

Transmittal of Draft Nigeria Products Regulations to
Meet Obligations Under the Minamata Convention on Mercury

Attached for your consideration are three draft regulations prepared by the Natural Resources Defense Council (NRDC)¹, in consultation with SRADev Nigeria, which would enable the government of Nigeria to meet the mercury product phase out obligations under Article 4 of the Minamata Convention on Mercury.

To prepare these drafts, NRDC reviewed Nigeria's statutory and regulatory authorities relevant to Article 4 of the Convention, including

- Standards Organization Nigeria Establishment Act (1970)
- National Environmental Standards and Regulations Enforcement Agency (NESREA) Establishment Act (2007)
- National Environmental (Electrical/Electronic Sector) Regulations (2011) of NESREA
- National Environmental (Chemical, Pharmaceutical, Soap and Detergent Manufacturing Industry) Regulations (2009) of NESREA
- National Agency for Food and Drug Administration and Control (NAFDAC) Establishment Act (1993)
- NAFDAC Cosmetics Products (Prohibition of Bleaching Agent) Regulations S.I. 2005
- NAFDAC Cosmetics Products (Labeling) Regulations S.I. 2005
- Guidelines for Importation of Chemical Products (NAFDAC/NCS/002/00)
- Guidelines for Registration of Imported Cosmetics (NAFDAC/RR/001/00)
- Guidelines for Registration of Imported Medical Devices (NAFDAC/RR/007/00)
- NAFDAC Pesticide Registration Regulations S.I. (2005)

Based upon this review, NRDC determined that Nigeria has sufficient statutory authority to issue regulations as needed to implement Article 4 of the Convention, under NESREA alone or in combination with NAFDAC. However, we also conclude that additional regulations will need to be promulgated under these authorities to cover the products specified in Part 1 of Annex A to the Convention.²

We provide three separate draft regulations, consistent with the current structure of Nigeria's regulations. First, we provide minor modifications to Nigeria's existing cosmetics regulation

¹ NRDC is acting as an advisor to the Sustainable Research and Action for Environmental Development (SRADev) under a European Environmental Bureau/Zero Mercury Working Group (EEB/ZMWG) project funded by the European Commission (EC) through the Food and Agriculture Organization (FAO) of the United Nations (UN). The EEB/ZMWG project is entitled: ***"Contributing to the preparation/implementation of the Minamata Convention on Mercury, with a focus on developing strategies for phasing out mercury-added products and on reducing mercury use in Artisanal and Small Scale Gold Mining through development of National Action Plans."***

² We reach no conclusion about whether additional authorities are needed to implement the dental amalgam phase down measures identified in Part II of Annex A. Such an analysis can only be performed after Nigeria selects the measures it chooses to implement among the options in Part II of Annex A.

(Appendix 1). These modifications are intended to mirror Convention requirements, but we note Nigeria's current regulations may satisfy Convention requirements as well.³

Second, for the medical devices or products restricted under the Convention and covered by NAFDAC, we draft a second set of regulations for such products, addressing new types of medical devices as well (Appendix 2). Third, for all other mercury-added products covered under Annex A of the Convention, and potential new types of products, we provide draft regulations under NESREA (Appendix 3).

While we have provided three separate draft rules consistent with Nigeria's current regulatory structure, Nigeria may wish to use this opportunity to consider whether consolidation of legal authorities covering mercury (and other chemical) products into one agency and set of authorities (under NESREA) would enhance program effectiveness and enforcement. The Convention does not dictate how Nigeria should organize itself, and the draft regulations we provide can be combined as Nigeria deems appropriate.

Nigeria may also use this opportunity to consider related capacity building and enforcement mechanisms as it prepares for Article 4 implementation. For example, Nigeria may consider capacity building needs related to the measurement of mercury in products (i.e., use of XRF machine, laboratory capacity, etc), awareness raising (i.e., education and outreach to cosmetics users), and enforcement (including regional and local levels of government). The details of the Specific International Programme (SIP) will be considered and adopted at COP 1 (see Article 13, Paragraph 9), and such capacity building needs may fall within this financial assistance mechanism under the Convention. Nigeria may also consider adjusting the fines and penalties for violations, particularly for manufacture and importation.

³ For example, in our draft cosmetics regulation, we add an express prohibition against the export of mercury-added cosmetics to the existing regulations, as the Convention stipulates. However, since the existing regulations already prohibit the manufacture, import, and distribution of mercury-added cosmetics, it may be effectively argued that export is not possible under the existing rules, and thus the existing rules are sufficient to meet Convention obligations.

Appendix 1

S. I. of 2005

Draft Minamata Convention Revisions – September 2016

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL ACT (AS AMENDED)

Cosmetics (Prohibition of Bleaching Agents) Regulations 2005

Commencement:

In exercise of the powers conferred on it by sections 5 and 29 of the National Agency for Food and Drug Administration and Control Act 1993 and of 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 Minister of Health, hereby makes the following Regulations -

1. Prohibition of Unsafe Cosmetics

(1) No person shall import, manufacture, distribute, display for sale or offer for sale any cosmetics, which are adulterated or which contains any substance which when used according to the direction on the label accompanying the cosmetic product is likely to cause injury to the health of the user.

(2) No person shall import, export, manufacture, distribute, sell, display for sale or offer for sale any cosmetic product which contains any of the skin bleaching agents listed in the Schedule A to these Regulations.

3. Penalty

(1) A person who contravenes any of the provisions of these regulations is guilty of an offence and liable on conviction to imprisonment for a term not exceeding ~~one~~ ___ year or to a fine not exceeding N~~50,000~~_____ or to both such fine and imprisonment.

(2) Where an offence under these Regulations which has been committed by a body Corporate is proved to have been committed with the consent or connivance of or attributable to any neglect on the part of any director, manager, secretary or other similar officer of the body corporate or any person purporting to act in any of those capacities, he as well as the body corporate, shall be deemed to be guilty of the offence and shall be liable on conviction to a fine not exceeding ₦_____ ~~100,000~~.

3. Forfeiture

In addition to the penalty specified in regulation 2(1) of these Regulations, a person convicted of an offence under these Regulations shall forfeit to the Agency the Cosmetic product and whatsoever is used in connection with the commission of the offence.

4. Repeal

(1) The Cosmetic Product (Prohibition of Bleaching Agents, Etc) Regulations 1995 are hereby repealed.(2) The repeal of the Regulation specified in sub-regulation (1) of this Regulation shall not affect any thing done or purported to be done under the repealed Regulations.

5. Interpretation

For the purpose of these Regulations, unless the context otherwise requires: -

“**Adulterated cosmetic**” means any of the following, that is, if -

- (a) it contains more than a trace of mercury or any mercury ~~compound salt~~ which under normal condition of manufacturing practice is unavoidable; or
- (b) contains more than a trace of mercury or any mercury ~~compound salt~~ calculated as the metal or preservative; or
- (c) contains beyond 2% hydroquinone; or
- (d) bears or contains any poisonous or deleterious substances as to render it injurious to a user under the conditions prescribed in its labeling or under such conditions of use as are customary or usual for the cosmetic product; or
- (e) has been prepared, packed or held under unsanitary conditions thereby rendering it likely to be injurious to health; or
- (f) the container in which it is packed is composed in whole or part of poisonous or delirious substance which may render the contents injurious to health; or
- (g) contains more than the permissible limit of an ingredient; or
- (h) revalidates any information originally indicated on its label or container by the manufacturer.

“**cosmetics**” includes any substance or mixture of substances intended to be rubbed, poured, sprinkled or sprayed, introduced into or otherwise applied to the human body or

any part thereof for cleansing, beautifying, promoting attractiveness or altering the complexion, skin, hair or teeth and includes deodorants and detergent powder.

6. Citation

These Regulations may be cited as the Cosmetics Products (Prohibition of Bleaching Agents) Regulations 2005.

SCHEDULE A

1. CORTICOSTEROIDS
2. MERCURY AND MERCURY COMPOUNDS

MADE at Abuja this day of 2005

DR. ANDEM NYONG ANDEM
Chairman Governing Council
National Agency for Food and Drug Administration
and Control (NAFDAC)

Appendix 2

NRDC Draft Minamata Convention Regulations – September 2016

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL ACT (AS AMENDED)

Mercury-Added Medical Device and Topical Antiseptic Regulations (201X)

In exercise of the powers conferred on it by sections 5 of the National Agency for Food and Drug Administration and Control Act 1993 and of 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 Minister of Health, hereby makes the following Regulations -

Prohibition of Mercury-Added Topical Antiseptics and Medical Devices

1. No person shall manufacture, import, or export any of the following mercury-added products after the effective dates specified below:

(a) topical antiseptics, effective _____,

(b) fever thermometers, effective _____.

(c) sphygmomanometers, effective _____, except as provided in Section 2.

2. The prohibitions under Section 1(c) shall not apply to a mercury-added sphygmomanometer used only for research or calibration purposes, or as a reference standard.

New Mercury-Added Medical Devices

3. Effective _____, no person shall manufacture, import, or export a type or category of mercury-added medical device not previously manufactured or imported into the country prior to the effective date of these Regulations, unless the Agency issues a permit to allow such manufacture, import, or export. The Agency may issue a permit to exempt a certain mercury-added medical device type or category from this prohibition only after determining that the device type or category provides significant public health or environmental benefits and no comparable mercury free alternatives are available.

4. An application for a permit under Section 4 must be submitted to the Agency and contain the following information and documents:

(a) respecting the applicant,

(i) their name, civic and postal addresses, telephone number and, if any, fax number and email address, and

(ii) if applicable, the name, title, civic and postal addresses, telephone number and, if any, fax number and email address of their duly authorized representative;

(b) respecting the product,

(i) its common or generic name and its trade name, if any,

(ii) the total quantity of mercury contained in the product, expressed in milligrams,

(iii) the estimated quantity to be manufactured or imported by the applicant in a calendar year, and

(iv) an identification and description of each known use;

(c) evidence that, at the time of the application, there is no technically or economically feasible alternative to or substitute for the product that

(i) achieves a similar result as would be achieved by using the product containing mercury, and

(ii) has a less harmful effect on the environment or on human health than the product containing mercury;

(d) a copy of a plan that identifies and describes the measures that the applicant will take to minimize or eliminate any harmful effect that the mercury contained in the product has or may have on the environment and human health, including measures to ensure that the mercury is handled safely and is not released into the environment during normal use of the product and at the end of its useful life;

(e) a statement that the plan is to be implemented within 30 days after the day on which the permit is issued;

(f) the location where the information and supporting documents are kept;

(g) in the case of a renewal permit application for manufacture-

(i) the quantity of the product manufactured at each manufacturing plant during the previous calendar year,

(ii) the date of manufacture; and

(h) in the case of a renewal application for import-

(i) the quantity of the product imported during the previous calendar year,

(ii) the name, civic and postal addresses, telephone number and, if any, the fax number and email address of the principal place of business of the shipper,

- (iii) the port of entry at which the product was imported,
- (iv) the date of import,
- (v) the Harmonized Commodity Description and Coding System number for the product,
- (vi) the importer number for the product shipped, and
- (vii) copies of the bill of lading, invoice and all documents submitted to the [Nigeria Customs Agency] for the product shipped.

5. The Agency shall not issue a permit if

- (a) the Agency has reasonable grounds to believe that the applicant has provided false or misleading information in support of their application; or
- (b) the information and documents required under Section 4 have not been provided or are insufficient to enable the Agency to process the application.

6. A permit expires three years after the day on which it is issued, unless it is renewed under Section 4.

7. In order to have a permit renewed, a permit holder must submit to the Agency a renewal application, in accordance with Section 4, at least 90 days before the day on which the permit expires and must include the number of the permit in that renewal application.

Offences

8. It shall be an offence for a person to manufacture, import, or export a mercury-added product in contravention of these Regulations.

9. It shall be an offence if a person fails to submit required documents or information within the specified time period in these Regulations.

10. It shall be an offence if a person, body corporate, or organization fails to comply with any permit conditions, enforcement or closure notice, or with any reasonable requirement imposed by a notice served by the Agency under these Regulations;

11. It shall be an offence to make a statement which is known to be false or misleading, including but not limited to where the statement is made:

- (a) in purported compliance with a requirement to furnish any information pursuant to the provisions of these Regulations;

(b) for the purpose of obtaining a permit for the body corporate or organization;

(c) to intentionally make a false entry in any record pertaining to the permit; or

(d) with intent to deceive, to forge or use any document issued or authorized to be issued under any permit condition.

12. It shall be an offence if a person, body corporate, or organization fails to:

(a) produce documents or release information when required by the inspectors;

(b) knowingly obstructs the inspectors from performing their duties; or

(c) dismisses, suspends, sanctions, or otherwise penalizes employees who report any violations of the Act, or who report instances of contraventions of these Regulations.

13. It shall be an offence to fail to create or maintain records as required by these Regulations.

Penalty

14. A person who contravenes any of the provisions of these regulations is guilty of an offence and liable on conviction to imprisonment for a term not exceeding ____ year or to a fine not exceeding _____ or to both such fine and imprisonment.

15. Where an offence under these Regulations which has been committed by a body Corporate is proved to have been committed with the consent or connivance of or attributable to any neglect on the part of any director, manager, secretary or other similar officer of the body corporate or any person purporting to act in any of those capacities, he as well as the body corporate, shall be deemed to be guilty of the offence and shall be liable on conviction to a fine not exceeding N_____.

16. In addition to the penalty specified in these Regulations, a person convicted of an offence under these Regulations shall be responsible for the proper management and disposal of the mercury-added products manufactured, imported, or exported unlawfully, and shall be responsible for remediation of releases to the standards prescribed by the Agency arising from the unlawful manufacture, import, or export.

Interpretation

17. For the purpose of these Regulations, unless the context otherwise requires: -

“Act” means the National Agency for Food and Drug Administration and Control Act ,1993.

“Mercury” means elemental mercury and any of its compounds.

“Mercury-added product” means a product or product component that contains mercury that was intentionally added.

“Person” means a natural and juristic personality (including facility).

Citation

18. These Regulations may be cited as the Mercury-Added Topical Antiseptics and Medical Device Regulations (201X)

Appendix 3

NRDC Draft Minamata Convention Regulations – September 2016

NATIONAL MERCURY CONTENT PRODUCT REGULATIONS (201X)

In exercise of the powers conferred upon me by Section 34 of the National Environmental Standards and Regulations Enforcement Agency (Establishment Act, 2007), and all other powers enabling me in that behalf, I _____, Minister of Environment, make the following Regulations:

Purpose

1. The purpose of these Regulations is to prevent and minimize mercury pollution arising from the manufacture, use, and disposal of mercury-added products, and to enable compliance with the Minamata Convention on Mercury.

Prohibitions

2. Except as provided in Section 4, no person shall manufacture, import, or export any of the following mercury-added products after the effective dates specified below:

(a) batteries, except for button zinc silver oxide batteries with a mercury content < 2% and button zinc air batteries with a mercury content < 2%, effective _____;

(b) switches and relays, except very high accuracy capacitance and loss measurement bridges and high frequency radio frequency switches and relays in monitoring and control instruments with a maximum mercury content of 20 mg per bridge, switch or relay, effective _____;

(c) compact fluorescent lamps (CFLs) for general lighting purposes that are ≤ 30 watts with a mercury content exceeding 5 mg per lamp burner, effective _____;

(d) triband phosphor linear fluorescent lamps (LFLs) for general lighting purposes < 60 watts with a mercury content exceeding 5 mg per lamp, effective _____;

(e) halophosphate phosphor linear fluorescent lamps (LFLs) for general lighting purposes ≤ 40 watts with a mercury content exceeding 10 mg per lamp, effective _____;

(f) high pressure mercury vapour lamps (HPMV) for general lighting purposes, effective _____;

(g) effective _____ mercury in cold cathode fluorescent lamps (CCFLs) and external electrode fluorescent lamps (EEFLs) for electronic displays:

(i) short length (≤ 500 mm) with mercury content exceeding 3.5 mg per lamp;

(ii) medium length (> 500 mm and $\leq 1\,500$ mm) with mercury content exceeding 5 mg per lamp; and

(iii) long length ($> 1\,500$ mm) with mercury content exceeding 13 mg per lamp;

(h) pesticides and biocides, including but not limited to biocides in paints, effective _____;

(i) barometers, effective _____;

(j) hygrometers, effective _____

(k) manometers, effective _____; and

(l) non-fever thermometers, effective _____.

3. The prohibitions in Section 2 apply to the mercury-added products sold individually and to the assembly of the mercury-added products into larger products.

4. Upon application, the Agency may exempt a mercury-added product from the prohibitions in Section 2 if the Agency determines:

(a) the mercury-added product is essential for civil protection and military uses;

(b) for replacement switches and relays, CCFLs, EEFLs, or measuring devices listed in Sections 2(i)-(l) that are components of larger equipment manufactured before the effective date of the prohibition, there is no feasible mercury free alternative available for the equipment;

(c) the product is used for research, calibration of instrumentation, or as a reference standard; or

(d) the measuring devices listed in Sections 2(i)-(l) are installed in large scale equipment or used in high precision measurement, and no suitable mercury free alternatives are available.

New Mercury-Added Products

5. Effective _____, no person shall manufacture, import, or export a mercury-added product type or category not previously manufactured or imported into this country prior to the effective date of these Regulations, unless the Agency

issues a permit to allow such manufacture, import, or export. The Agency may issue a permit to exempt a certain mercury-added product type or category from this prohibition only after determining that the product type or category provides significant public health or environmental benefits and no comparable mercury free alternatives are available.

6. An application for a permit under Section 5 must be submitted to the Agency and contain the following information and documents:

- (a) respecting the applicant,
 - (i) their name, civic and postal addresses, telephone number and, if any, fax number and email address, and
 - (ii) if applicable, the name, title, civic and postal addresses, telephone number and, if any, fax number and email address of their duly authorized representative;
- (b) respecting the product,
 - (i) its common or generic name and its trade name, if any,
 - (ii) the total quantity of mercury contained in the product, expressed in milligrams,
 - (iii) the estimated quantity to be manufactured or imported by the applicant in a calendar year, and
 - (iv) an identification and description of each known use;
- (c) evidence that, at the time of the application, there is no technically or economically feasible alternative to or substitute for the product that
 - (i) achieves a similar result as would be achieved by using the product containing mercury, and
 - (ii) has a less harmful effect on the environment or on human health than the product containing mercury;
- (d) a copy of a plan that identifies and describes the measures that the applicant will take to minimize or eliminate any harmful effect that the mercury contained in the product has or may have on the environment and human health, including measures to ensure that the mercury is handled safely and is not released into the environment during normal use of the product and at the end of its useful life;
- (e) a statement that the plan is to be implemented within 30 days after the day on which the permit is issued; and
- (f) the location where the information and supporting documents are kept.

7. The Agency shall not issue a permit if

- (a) the Agency has reasonable grounds to believe that the applicant has provided false or misleading information in support of their application; or

(b) the information and documents required under Section 6 have not been provided or are insufficient to enable the Agency to process the application.

8. A permit expires three years after the day on which it is issued, unless it is renewed under Section 6.

9. In order to have a permit renewed, a permit holder must submit to the Agency a renewal application, in accordance with Section 6, at least 90 days before the day on which the permit expires and must include the number of the permit in that renewal application.

Recordkeeping and Reporting

10. Any person that manufactures or imports a mercury-added product must submit a report to the Agency in respect of the 2018 calendar year and every third calendar year after that year, on or before March 31 of the calendar year following the year in respect of which the report is prepared.

11. The report must include the following information:

(a) respecting the person,

(i) their name, civic and postal addresses, telephone number and, if any, fax number and email address, and

(ii) if applicable, the name, title, civic and postal addresses, telephone number and, if any, fax number and email address of their duly authorized representative; and

(b) respecting the product,

(i) its common or generic name and its trade name, if any,

(ii) the name of the product category,

(iii) the total quantity of mercury contained in the product, expressed in milligrams,

(iv) the quantity of the product manufactured during the calendar year in question, if applicable, and

(v) the quantity of the product imported during the calendar year in question, if applicable.

12. Any information required to be submitted to the Agency under these Regulations must be submitted in the form and format specified by the Agency and must bear the signature of the person that manufactures or imports the product containing mercury or of their duly authorized representative.

13. Any person that manufactures or imports a product that contains mercury must maintain records that demonstrate that the product was manufactured or imported in accordance with the Act and these Regulations and that include the following information:

- (a) in the case of a person that manufactures a product,
 - (i) the common or generic name of the product manufactured, and its trade name, if any,
 - (ii) the name of the product category,
 - (iii) the quantity of the product manufactured at each manufacturing plant,
 - (iv) the total quantity of mercury contained in the product, expressed in milligrams, and
 - (v) the date of manufacture; and
- (b) in the case of a person that imports a product,
 - (i) the common or generic name of the product imported, and its trade name, if any,
 - (ii) the name of the product category,
 - (iii) the quantity of the product imported,
 - (iv) the total quantity of mercury contained in the product, expressed in milligrams,
 - (v) the name, civic and postal addresses, telephone number and, if any, the fax number and email address of the principal place of business of the shipper,
 - (vi) the port of entry at which the product was imported,
 - (vii) the date of import,
 - (viii) the Harmonized Commodity Description and Coding System number for the product,
 - (ix) the importer number for the product shipped, and
 - (x) copies of the bill of lading, invoice and all documents submitted to the [Nigeria Customs Agency] for the product shipped.
- (c) The records and supporting documents must be kept for a period of at least five years after the day on which the records are made.

14. Any person that submits information to the Minister under these Regulations must keep a copy of that information and any supporting documents for a period of at least five years after the day on which the information is submitted.

15. The records, copies of information submitted to the Agency and supporting documents must be kept at the person's principal place of business in Nigeria or at any other place in Nigeria where they can be inspected. If they are kept at any place

other than the person's principal place of business, the person must provide the Agency with the civic address of that place.

Offences

16. It shall be an offence for a person to manufacture, import, or export a mercury-added product in contravention of these Regulations.

17. It shall be an offence if a person fails to submit required documents or information within the specified time period in these Regulations.

18. It shall be an offence if a person, body corporate, or organization fails to comply with any permit conditions, enforcement or closure notice, or with any reasonable requirement imposed by a notice served by the Agency under these Regulations;

19. It shall be an offence to make a statement which is known to be false or misleading, including but not limited to where the statement is made:

(a) in purported compliance with a requirement to furnish any information pursuant to the provisions of these Regulations;

(b) for the purpose of obtaining a permit for the body corporate or organization;

(c) to intentionally make a false entry in any record pertaining to the permit; or

(d) with intent to deceive, to forge or use any document issued or authorized to be issued under any permit condition.

20. It shall be an offence if a person, body corporate, or organization fails to:

(a) produce documents or release information when required by the inspectors;

(b) knowingly obstructs the inspectors from performing their duties; or

(c) dismisses, suspends, sanctions, or otherwise penalizes employees who report any violations of the Act, or who report instances of contraventions of these Regulations.

21. It shall be an offence to fail to create or maintain records as required by these Regulations.

Penalty

22. A person who contravenes any of the provisions of these Regulations is guilty of an offence and liable on conviction to imprisonment for a term not exceeding ____ year or to a fine not exceeding _____ or to both such fine and imprisonment.

23. Where an offence under these Regulations which has been committed by a body Corporate is proved to have been committed with the consent or connivance of or attributable to any neglect on the part of any director, manager, secretary or other similar officer of the body corporate or any person purporting to act in any of those capacities, he as well as the body corporate, shall be deemed to be guilty of the offence and shall be liable on conviction to a fine not exceeding N_____.

24. In addition to the penalty specified in these Regulations, a person convicted of an offence under these Regulations shall be responsible for the proper management and disposal of the mercury-added products manufactured, imported, or exported unlawfully, and shall be responsible for remediation of releases to the standards prescribed by the Agency arising from the unlawful manufacture, import, or export.

Interpretation

25. In these Regulations unless the context otherwise requires---

“Act” means the National Environmental Standards and Regulations Enforcement Agency (Establishment) Act, 2007.

“Mercury” means elemental mercury and any of its compounds.

“Mercury-added product” means a product or product component that contains mercury that was intentionally added, and is not a food, drug, cosmetic, or medical device.

“Person” means a natural and juristic personality (including facility).

Citation

26. These Regulations may be cited as the National Mercury Content Product Regulations (201X).