprehensible information on consumer products so that they are used appropriately is the objective of hazard communication in this sector. In the consumer sector the label in most cases is likely to be the sole source of information readily available to consumers. The label, therefore, needs to be sufficiently clear and relevant to the use of the product.

Providing sufficient information to consumers in the simplest and most easily understandable terms presents a considerable challenge. The problems of making readily comprehensible information available to consumers are also made more difficult by the wide range of chemicals and uses in the home.

The current global situation for chemical classification and labeling have been diverse, misleading and conflicting between and among national and international institutions. In some cases, there is little or no system at all. The result is increased costs as well as potential increased risk to workers and consumers regarding the various hazards due to the differences in hazard communication methods. The GHS was created by the United Nations (UN) system to harmonize the different or lacking hazard classification and communication systems within a country and between countries and regions. It was also included in the United Nations Environment Programmes' Global Plan of Action under the Strategic Approach to International Chemicals Management (UNEP-SAICM).

The GHS System for classification and labeling of chemicals is an international policy on chemical safety regulations which is a harmonized, common and coherent approach in defining and classifying hazards, and communicating information on labels and safety data sheets. Target audiences include workers, consumers, transport workers, and emergency responders. It is envisioned that the implementation of the GHS will enhance protection of human health and the environment, promotes sound management of chemicals by promoting greater consistency across countries and facilitate trade by reducing the barriers of complying with multiple inconsistent classification and labeling schemes.

The Department of Health (DOH) provides the following policies and guidelines for the chemical classification and labeling of consumer products regulated under the Department, pursuant to but not limited to, among others, the following laws, rules and regulations:

1. Presidential Decree No. 881 entitled empowering the Secretary of Health to regulate the labeling, sale and distribution of hazardous substances
2. Administrative Order No. 311s. 1977 – Labeling requirement of Hazardous Substances
3. Republic Act No.7394 or the Consumer Act of the Philippines also known as “An act to ensure the safety and purity of foods, drugs, and cosmetics being made available to the public by creating the food and drug administration which shall administer and enforce the laws pertaining thereto”
4. Republic Act No. 9711 “An Act strengthening and rationalizing the regulatory capacity of the Bureau Of Food And Drugs (BFAD) by establishing adequate testing laboratories and field offices, upgrading its equipment, augmenting its human resource complement, giving authority to retain its income, renaming it the Food And Drug Administration (FDA), amending certain sections of Republic act no. 3720, as amended, and appropriating funds thereof”

Under the Joint DTI-DENR-DA-DOF-DOH-DILG-DOLE-DOTC Administrative Order no. 01 series of 2009, the DOH together with the Department of Trade and Industry have been assigned to develop and formulate the pertinent implementing rules and regulations adopting the GHS and its principles of application for specific consumer products it regulates.

It is in this regard, that the Department has formulated and developed the procedural rules and regulation for strengthening the implementation of GHS principles within its regulatory framework. It is envisioned that application of GHS principles in household hazardous chemicals and consumer product regulation will enhance protection of human health and the environment by providing clear and consistent label information to users, workers, the general public including vulnerable groups. The prevention of exposure to chemicals is a public health issue. Good hazard communication, together with the use of appropriate packaging, play an important part in exposure prevention

## II. OBJECTIVES

General Objective: To formulate and develop procedural rules and regulations in the implementation of GHS to appropriate household hazardous chemicals and consumer products (within the scope covered under the GHS) regulated by the Department

### Specific Objectives:

1. Institutionalize harmonized criteria for classifying substances and mixtures according to their health, environmental and physical hazards

2. Develop the procedural guidelines for the implementation of the GHS chemical hazard communication tools, as appropriate, for household hazardous chemicals and consumer products regulated by the Department, as follows:
  - a. Safety Data Sheets (SDS)
  - b. Labels
3. *Educate and promote awareness among consumers and manufacturers on GHS concepts and principles.*
4. Provide a feedback mechanism from the DOH poison centers and its emergency response units relative to hazard and precautionary information, especially on the first aid and specific treatments are appropriate.

### **III. Scope and Coverage**

The component parts of the GHS that will be covered in these rules and regulations shall include the following:

- harmonized criteria for classifying substances and mixtures according to their health, environmental and physical hazards; and
- harmonized hazard communication elements (pictograms, signal words, hazard statements and precautionary statements), including requirements for labeling and safety data sheets

These rules and regulations shall cover all household hazardous chemicals and consumer products regulated by the Department. Pharmaceuticals, food additives, cosmetics, and pesticide residues in food are not covered by the GHS in terms of labeling at the point of intentional intake. However, these types of chemicals are covered where workers may be exposed, and, in transport if potential exposure warrants. In addition, these guidelines shall not cover substances intended for use as fuels stored in containers, and used in heating, cooking or refrigeration system.

### **IV. Definition of Terms**

1. Chemicals - 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 chemical reaction or occurring in nature; and (ii) Any element or uncombined chemical.
2. Chemical identity – means a name that will uniquely identify a chemical. This can be a name that is in accordance with the nomenclature of the International Union of Pure and Applied Chemistry (IUPAC) or the Chemical Abstract Service or a technical name.
3. Chemical 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 a chemical reaction, if none of the chemical substances comprising the combination is a new chemical substance and if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined. This shall include non-biodegradable mixtures.

4. Corrosive – means any substance which on contact with living tissue will cause destruction of human tissue by chemical action.
5. Exposure - amount of chemical that is available for absorption into the body through possible routes of entry into the body i.e. inhalation, ingestion and skin absorption.
6. Department – refer to the Department of Health
7. Distributor/importer/exporter -means any establishment that imports or exports raw materials, active ingredients and/or finished products for its own use or for wholesale distribution to other establishments or outlets. If the distributor/importer/ exporter sells to the general public, it shall be considered a retailer.
8. Distributor/wholesaler - means any establishment that procures raw materials, active ingredients and/or finished products from local establishments for local distribution on wholesale basis.
9. Establishment - means a sole proprietorship, a partnership, a corporation, an institution, an association, or an organization engaged in the manufacture, importation, exportation, sale, offer for sale, distribution, donation, transfer, use, testing, promotion, advertising, or sponsorship of health products including the facilities and installations needed for its activities.
10. FDA – refer to the Food and Drug Administration
11. GHS – is an acronym for Globally Harmonized System for Classification and Labeling of Chemicals. The GHS is a United Nations (UN)-indorsed system for standardizing and harmonizing the classification and labeling of chemicals.
12. Importation- means the entry of a products or substances into the Philippines (through the seaports or airports of entry) after having been properly cleared through or still remaining under customs control, the product or substance of which is intended for direct consumption, merchandising, warehousing, or for further processing.
13. Irritant – means any substance which may on immediate, prolonged or repeated contact with normal living tissue induce a local inflammation reaction
14. Label –means a display of written, printed, or graphic matter upon the immediate container of any article and a requirement made by or under authority of this Act that any word, statement, or other information appearing on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or easily legible through the outside container or wrapper.
15. Manufacturer - in relation to a health product, means an establishment engaged in any and all operations involved in the production of health products including preparation, processing, compounding, formulating, filling, packing, repacking, altering, ornamenting, finishing and labeling with the end in view of its storage, sale or distribution. A trader shall be categorized as 'a manufacturer.'
16. Hazards – refer to the inherent characteristics of chemical substances and mixtures that are potentially dangerous or which have the capacity to do harm to the health and the environment.
17. Hazardous substances are substances which present either:
  - 17.1 short-term acute health hazards, such as acute toxicity by ingestion, inhalation or skin absorption, corrosivity or other skin or eye contact hazards or the risk of fire or explosion; or

- 17.2 long-term chronic health hazards which upon repeated exposure can result to any of the following adverse health effects such as cancer, damage to the different organ systems, endocrine disruptors, etc.
18. Household/urban hazardous substance' is: defined as (1) Any substance or mixture of substances intended for individual or limited purposes and which is toxic, corrosive, an irritant, a strong sensitizer, is flammable or combustible, or generates pressure through decomposition, heat or other means, if such substance or mixture of substances may cause substantial injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable ingestion by children, but shall not include agricultural fertilizer, pesticide, and insecticide, and other economic poisons, radioactive substance, or substances intended for use as fuels, coolants, refrigerants and the like; (2) Any substance which the FDA finds to be under the categories enumerated in clause (1) of this paragraph; (3) Any, by or other articles intended for use by children which the FDA may determine to pose an electrical, chemical, physical, or thermal hazard; and (4) This term shall not apply to food, drugs, cosmetics, devices, or to substances intended for use as fuels when stored in containers and used in the heating, cooking or refrigeration system of a house, but such term shall apply to any article which is not in itself an agricultural pesticide but which is a hazardous substance, as construed in paragraph (1) of this section, by reason of bearing or containing such harmful substances described therein.
19. Licensing - the process of approval of an application to operate or establish an establishment prior to engaging in the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and where applicable the use, testing, promotion, advertisement, and/or sponsorship of health products
20. Misbranding - in addition to definitions in existing laws, misinformation or misleading information on the label or other information materials authorized by the FDA. It shall not refer to copyright, trademark, or other intellectual property-like instruments.
21. Poison - any agent capable of producing deleterious effects in a biologic system, seriously injuring function or producing death.
22. Registration- means the process of approval of an application to register health products prior to engaging in the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and where applicable, the use, testing, promotion, advertisement, and/or sponsorship of health products.
23. Trader - means any establishment which is a registered owner of a health product and procures the raw materials and packing components and provides the production monographs, quality control standards and procedures, but subcontract the manufacture of such product to a licensed manufacturer. In addition, a trader may also engage in the distribution and/or marketing of its products.
24. Retailer - means any establishment which sells or offers to sell any health product directly to the general public.
25. Risk - the potential (likelihood) that injury (biological damage) will occur in a given situation that is, the interaction of hazard (nature/incident) and the vulnerability (man/society).

26. Safety data sheet (SDS) – is a document that provides important physical characteristics, ecological, safety and toxicological information on chemical substances or mixtures of ingredients used at the workplace, transported or maybe utilized by the consumer.
27. Toxicity - the ability of a substance to cause injury, illness or death to humans through possible routes of entry (i.e. ingestion, inhalation, dermal absorption, etc) into the body.
28. Unreasonable risk - expected frequency of undesirable effects or adverse responses arising from a given exposure to a substance.

## V. Guiding Principles

1. **Prevention.** Importance of precautionary measures in avoiding human health and environmental impacts
2. **Precautionary principle.** As embodied under the Rio Declaration under Principle 15 states that where there are threats of serious or irreversible damage to the environment, lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation.
3. **Workers' Right to Know.** Information on the hazards in their workplaces, confidentiality (privacy) of health information, access to training and education and maintenance of a healthy and safe workplace.
4. **Integrated life-cycle approach.** Involves strong controls from the manufacture of a chemical to its storage, transport, treatment, reuse, recycling, recovery and final disposal.
5. **Product Stewardship.** A product-centered approach to environmental protection and calls on those in the product lifecycle—manufacturers, retailers, users, and disposers—to share responsibility for reducing the environmental and health impacts of products
6. **Extended Product Responsibility.** Mandates producer take back and recycling of products until the end of their useful lives
7. **Coherence/Integrated.** Importance of encouraging closer coordination and cooperation among stakeholders on a shared framework of action
8. **Synergies.** Need to explore and exploit synergies and untapped potential that may exist in the shared agendas of various stakeholders and between sectors.
9. **Private-Public Partnership.** Cooperative venture between the public and private sectors, built on the expertise of each partner, that best meet clearly defined public needs through allocation of resources, risks and rewards.

## VI. General Procedures and Requirements

In addition to the existing rules and regulations for the registration of household hazardous chemicals and related materials regulated by the Food and Drug Administration, the following procedures and requirements shall be prescribed for importers, distributors, manufacturers, users and transporters. These procedures and requirements shall legally prescribe SDS and labelling of toxic chemicals and mixtures. It hereby provides:

1. Adoption of the UN GHS Fourth Revised Edition published in 2011. Corresponding updating/amendment shall be undertaken in the event of updated information published by the UN GHS Committee.

- 1.1 The GHS Committee shall prepare the corresponding operational guidelines for the classification and labeling for household chemicals/consumer products regulated under the jurisdiction of the FDA.
- 1.2 Said committee shall select the appropriate building blocks appropriate for consumer chemicals/products regulated under the jurisdiction of the FDA.
2. Preparation and Submission of SDS and Labels of household chemicals/consumer products regulated under the jurisdiction of the FDA, as follows:
  - 2.1 Adopt the harmonized criteria for classifying substances and mixtures according to their health, environmental and physical hazards based on the GHS revised 4<sup>th</sup> edition or corresponding revisions/amendments;
  - 2.2 All importers, manufacturers, suppliers and distributors shall prepare the SDS and labels, as necessary and applicable;
  - 2.3 All importers, manufacturers, suppliers and distributors shall submit SDS and labels using the GHS format when securing for permits, licenses and clearances covered with a notarized letter, as necessary and applicable;
  - 2.4 Appropriate pictograms, signal words, hazard and precautionary statements must be placed at the storage or warehouse facility/premises and on transport;
  - 2.5 Provisions on labeling and relabeling
  - 2.6 Provision on confidential business information (CBI)

**VI. Strategic Approach in Ensuring Implementation of the GHS for Household Chemicals/Consumer Products Regulated Under the FDA :**

**A. Strengthening of multi-stakeholder coordination and cooperation** – different agencies shall participate in the consultation/implementation of GHS in households/consumer products in different phases of the chemical life-cycle. Decisions on the implementation of these regulations in the country will be consulted with, discussed and agreed upon by relevant agencies or Departments, industry, consumer groups, academe and non-government organizations.

**B. Strengthening Organizational Structure for the Implementation of GHS for Household Chemicals/Consumer Products Regulated Under the FDA at Different Levels of Governance**

[Consumer Protection Sector under FDA and DTI]

[Support mechanism: Through Executive Order No. 489 signed 22 November 1991, the Inter-Agency Committee on Environmental Health (IACEH) was established with the Secretary of Health designated as Chair and the Secretary of the Environment and Natural Resources as the

Vice-Chair. The Environmental and Occupational Health Office of the National Center for Disease Prevention and Control under the Support to Service Delivery Team II serves as the Secretariat for the IACEH]

In cases where technical assistance on the implementation of GHS in Consumer Products may be needed, these shall be referred to the Centers for Health Development in the different regions in the country through the Regional FDA Coordinators. The Local Government Unit (LGU) is encouraged to adopt the structure and composition at the regional/provincial/municipal/city level.

The following agencies which are involved in the implementation of GHS in consumer products will be convened for consultations. These initially include:

- Department of Environment and Natural Resources which is responsible for formulating and implementing environmental policies, laws, plans and programs including those related to industrial chemical management and hazardous waste management.
- Department of Health which is responsible for the development and formulation of policies, plans and programs to protect individuals, families and communities exposed to hazards and risks that could affect their health
- Department of Labor and Employment which is responsible for occupational safety and health, working conditions and employees compensation
- Department of Agriculture which is responsible for the registration, labeling and use of pesticides and fertilizers and development of MRLs.
- Department of Transportation and Communication which is responsible for the promotion, development and regulation of a dependable and coordinated network of transport of chemicals including the enforcement of marine pollution regulations, including oil spill response.
- Department of Interior and Local Government which is responsible for the regulations on flammable and combustible chemicals including hazardous materials response
- Department of Finance which is responsible for the entry/importation of hazardous chemicals
- Department of Trade and Industry which is responsible for the registration of chemical products
- Department of Energy which is responsible for the energy sustainable plan in the country including the regulations on petroleum products
- Department of Justice which is responsible for the use of chemicals which may be used for precursors in illegal drugs
- National Economic Development Authority which is responsible for mainstreaming chemicals in the national development agenda
- Other government agencies which may be called upon, as necessary.
- Academe, industry, consumer groups and non-government organizations

E. Information Gathering and Dissemination

Development of an integrated, harmonized database that can be referred to for information such as relevant laws, chemical lists and their active ingredients/adjuvants, toxicity information, post-monitoring of consumer products and registry of poisoning cases.

F. Capacity for Risk Assessment & Interpretation

Establish harmonized approaches to risk-based assessment procedures for household chemicals/consumer products. This will include review and evaluation of health, physical and environmental hazards including exposure assessment scenarios, as may be necessary. Precautionary approach and the risks to the vulnerable population will be the primordial consideration.

H. Capacity for Implementation & Enforcement

An integrated approach through institutional arrangements shall be considered in responding to these concerns. Inter-agency coordination on the drafting, interpretation and enforcement of rules and regulations on the implementation of GHS in household chemicals/consumer products shall be undertaken. Further, outdated laws, rules and regulations shall be updated to strengthen implementation of programs for consumer protection.

I. Post-Monitoring and Evaluation Activities

Protocols stating specific roles and responsibilities of agencies/institutions shall be established. Technical cooperation and collaboration with the consumer protection groups, private sector and international agencies shall be considered and enhanced. Recall of products shall follow existing procedures established under the FDA.

Creation of monitoring and evaluation system should provide efficiency in the implementation of the program. Thus, necessary interventions can be made in an appropriate manner

K. Risk communication and Effective Education

Coordinated efforts among agencies to educate the public on the hazards and risks of household chemicals and consumer products, pictograms, precautionary statements and related concerns shall be encouraged including peer-review of educational materials among agencies.

M. Research

Evidence-based research studies shall be done to support policy formulation and standard setting. These efforts include conduct of relevant health studies,

toxicological research, database generation, disease tracking, and surveillance studies.

## VII. Budget and Financing

The Department of Health (DOH) shall allocate a corresponding yearly budget based on the implementation of the GHS in consumer products under the FDA and EOHO-NCDPC.

The DOH shall encourage other national government agencies and the local government units to fund their local GHS programs to implement their respective thrusts and concerns at the local level.

## VIII. Transition of Implementation Period

The implementation of the GHS classification and labeling shall be harmonized with the implementation schedule prescribed by the Environmental Management Bureau-Department of Environment and Natural Resources for industrial chemicals, as follows;

- A. Two (2) years of transition period after the effectivity of this Order shall be provided for complete and strict compliance of the following single substances and compounds covered under the following
  1. Chemicals classified under RA 6969
    - 1.1 Chemical Control Order (CCO)
    - 1.2 Priority Chemicals List (PCL)
- B. Two years after the aforesaid transition period, this Order shall take effect on the following:
  1. High Volume Toxic Chemicals
- C. A year after the aforesaid two periods, this Order shall take effect on:
  1. Toxic Chemicals under the IATA and IMDG lists of dangerous goods.
- D. On the seventh year and thereafter, mixtures shall be followed.
- E. For household pesticides – existing regulations under PD 881 and PD 1144 and its existing rules, regulations and guidelines for the classification and labeling shall be followed until such time that the harmonized guidelines for the GHS Classification and Labeling under the UN GHS Committee and the World Health Organization shall have been integrated.

## IX. Separability Clause

In the event that any provision or part of this order is declared unauthorized or rendered invalid by any court of law or competent authority, those provisions not affected by such declaration shall remain valid and effective.

**X. Penalty Clause**

Any violations of the provisions specified in this Administrative Order will subject those persons responsible therefor to administrative sanctions under Presidential Decree No. 881, Administrative Order No. 311s. 1977, Republic Act No. 7394 or the Consumer Act of the Philippines, Republic Act No. 9711 and its corresponding implementing rules and regulations and other existing pertinent laws.

**XI. Effectivity**

This Order shall take effect thirty days (30) publication in two newspapers of general circulation and submission of a copy hereof to the Office of the National Registry of the University of the Philippines Law Center.

**ENRIQUE T. ONA, MD**  
Secretary of Health