



**LEGAL GAP ANALYSIS ON POLICY AND LEGAL
FRAMEWORKS RELATED TO MANAGEMENT AND
CONTROL OF MERCURY ADDED PRODUCTS IN KENYA**



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SECTION ONE

I.0 INTRODUCTION

This Section provides a brief introduction to the Minamata Convention on Mercury as well as a general discussion of the mercury added products (MAPs) subject to Article 4 and Annex I of the Convention. In addition, the Section gives the background of the project under which this Legal Gaps Analysis has been carried out, the scope of the analysis and the methodology used for the study.

I.1 The Minamata Convention on Mercury

The Minamata Convention on Mercury is an international treaty whose objective is to ‘protect the human health and the environment from anthropogenic emissions and releases of mercury and mercury compounds’. The Convention was agreed upon at the fifth session of the Intergovernmental Negotiating Committee on Mercury in Geneva, Switzerland, on 19 January 2013 and adopted later that year on 10 October 2013 at the Diplomatic Conference (Conference of Plenipotentiaries), in Kumamoto, Japan. The Convention entered into force on 16th August 2017, ninety days after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession in accordance with Article 31. Kenya is signatory to the Minamata Convention on Mercury but is yet to ratify the same. However, the Ministry of Environment and Forests has already initiated the process of ratification and is closely working with the State Law Office in this regard. The Ministry projects that the ratification process will be concluded within the lifetime of the current Government, i.e., before 2022¹.

I.2 Mercury Added Products under the Minamata Convention

For the purpose of the Convention, “mercury-added product” is defined as “a product or product component that contains mercury or a mercury compound that was intentionally added”². This broad definition covers both fabricated and formulated mercury-added products. Fabricated products refer to a combination of individual components, one or more of which has mercury added, that combine to make a single unit, and may include measuring devices,

¹ Interview with Ministry of Environment and Forests on 15.08.2018

² Article 2(f) of the Minamata Convention on Mercury

thermostats, switches and relays, dental amalgam, lamps, and batteries. A formulated product on the other hand is a chemical product, including, but not limited to, laboratory chemicals, cleaning products, cosmetics, pharmaceuticals, and coating materials that are sold as a consistent mixture of chemicals, acids, alkalis, bleach, stains, reagents, preservatives, fixatives, buffers and dyes.

Article 4 of the Minamata Convention on Mercury focuses on the supply of mercury-added products (MAPs) through manufacture, import and export of such products rather than on their use, which may therefore continue until the end of their lifetime³. Article 4 employs two approaches to controlling mercury in products, namely setting a phase-out date for some, and specifying measures to be taken in allowing continued use for others as outlined in Annex A (Part I and Part II).

Table I below outlines the mercury added products listed in Annex A (Part I) of the Minamata Convention on Mercury that are subject to a phase-out date of year 2020 (date after which the manufacture, import or export of the product shall not be allowed)⁴.

Table I – Mercury added products subject to phase-out by 2020

Batteries, except for button zinc silver oxide batteries with a mercury content < 2% and button zinc air batteries with a mercury content < 2%
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
Compact fluorescent lamps (CFLs) for general lighting purposes that are ≤ 30 watts with a mercury content exceeding 5 mg per lamp burner
Linear fluorescent lamps (LFLs) for general lighting purposes: (a) Triband phosphor < 60 watts with a mercury content exceeding 5 mg per lamp; (b) Halophosphate phosphor ≤ 40 watts with a mercury content exceeding 10 mg per lamp

³ UNITAR, *Overview of key operational articles under the Minamata Convention on Mercury, 2016*

⁴ *Products subject to Article 4 paragraphs 1 and 2 of the Minamata Convention*

High pressure mercury vapour lamps (HPMV) for general lighting purposes
Mercury in cold cathode fluorescent lamps and external electrode fluorescent lamps (CCFL and EEFL) for electronic displays: short length (≤ 500 mm) with mercury content exceeding 3.5 mg per lamp medium length (> 500 mm and $\leq 1\ 500$ mm) with mercury content exceeding 5 mg per lamp long length ($> 1\ 500$ mm) with mercury content exceeding 13 mg per lamp
Cosmetics (with mercury content above 1ppm), including skin lightening soaps and creams, and not including eye area cosmetics where mercury is used as a preservative and no effective and safe substitute preservatives are available
Pesticides, biocides and topical antiseptics
The following non-electronic measuring devices except non-electronic measuring devices installed in large-scale equipment or those used for high precision measurement, where no suitable mercury-free alternative is available: barometers; hygrometers; manometers; thermometers; sphygmomanometers.

Table 2 below outlines the mercury added products listed in Annex A (Part II) of the Minamata Convention on Mercury that require measures to be taken by Parties to phase down their use, taking into account the Party's domestic circumstances and relevant international guidance⁵.

⁵ Products subject to Article 4 paragraph 3 of the Minamata Convention

Table 2 - Mercury Added Products that require phase-down measures to be taken by Parties

Product	Provision
Dental Amalgam	<p>Measures to be taken by a Party to phase down the use of dental amalgam shall take into account the Party's domestic circumstances and relevant international guidance and shall include two or more of the measures from the following list:</p> <ul style="list-style-type: none"> (i) Setting national objectives aiming at dental caries prevention and health promotion, thereby minimizing the need for dental restoration; (ii) Setting national objectives aiming at minimizing its use; (iii) Promoting the use of cost-effective and clinically effective mercury-free alternatives for dental restoration; (iv) Promoting research and development of quality mercury-free materials for dental restoration; (v) Encouraging representative professional organizations and dental schools to educate and train dental professionals and students on the use of mercury-free dental restoration alternatives and on promoting best management practices; (vi) Discouraging insurance policies and programmes that favour dental amalgam use over mercury-free dental restoration; (vii) Encouraging insurance policies and programmes that favour the use of quality alternatives to dental amalgam for dental restoration; (viii) Restricting the use of dental amalgam to its encapsulated form; (ix) Promoting the use of best environmental practices in dental facilities to reduce releases of mercury and mercury compounds to water and land.

1.3 Background to the Project

The Centre for Environment Justice and Development (CEJAD), a national Non-Governmental Organization (NGO) in Kenya working on chemicals and waste management is implementing a project titled: *“Contribution towards early ratification and implementation of the Minamata Convention on Mercury and towards phasing out Mercury Added Products (MAPs) – Phase II in Kenya”*. CEJAD is implementing this project in partnership and with funding from the European Environmental Bureau and the Zero Mercury Working Group.

The overall objective of the project is to contribute to the preparation for the early ratification and implementation Minamata Convention on Mercury in Kenya, with a focus on the

development and implementation of strategies for the Mercury Added Products (MAPs) phase out provisions. Specifically, the project aim to strengthen legal frameworks for implementation of MAPs phase out in Kenya including monitoring of imported MAPs by relevant government agencies to control their entry into the Kenya.

This Legal Gaps Analysis on Policy and Legal Frameworks Related to Management and Control of Mercury Added Products in Kenya was commissioned by CEJAD as part of the actions towards preparation for the early ratification and implementation Minamata Convention on Mercury in Kenya, with a focus on the development and implementation of strategies for the Mercury Added Products (MAPs) phase out provisions. The objective of the Analysis is to identify gaps in existing policies and legislation in order to assist Kenya in complying with the obligations of the Convention. In addition, this Analysis will contribute to the development and implementation of a roadmap, following consultation with relevant authorities, to phase out mercury added products in Kenya.

I.4 Scope of this Analysis

This Legal gaps Analysis covers the current policy, legislative and regulatory framework for management and control of mercury added products (MAPs) in Kenya. Specifically, the Analysis involved the following exercises:

- i) Mapping and reviewing existing and proposed Kenya policies, laws and regulations for sound chemicals management, specifically mercury and mercury added products in Kenya;
- ii) Evaluating and determining whether and how these policies, laws and regulations provide sufficient authority to comply with the obligations in Article 4 and Annex A of the Minamata Convention on Mercury;
- iii) Identifying any and all gaps, fragmented and conflicting ones;
- iv) Providing relevant examples where products have been banned in Kenya in the past, due to international obligations or otherwise;
- v) Recommending policy options (e.g. revisions of existing legislation or developing a new framework) for the relevant government authorities to fill identified gaps in order to comply with the obligations of Parties under the Convention.

I.5 Methodology

This Legal Gap Analysis was conducted through the following methods:

i) Desk top review

A detailed desktop review was conducted and covered several policies, legislations and regulatory instruments including: the Constitution of Kenya; relevant sectoral policies, laws, subsidiary legislations, and standards; several publications including books, journals, and official government reports.

ii) Key informant interviews

The key informant interviews were semi-structured in nature and consisted of a series of questions designed to elicit specific answers on the part of key informants in selected Kenya governmental agencies that have some role relevant to control and regulation of MAPs in Kenya. The institutions interviewed included: Ministry of Environment and Forests, Ministry of Health, National Environment Management Authority, Kenya Revenue Authority and Kenya Bureau of Standards.

SECTION TWO

2.0 CURRENT POLICY, LEGISLATIVE AND REGULATORY FRAMEWORKS FOR MANAGEMENT AND CONTROL MERCURY ADDED PRODUCTS IN KENYA

This Section provides a detailed analysis of the relevant policies, legislative and regulatory instruments that have a bearing on mercury added products in Kenya. It not only discusses relevant constitutional provisions but also looks at various sectoral policies, laws, regulations, rules, orders and standards.

2.1 Constitution of Kenya, 2010⁶

Article 42 of Kenya's Constitution guarantees every person in Kenya the right to a clean and healthy environment, which includes the right to have the environment protected for the benefit of present and future generations through legislative and other measures. Article 69 of the Constitution goes further to outline several obligations of the State with respect to the environment. However, there is no specific obligation relating to the sound management of chemicals and toxics, including mercury. The closest the Constitution comes to this is in Article 69 (g) wherein the State is obligated to 'eliminate processes and activities that are likely to endanger the environment' – a general statement that may be broadly interpreted to encompass the sound management of chemicals, including the control and management of MAPs.

On another front, Article 46 of the Constitution guarantees consumers the following rights:

- The right to goods and services of reasonable quality;
- The right to information necessary for consumers to gain full benefit from goods and services
- The right to the protection of their health, safety, and economic interests;
- The right to compensation for loss or injury arising from defects in goods or services.

⁶ *Government of Kenya, 2010*

This Article applies to goods and services offered by public entities and private persons in equal measure. Its provisions lay a strong foundation for the protection of consumers against the harmful effects of mercury added products in Kenya.

In addition, Article 69 of the Constitution places several obligations upon the State in respect to the environment. Of relevance to the control and/or management of mercury added products in Kenya are the State's obligations to: establish systems of environmental impact assessment, environmental audit and monitoring of the environment; and, eliminate processes and activities that are likely to endanger the environment.

2.2 National Environment Policy, 2013⁷

Kenya's National Environment Policy provides the framework for an integrated approach for sustainable environmental and natural resources management. The Policy proposes a broad range of measures and actions for responding to various environmental issues in the country. The Policy recognizes that chemicals are an important contributor to national development across all sectors as they form an important input to agriculture, manufacturing, energy, leisure and as ingredients to commonly used materials such as plastics and electronics; in addition, chemicals improve the quality of life as medicines, cosmetics, foods, leisure etc. However, the Policy also recognizes that chemicals can also pose a danger to health and the environment due to their inherent toxic and hazardous nature. The Policy therefore proposes broad measures for sound management of the inherent risks of chemicals at production, transportation, use and disposal at end of life. Among the actions proposed by the policy are that the Government will:

- i) Develop a national policy on toxic and hazardous substances.
- ii) Establish appropriate toxic and hazardous substances disposal facilities.
- iii) Collaborate with international community in curbing dumping of obsolete or banned toxic and hazardous substances and enforce the relevant MEAs.
- iv) Implement the international process of the Strategic Approach to International Chemicals Management (SAICM)

⁷ Government of Kenya, Ministry of Environment, Water and Natural Resources, 2013

2.3 Kenya Health Policy 2012 – 2030⁸

The Kenya Health Policy, 2012 – 2030 aims at ensuring significant improvement in the overall status of health in Kenya in line with the country's long term development agenda, Vision 2030, the Constitution of Kenya, 2010 and global commitments. The Policy seeks to steer the country towards attaining the highest possible standards of health, in a manner responsive to the needs of the population. This Policy focuses on two key obligations: contribution to economic development as envisioned in the country's Vision 2030; and realization of fundamental human rights as enshrined in the Constitution of Kenya. Thus, the Policy emphasizes equity, people centeredness and participatory approach, efficiency, multi-sectoral approach and social accountability in delivery of health care services. However, the policy is silent on the health impacts and mitigation measures relating to exposure to chemicals including MAPs.

2.4 Ministry of Health Ministerial Strategic and Investment Plan (2014 – 2018)⁹

This plan was intended to give effect to efforts by the Ministry of Health to conform to Kenya's social and economic development agenda by:

- i) Adhering to the Constitution of Kenya requirement that attainment of the highest attainable standard of health is a Right, among other constitutional provisions related to health;
- ii) Integrating all the international commitments related to health including International Health Regulations, Aid Effectiveness, MDGs among others;
- iii) Instituting measures to contribute to the Kenya Vision 2030's aim of providing an efficient, integrated, high quality and affordable health care system Obtaining guidance from the Kenya Health Policy 2014-2030 and Kenya Health
- iv) Sector Strategic and Investment Plan 2014-2018.

This Plan however did not have any outputs related to hazardous chemicals and wastes including mercury and mercury added products.

⁸Government of Kenya, Ministry of Medical Services and Ministry of Public Health, 2012

⁹ This plan covered the period July 2014 – June 2018

2.5 Healthcare Waste Management Plan (2016 – 2021)¹⁰

This Plan aims at reducing or eliminating the risks associated with improper management and use of inadequate or harmful treatment technologies for healthcare waste in Kenya. The strategic priorities outlined in the Plan include: review and updating of policies, standards and guidelines; improving infrastructure and equipment for treatment of healthcare waste; improving efficiency; capacity building; promoting best practices and enhancing monitoring, learning and research for better healthcare waste management. Through this Plan, the Ministry of Health has developed Standard Operating Procedures (SOPs) for the handling and management of healthcare waste in Kenya¹¹. The Plan outlines different treatment methods for healthcare waste including thermal and non-thermal technologies, as well as options for final disposal. Among the waste categories covered in the Plan are chemical wastes which are defined to include laboratory reagents, film developer, expired disinfectants, solvents, waste with high content of heavy metals e.g. batteries, broken thermometers and blood pressure gauges. This categorization includes MAPs within the healthcare system.

2.6 National Policy on Injection and Medical Waste Management¹²

The overall goal of this Policy is to promote safe injection practices and proper management of medical waste both in health care settings and the community. The guiding principles for the implementation of this policy include: access to information and training by health workers, communities and all stakeholders; establishment of organizational structures at all levels for the implementation of injection safety and related medical waste management; environmental protection through appropriate waste disposal methods; sustained supplies of injection and waste management equipment through an effective logistic system; minimization of risks to patients, health workers, communities and the environment through application of safer devices and disposal methods; observation of professional ethics in injection and waste management practices; and involvement of all relevant stakeholders. The provisions of the Policy on waste are specifically targeting injection waste; hence MAPs are not addressed as they do not fall within the scope of the Policy.

¹⁰ Government of Kenya, Ministry of Health, 2016

¹¹ Interview with Ministry of Health on 24. 08.2018

¹² Government of Kenya, Ministry of Health, 2007

2.7 Kenya National Pharmaceutical Policy, 2008¹³

This Policy focuses on strengthening the management and delivery of pharmaceutical services through relevant legislative and institutional reforms, regulation and quality control. On quality assurance, the Policy seeks to put in place necessary legal and institutional frameworks to ensure that medicines meet internationally acceptable standards on quality, safety and efficacy. The actions set out in the Policy in this regard include the development and implementation of a coherent national quality assurance programme, coupled with institutional strengthening and capacity building. The Policy does not mention medicines with mercury compounds, but this can be presumed to be a sub-set under the quality assurance aspect of safety.

2.8 Draft Guidelines for Safe Management of Pharmaceutical Waste¹⁴

These Guidelines are currently under development with the aim of ensuring that pharmaceutical waste is managed in a manner that protects human health and the environment against any adverse effects. The draft Guidelines has put forward proposals for the safe storage, transportation, treatment and disposal of pharmaceutical waste in Kenya. The Guidelines are intended to complement existing legal frameworks for safe management of pharmaceutical waste. Just like in the Healthcare Waste Management Plan, chemical wastes are among the waste categories covered in the draft Guidelines. These include laboratory reagents, film developer, expired disinfectants, solvents; waste with high content of heavy metals e.g. batteries, broken thermometers and blood pressure gauges. The draft Guidelines propose that all disposal of pharmaceutical waste (with the exception of returning to donor or manufacturer) shall be done under the supervision of a Pharmacy and Poisons Board Inspector and at NEMA approved pharmaceutical waste disposal facilities.

2.9 Environmental Management and Co-ordination Act¹⁵

The Environmental Management and Co-ordination Act (EMCA) is Kenya's framework environmental legislation that establishes the legal and institutional framework for the management of the environment in Kenya. The Act gives powers to the Cabinet Secretary

¹³ *Government of Kenya, Ministry of Medical Services, 2008*

¹⁴ *Government of Kenya, Ministry of Health, 2018*

¹⁵ *Act No. 8 of 1999, with amendments up to 2018*

(Minister) responsible for environmental matters to make regulations prescribing the procedure and criteria for, *inter alia*, classification, registration, labeling, packaging, advertising, control of imports and exports, distribution, storage, transportation, handling and disposal of chemicals and hazardous materials, and restriction and banning of toxic and hazardous substances¹⁶. However, these regulations are yet to be put in place.

Whereas the provisions of EMCA do not specifically mention mercury or mercury added products, the same are covered broadly under ‘chemicals and hazardous materials’. The Act defines “chemical” as “a chemical substance in any form whether by itself or in a mixture or preparation, whether manufactured or derived from nature and for the purposes of this Act includes industrial chemicals, pesticides, fertilizers and drugs”; and “hazardous substance” is defined as “any chemical, waste, gas, medicine, drug, plant, animal or microorganism which is likely to be injurious to human health or the environment”¹⁷.

2.10 Environmental Impact Assessment and Audit Regulations¹⁸

These Regulations are subsidiary legislation under EMCA. According to the Regulations, any project likely to have a negative environmental impact; or for which an environmental impact assessment (EIA) is required under the Act (EMCA) or these Regulations, cannot be implemented unless an environmental impact assessment has been concluded and approved in accordance with these Regulations. In this respect, no licensing authority under any law in force in Kenya shall issue a licence for any project for which an environmental impact assessment is required unless the applicant produces to the licensing authority a licence of environmental impact assessment issued by NEMA. Among the activities listed as requiring EIA, and which are relevant for the subject of mercury and MAPs, include: extracting alluvial gold with use of mercury; introduction of new pesticides; large scale pest control programmes; widespread introduction of fertilizers; fertilizer manufacture or processing; sites for solid waste disposal; sites for toxic, hazardous and dangerous wastes; and installations for disposal of industrial wastes.

¹⁶ Section 92 of EMCA

¹⁷ Section 2 of EMCA

¹⁸ Legal Notice No. 101/2003, Corr. No. 40/2003, Legal Notice No. 133/2007, Legal Notice No. 30/2009

For existing facilities, the Regulations require that the same must submit annual Environmental Audit reports that should contain relevant information including: the past and present impacts of the project; the responsibility and proficiency of the operators of the project; existing internal control mechanisms to identify and mitigate activities with a negative environmental impact; existing internal control mechanisms to ensure the workers' health and safety; and the existence of environmental awareness and sensitization measures, including environmental standards, and regulations, law and policy, for the managerial and operational personnel.

The Environmental Impact Assessments and Audits are important tools that can assist relevant authorities such as NEMA to monitor the activities of facilities, including those that may have mercury compounds as components in their production processes or products, as a way of enforcing compliance with the MAPs requirements under the Minamata Convention. However, currently NEMA lacks adequate capacity (technical, financial and human resources) for effective monitoring and enforcement¹⁹.

2.11 Waste Management Regulations²⁰

These Regulations are subsidiary legislation under EMCA and are intended for the sound management of different categories of waste in Kenya. Among the categories of waste covered are hazardous and toxic wastes. The Regulations also emphasize the requirement for EIA by stating that no person shall engage in any activity likely to generate any hazardous or toxic waste without a valid EIA licence issued by NEMA under the provisions of the Act. The Regulations also cover in detail the manner of handling, storage, transportation and disposal of hazardous and toxic wastes. The Fourth Schedule of the Regulations list the types of wastes considered as hazardous. These include wastes containing mercury and/or mercury compounds listed as follows—

- (a) wastes containing 0.1% or more by weight of any of the following mercury and/or mercury compounds—Mercury, Mercury benzoate, Ethyl mercury chloride, Mercurous chloride, Mercuric chloride, Mercury ammonium chloride, Methylmercuric chloride, Mercuric oxycyanide, Mercury oleate, Mercury gluconate, Mercury acetate, Mercury

¹⁹ Interview with NEMA on 25.07.2018

²⁰ Legal Notice No. 121 of 2006

salicylate, Mercuric oxide, Mercury cyanide, Mercury potassium cyanide, Diethyl mercury, Dimethyl mercury, Mercury (I) bromide, Mercurous nitrate, Mercuric nitrate, Phenyl mercuric hydroxide, Mercuric thiocyanate, Mercuricarsenate, Mercury (II) iodide, Mercury potassium iodide, Mercury fulminate, Mercury sulphide, Mercurous sulfate, Mercuric sulphate;

- (b) wastes containing 1% or more by weight of any of the following mercury and/or mercury compounds—Mercury nucleate, Mercurous acetate, Phenylmercury acetate, Phenylmercuric nitrate, Thimerosal;
- (c) Wastes containing mercury and/or mercury compounds other than those listed in (a) and (b) above.

However, the key challenge that NEMA faces is inadequate capacity for surveillance, monitoring and enforcement of the Regulations²¹.

2.12 Standards Act²²

The Standards Act governs the standardization of the specification of commodities and codes of practice in Kenya. The Law establishes a Kenya Bureau of Standards (KEBS) as the lead agency for all matters relating to standardization in Kenya. The National Standards Council established under the Act is may declare any specification or code of practice framed or prepared by KEBS to be a Kenya Standard. The following is a list of the Kenya Standards touching on various mercury added products:

- i) KS OIML R 7:1979 - Clinical thermometers (mercury-in-glass, with maximum device). This Standard applies to clinical thermometers of the mercury-in-glass type, with a maximum device, intended for measurement of the internal human body temperature.
- ii) KS ISO 1560:1985 Dental mercury. This Standard specifies requirements and test methods for mercury suitable for the preparation of dental amalgam, together with requirements for packaging and marking.
- iii) KS ISO 17318:2015 – Fertilizers and soil conditioners - Determination of arsenic, cadmium, chromium, lead and mercury contents. This Standard specifies the test methods for determination of metals soluble in nitric acid:

²¹ Interview with NEMA on 25.07.2018

²² Chapter 496, Laws of Kenya

arsenic, cadmium, chromium, lead, and mercury contents in fertilizers.

- iv) KS 2262:2010 Fluorescent lamps and other lamps containing mercury - Specifications and disposal requirements. This Standard establishes the performance, safety, environmental and health requirements for compact fluorescent lamps (CFLs), tubular fluorescent lamps (TFLs) and certain other lamps containing mercury used for general lighting purposes, household room illumination, industrial purposes or other specialized purposes.
- v) KS ISO 8124-3:1997 Safety of toys - Part 3: Migration of certain elements. This Standard specifies maximum acceptable levels and methods of sampling and extraction prior to analysis for the migration of the elements antimony, arsenic, barium, cadmium, chromium, lead, mercury and selenium from toy materials and from parts of toys
- vi) KS ISO 8124-5:2015 – Determination of total concentration of certain elements in toys. This Standard specifies methods of sampling and digestion prior to analysis of the total concentration of the elements antimony, arsenic, barium, cadmium, chromium, lead, mercury, and selenium from toy materials and from parts of toys.
- vii) KS ISO 6152:1982 – Thermometers for use with alcoholometers and alcohol hydrometers. This Standard specifies short-stem precision mercury-in-glass thermometers for use with alcoholometers and alcohol hydrometers.

Where a Kenya Standard has been declared by the Standards Council pursuant to this Act, the Cabinet Secretary (Minister), on the advice of the Standards Council, is required to prescribe a date, by order in the Kenya Gazette, after which no person shall manufacture or sell any commodity, method or procedure to which the relevant specification or code of practice relates unless it complies with that specification or code of practice²³. It is this provision, coupled with the consumer rights provisions in the Constitution that grants KEBS the leeway and authority to declare and publish the list of banned products, including certain MAPs in Kenya.

²³ Section 9(2) of the Standards Act

2.13 Verification of Conformity to Kenya Standards of Imports Order, 2005²⁴

This Order is a subsidiary legislation under the Standards Act. Pursuant to the provisions of this Order, all importers of goods must ensure that the goods meet the relevant Kenya Standards or approved specifications. KEBS is required to publish a list of goods which shall be subjected to verification of conformity to Kenya Standards or approved specifications. Goods that do not conform to the Kenya Standards or approved specifications are not permitted into Kenya, and must be re-shipped, returned or destroyed at the expense of the importer. The goods subject to pre-shipment verification for conformity with Kenya Standards include: food and food products, mechanical products and gas appliances, electrical and electronic products, chemical products (including cosmetic and hygiene products), civil & construction products, textile products, and medical related products (food supplements, cosmetic products with therapeutic action, medical devices, herbals, other borderline products)²⁵.

The provisions of this Order apply in conjunction with the requirements of section 9(2) of the Standards Act (discussed above) which empower the Cabinet Secretary to prescribe a date, by order in the Kenya Gazette, after which no person shall manufacture or sell any commodity, method or procedure that does not comply with the prescribed specification or code of practice outlined in the relevant Kenya Standard. In line with these provisions, all soaps and skin lightening creams containing mercury and its compounds are banned in Kenya. KEBS Inspectors appointed in line with the provisions of the Standards Act are mandated to carry out surveillance and enforcement of such bans²⁶.

Despite the existing ban by KEBS on all soaps and skin lightening creams containing mercury and its compounds, some of these products are still available in Kenya, albeit illegally. According to KEBS²⁷, there are several challenges that impede effective enforcement of the ban. These include:

²⁴ Legal Notice No. 78 of 2005

²⁵ The latest list was published on 19th February 2018

²⁶ Part IV of the Act covers all aspects relating to enforcement, including appointment and powers of inspectors.

²⁷ Interview with KEBS on 11.08.2018

- i) Kenya's porous borders, for example the border with Somalia, as well as the unmanned entry points through Lake Victoria, enable smugglers to bring in some of the banned products;
- ii) The informal business sector and particular the micro- enterprise sector is large and mostly unregulated. This environment allows for the entry of some of the banned products into the Kenyan market;
- iii) KEBS lacks sufficient resources such as finances; skilled manpower and equipment to enable it carry out efficient surveillance and enforcement.

2.14 Consumer Protection Act²⁸

The Consumer Protection Act is a legislation that provides for the protection of the consumer and prevention unfair trade practices in consumer transactions. Section 5 (1) of the Act re-emphasizes the right to goods and services of reasonable merchantable quality as enshrined in Kenya's Constitution. The quality envisioned here can be interpreted to be in terms of Kenya Standards on the quality of various goods and services. The Act lays a legal basis for the protection of consumers against the harmful effects of any goods that do not meet Kenya quality standards, and these may include certain mercury added products that may be regulated, controlled or prohibited by law.

2.15 Pest Control Products Act²⁹

The Pest Control Products Act is the legislation that regulates the manufacture, importation, exportation, distribution and use of products used for the control of pests and of the organic function of plants and animals in Kenya. Section 15 of the Act empowers the Cabinet Secretary (Minister) responsible for matters relating to agriculture to make regulations respecting, inter alia, manufacture, importation, exportation, classification, registration, storage, distribution, display, packaging, labeling, advertising, and use of any pest control product in Kenya.

²⁸ Act No. 46 of 2012, L.N. 50/2013, Act No. 14 of 2015, Act No. 38 of 2016

²⁹ Chapter 346, Laws of Kenya

2.16 The Pest Control Products (Registration) Regulations, 1984³⁰

These Regulations provide for the registration of pest control products in accordance with provisions the Pest Control Products Act. The Regulations lay down procedures and requirements of registration and specify circumstances when no registration is required as well as products that are exempted from registration. Before any pest control product is registered for use in Kenya, the Pest Control Products Board considers the product's safety, efficacy, quality and economic value in line with the provisions of these Regulations.

The Board may refuse to register a pest control product for several reasons, including, if in its opinion the use of the pest control product would lead to an unacceptable risk or harm to things on or in relation to which the pest control product is intended to be used; or public health, plants, animals or the environment. The Board may also suspend or revoke registration of a pest control product on several grounds including, that new information has become available to the Board which renders the pest control product unsafe or dangerous. In exercise of these powers, the Board may ban the manufacture, importation, storage, distribution, and handling and use certain pest control products in Kenya. Currently the Board has listed Mercury Compounds (used as fungicides and in seed treatment) among the banned products in Kenya³¹.

2.17 Health Act³²

The Health Act provides for, among others, the regulation of health care service and health care service providers, health products and health technologies in Kenya. Section 66 of the Act requires all health products including medicines, vaccines, and technologies intended for sale to members of the public to meet safety standards before they are licensed. Under the provisions of section 67, the national government is required to provide guidelines for the procurement, distribution and management of health products and technologies including essential medicines, laboratory chemicals and reagents and non-pharmaceuticals at all levels of the national health system. So far these guidelines have not been developed. As a result, there are no express

³⁰ Legal Notice No. 46 and 109 of 1984, with amendments through Legal Notice No. 123 of 2006

³¹ Official PCPB Website <http://www.pcpb.or.ke/bannedproductsviewform.php>, accessed on 16.08.2018

³² Act No. 21 of 2017

controls on procurement of mercury based medicinal products and technologies in Kenya's health sector.

The Ministry of Health nevertheless confirms that alternatives to mercury added products are currently available in the Kenyan market such as those for dental amalgam, body thermometers and facility related systems and equipment. The uptake of such alternatives is however still very low, especially in the rural areas, due to various factors such as cost, low awareness among the medical practitioners and the general public on these alternatives as well as negative perception/attitude on the alternatives³³.

2.18 Public Health Act³⁴

The Public Health Act aims at securing, protecting and maintaining the health of the public in Kenya. However, the Act does not have any specific provisions to protect the public from the effects of exposure to chemicals and chemical compounds such as mercury added products. Despite the legal gap respecting chemicals exposure, the Ministry of Health is actively involved in efforts to reduce public exposure to harmful chemicals including mercury. As part of these efforts, the Ministry of Health has developed internal guidelines on sound management of hazardous chemical wastes (including MAPs) from the healthcare system in Kenya. All such wastes are required to be safely disposed through hazardous waste handlers licensed by NEMA. In addition, the Ministry of Health in collaboration with the Ministry of Environment has conducted training of trainers at both national and county levels on sound healthcare waste management and disposal. However, the Ministry still lacks guidelines on the handling and disposal of used/waste fluorescent tubes and bulbs which still end up in the general waste category³⁵.

2.19 The Kenya Medical Supplies Authority (KEMSA) Act³⁶

This Law establishes KEMSA as a state corporation under the Ministry of Health to discharge various functions, key among them being to procure, warehouse and distribute drugs and

³³ Interview with Ministry of Health on 24. 08.2018

³⁴ Chapter 242, Laws of Kenya

³⁵ Ibid

³⁶ Act No. 20 of 2013 with amendments through Act No. 25 of 2015

medical supplies for prescribed public health programs, the national strategic stock reserve, prescribed essential health packages and national referral hospitals. The Act however does not define the procurement policy that KEMSA should use in relation to hazardous chemicals such as mercury. As such no clear guidelines are in place with respect the procurement and distribution of mercury based products and technologies within Kenya's healthcare system.

The Ministry of Health and KEMSA have nevertheless taken the initiative, even in the absence of legislation and guidelines, to phase down mercury based products and technologies within Kenya's healthcare system. In this regard, KEMSA has stopped procurement and/or importation of any healthcare mercury added products into the country³⁷. The challenge however still remains with County Governments which in certain instances directly procure medical supplies and equipment, in which case mercury based products could still enter the health care system³⁸.

2.20 Animal Diseases Act³⁹

This Law governs all matters relating to the control and management of animal diseases in Kenya. Under the provisions of Section 8 of the Act, the Director of Veterinary Services has power and may, by notice in the *Gazette*, prohibit or regulate the importation, exportation, sale, distribution or use of, *inter alia*, any vaccines and other biological or chemical products intended to be used for the control of animal disease. In exercise of the powers conferred by this section, the Director of Veterinary Services in the year 2010 prohibited the use of Chloramphenicol, among other drugs in food producing animals⁴⁰. Chloramphenicol is a broad spectrum antibiotic with bacteriostatic activity and is effective against a wide range of Gram-negative and Gram-positive organisms in animals and humans. The pharmaceutical particulars of Chloramphenicol include the mercury compound *Phenylmercuric nitrate* in the list of excipients⁴¹. However, this product does not appear in the customs list of prohibited items and may still enter the Kenyan market. According to the Ministry of Environment, however, Kenya may seek exemption of this product from the phase-out dates in Annex A when it ratifies the Convention

³⁷ Interview with Ministry of Health on 24. 08.2018

³⁸ *Ibid*

³⁹ Chapter 364, Laws of Kenya

⁴⁰ Legal Notice No. 25 of 2010

⁴¹ Swedish Health Products Regulatory Authority, 2018

as it may be an essential anti-biotic in the veterinary sector hence may need not be prohibited for the time being⁴².

2.21 Occupational Safety and Health Act⁴³

This Law provides for, among others, the safety, health and welfare of workers and all persons lawfully present at workplaces in Kenya. Part IX of the Act (sections 83 – 88) cover the safe transportation, handling, use and disposal of chemicals and other hazardous substances in places of work. However, the Act does not define “chemicals and hazardous substances”. In addition, the Act does not make any express mention of mercury and mercury added products within the setting of places of work.

2.22 Factories and Other Places of Work (Hazardous Substances) Rules⁴⁴

These Rules are subsidiary legislation made pursuant to the provisions of Section 88 of the Occupational Safety and Health Act. Rule 5 requires every employer to ensure that exposure of hazardous substance does not exceed the exposure limits set out in the First Schedule to the Rules. Among the substances listed in the schedule include mercury and mercury compounds. Whereas the maximum exposure limits are stated in the Rules, there is no express provision regulating the use of mercury and mercury added products in places of work.

2. 23 Pharmacy and Poisons Act⁴⁵

This is Kenya’s legislation that provides for the control and regulation of the profession of pharmacy and the trade in drugs and poisons. Under the provisions of Section 25, the Pharmacies and Poisons Board with the approval of the Cabinet Secretary (Minister) is mandated to prepare a list of the substances which are to be treated as poisons for the purposes of this Act. In this regard, there is in place the Poisons List Confirmation Order⁴⁶ that specifies all the poisons that may be manufactured, stocked, sold, transported or distributed by

⁴² Insights from Mr. Kirumba, Ministry of Environment and Forests, during the validation workshop for this report on 03.10.2018.

⁴³ Act No. 15 of 2007

⁴⁴ Legal Notice No. 60 of 2007

⁴⁵ Chapter 244, Laws of Kenya

⁴⁶ Legal Notice No. 168 of 1961, Corrigenda No. 66/1961, Legal Notice No 250 of 1961, Legal Notice No 423 of 1961, Legal Notice No 146 of 1963, Legal Notice No 242 of 1963, Legal Notice No 93/1964, Legal Notice No. 150/1968, and Legal Notice No 15 of 2002

licensed dealers. This list included mercury compounds such as mercuric chloride, mercuric iodide, organic compounds of mercury, nitrates of mercury, and cyanides of mercury. However, mercury compounds as components in adhesives, anti-fouling compositions, builders' materials, ceramics, distempers, electrical valves, enamels, explosives, fillers, fireworks, fluorescent lamps, glazes, glue, inks, lacquer solvents, loading materials, matches, medicated soaps, motor fuels and lubricants, paints other than pharmaceutical paints, photographic paper, pigment, plastics, propellants, rubber, varnishes, tyrothricin, and framycetin are exempted from the Act and Rules as relates to the list of poisons⁴⁷.

2.24 Pharmacy and Poisons (Control of Drugs) Rules⁴⁸

These Rules are subsidiary legislation pursuant to the provisions of Section 43 of the Pharmacy and Poisons Act which gives power to Cabinet Secretary (Minister), on the recommendation of the Pharmacy and Poisons Board, to prohibit or control the manufacture, sale, advertisement or possession of any secret, patent, proprietary or homoeopathic medicine, preparation or appliance. The list of prohibited drugs under these rules at the moment does not include any medications or appliances with mercury components.

2.25 Use of Poisonous Substances Act⁴⁹

This Law is intended for the protection of persons against risks of poisoning by certain substances in Kenya. The law seeks to control and regulate the use of a substance or a class of substances that, if used, would be likely to involve substantial risk of poisoning to persons. However, the Act does not specify the list of poisonous substances but leaves the same for the discretionary determination of the Minister (Cabinet Secretary). In addition, the law does not establish any proper institutional framework for its implementation and enforcement.

2.26 Food, Drugs and Chemical Substances Act⁵⁰

The Food and Chemical Substances Act is intended at preventing the adulteration of food, drugs and chemical substances. The Law prohibits the preparation, manufacturing, labeling, advertising, sale, importation, exportation or disposal of any food, drugs, chemical substances,

⁴⁷ Schedule II of the Rules, Legal Notices No. 92 of 1964 and 125 of 1969

⁴⁸ Legal Notices No. 147 of 1981, 142 of 1991 and 192 of 2010

⁴⁹ Chapter 247, Laws of Kenya

⁵⁰ Chapter 254, Laws of Kenya

cosmetics and devices other than in accordance with set national standards. The Act prohibits mercury content in all food products except for marine and fresh water animal products where a mercury exemption limit of 0.5 ppm applies⁵¹.

2.27 Customs and Excise Act⁵²

The Customs and Excise Act governs the management and administration of the customs, including the assessment, charge and collection of customs and excise duties. The Customs Service Department of the Kenya Revenue Authority (KRA) is mandated with administration of the Act. Whereas KRA's principal mandate is tax administration and revenue collection, the Customs Service Department also works in close collaboration with other government agencies to monitor and enforce prohibitions and/or restrictions of certain goods being imported into or exported from Kenya⁵³. As a result, the Customs and Excise Act in its schedules lists various restricted or prohibited products. Among the listed banned products are cosmetics containing mercury and mercury compounds.

2.28 East Africa Community Customs Management Act, 2004⁵⁴

Kenya is a member of the East Africa Community (EAC) – a treaty based regional intergovernmental organization of six Partner States: Burundi, Kenya, Rwanda, South Sudan, Tanzania, and Uganda, with its headquarters in Arusha, Tanzania. One of the integration pillars and critical milestones of the EAC is the Customs Union which has been in force since 2005, as defined in Article 75 of the Treaty for the Establishment of the East African Community⁵⁵. Under the Customs Union, the EAC Partner States have agreed to establish free trade on goods and services amongst themselves as well as a common external tariff (CET), whereby imports from countries outside the EAC zone are subjected to the same tariff when sold to any EAC Partner State.

The East Africa Community Customs Management Act is the regional legislation passed by the

⁵¹ *Food, Drugs and Chemical Substances (Food Labeling, Additives and Standards) Regulations, 1978*

⁵² *Chapter 472, Laws of Kenya*

⁵³ *Interview with KRA, 25.07.2018*

⁵⁴ *2004 edition with all amendments up to 2009*

⁵⁵ *The Treaty for the Establishment of the East African Community was signed on 30 November 1999 and entered into force on 7 July 2000 following its ratification by the original three Partner States – Kenya, Tanzania and Uganda. Rwanda and Burundi acceded to the Treaty on 18 June 2007 and became full members of the Community with effect from 1 July 2007. South Sudan was the last to accede to the Treaty on 15th April 2016 and became a full member on 5th September 2016.*

EAC Legislative Assembly to actualize the Customs Union. The Second Schedule⁵⁶ of the Act lists generally prohibited and restricted goods for import into the EAC. The prohibited goods include, among others, all soaps and cosmetic products containing mercury, mercury compounds as agricultural chemicals.

2.29 County Governments Act⁵⁷

The County Governments Act is a legislation intended to give effect to Chapter Eleven of the Constitution of Kenya by providing for county governments' powers, functions and responsibilities to deliver services to the people. Among the many functions of county governments include: establishing county legislation; and exercising executive functions in accordance with the relevant provisions of the Constitution of Kenya. As per the Fourth Schedule of the Constitution, some of the functions of county governments in sectors that may involve mercury added products are: agriculture, health services, veterinary services, control of air pollution and other public nuisances, soil and water conservation, water and sanitation, waste management, trade development and regulation. With these provisions, county governments have an opportunity to put in place county legislation to control mercury added products in all the sectors in which they have jurisdiction.

2.30 Draft National Policy on Chemicals Management

Kenya's Ministry of Environment and Forests has developed a draft Chemicals Management Policy with a view to providing a comprehensive framework for sound management of chemicals used in various sectors such as agriculture, industry, services, energy and transport. The draft Policy aims at minimizing the adverse negative effects of chemicals on human health and the environment by addressing highly toxic pesticides and hazardous industrial chemicals, Persistent Organic Pollutants (POPs), and persistent bio-accumulative substances that also include carcinogens, mutagens and reproductive toxins. Among the areas prioritized under the draft Policy include the control and management of mercury. The draft Policy does not, however, mention mercury added products although it can be presumed under the general subject of mercury. It is worthy to note, however, that the draft Policy was developed in 2011,

⁵⁶ The Second Schedule is in line with the powers conferred under sections 18, 19 and 20 of the Act.

⁵⁷ Act No. 17 of 2012, Act No. 13 of 2014, Act No. 1 of 2016, Act No. 7 of 2016, Act No. 17 of 2016, Act No. 43 of 2016, L.N. 59/2017, Act No. 4 of 2017, Act No. 6 of 2017, Act No. 24 of 2017, L. N. 170/2017

before the Minamata Convention on Mercury, thus it is understandable that mercury added products were not given any prominence.

2.31 Draft Chemicals Management Regulations⁵⁸

The draft Chemicals Management Regulations are currently under development by the National Environment Management Authority (NEMA) pursuant to the provisions of sections 97 and 147 of the Environmental Management and Coordination Act. The Sixth Schedule of the draft regulations list Mercury, Mercury compounds, Mercury-added products and manufacturing processes using mercury or mercury compounds as restricted products and activities. The draft goes further to give phase out schedules in terms of the Minamata Convention as follows:

- Phase –out date for mercury- added products year 2020.
- Phase-out date for chlor-alkali production using mercury 2025.
- Phase-out date for acetaldehyde production using mercury 2018
- Vinyl chloride monomer production to reduce use of mercury per unit production by 50% by the 2020 against 2010 use.
- Sodium or Potassium Methylate or Ethylate production to:
 - i. phase-out use of mercury within 10 years of entry into force of the Convention and
 - ii. reduce emissions and releases of mercury per unit production by 50% by 2020 against 2010 use.
- Polyurethane production to phase-out use of mercury catalysts within 10 years of entry into force of the Convention.

The draft regulations will be subjected to a public participation process within 2018 to obtain further stakeholders' inputs before they are finally conveyed to the State Law Office for further processing. However, it is not possible to project how soon the draft will become law as the ensuing processes after submission to the State Law office could still take several months⁵⁹.

⁵⁸ Draft as of August, 2018

⁵⁹ Interview with NEMA on 25.07.2018

SECTION THREE

3.0 SUMMARY OF POLICY/LEGAL GAPS AND RECOMMENDATIONS

POLICY/LEGAL INSTRUMENT	ASPECTS COVERED AND GAPS NOTED	RECOMMENDATIONS
<p><i>Constitution of Kenya</i></p>	<p>The Constitution guarantees everyone in Kenya the right to a clean and healthy environment; and obligates the State to eliminate processes and activities that are likely to endanger the environment through legislative and other processes. The Constitution also guarantees various consumers rights including the right to goods and services of reasonable quality; and the right to the protection of consumers' health, safety, and economic interests. However, the Constitution does not expressly provide for sound management of chemicals including MAPs. In addition, the Constitution places several obligations upon the State in respect to the environment that are of relevance to the control and/or management of mercury added products in Kenya, including the obligation to: establish systems of environmental impact assessment, environmental audit and monitoring of the environment; and, eliminate processes and activities that are likely to endanger the environment.</p>	<p>Parliament should pass a law for Sound Chemicals Management (including MAPs) in Kenya as part of strategies for actualizing the right to a clean and healthy environment for all in addition to actualizing the set consumer rights as well as state's obligations in relation to the environment under the Constitution.</p>

<p>National Environment Policy, 2013</p>	<p>The Policy proposes broad measures for sound management of the inherent risks of chemicals including: developing a national policy on toxic and hazardous substances; establishing appropriate toxic and hazardous substances disposal facilities; and collaborating with the international community in curbing dumping of obsolete or banned toxic and hazardous substances and enforcing relevant MEAs. However so far there is no national policy in place for toxic and hazardous substances, neither are there proper disposal facilities for toxic and hazardous substances including MAPs.</p>	<p>The Government should hasten implementation of the measures put forward in the policy which will include developing a national policy on toxic and hazardous substances (or finalizing the existing draft national chemicals management policy) to also cover MAPs; establishing appropriate toxic and hazardous substances disposal facilities; and hastening the ratification and implementation by Kenya of the Minamata Convention on Mercury as part of and collaboration with the international community in curbing dumping of obsolete or banned toxic and hazardous substances including MAPs.</p>
<p>Kenya Health Policy 2012 – 2030</p>	<p>This Policy focuses on the contribution of the health sector to economic development as well as realization of fundamental human right to health as enshrined in the Constitution of Kenya. The Policy lays out measures for curbing both communicable diseases and non-communicable conditions but does not mention at all the health impacts and mitigation measures relating to exposure to chemicals including MAPs.</p>	<p>Chemicals including MAPs are a major environmental health risk. Ignoring them may impede the achievement of the health policy aspirations. As such, any strategies for implementation of the Health Policy should take into account sound management of chemicals including MAPs with a view to minimizing exposure.</p>
<p>Ministry of Health Ministerial Strategic and Investment Plan</p>	<p>This Plan was intended to give effect to efforts by the Ministry of Health to conform to Kenya’s social and economic development agenda. It covered the period July 2013 – June 2018. The Plan however did not have any outputs related to hazardous chemicals and wastes including mercury and mercury added products.</p>	<p>Future Ministry of Health Strategic and Investment plans should make provision for sound management of healthcare related hazardous chemicals and wastes including mercury and mercury added products.</p>

<p>Healthcare Waste Management Plan</p>	<p>The Plan outlines different treatment methods for healthcare waste including thermal and non-thermal technologies, as well as options for final disposal. Among the waste categories covered in the Plan are chemical wastes which are defined to include laboratory reagents, film developer, expired disinfectants, solvents, waste with high content of heavy metals e.g. batteries, broken thermometers and blood pressure gauges. This categorization includes MAPs within the healthcare system.</p>	<p>The Plan should be implemented effectively to ensure sound management of chemical wastes with mercury and mercury compounds within the health care system.</p>
<p>National Policy on Injection and Medical Waste Management</p>	<p>The overall goal of this Policy is to promote safe injection practices and proper management of medical waste both in health care settings and the community. However, the provisions of the Policy on waste are specifically targeting injection waste; hence MAPs are not addressed as they do not fall within the scope of the Policy.</p>	<p>The Policy should be implemented in tandem with other policies touching on medical waste generally so that MAPs are not left out.</p>
<p>Kenya National Pharmaceutical Policy, 2008</p>	<p>On quality assurance, the Policy seeks to put in place necessary legal and institutional frameworks to ensure that medicines meet internationally acceptable standards on quality, safety and efficacy. The actions set out in the Policy in this regard include the development and implementation of a coherent national quality assurance programme, coupled with institutional strengthening and capacity building. The Policy does not mention medicines with mercury compounds, but this can be presumed to be a sub-set under the quality assurance aspect of safety.</p>	<p>Towards implementing the Policy, all relevant legislation should provide clear criteria on prohibition or otherwise of any medicines and other pharmaceutical products that may have mercury or mercury compounds as components.</p>
<p>Draft Guidelines for Safe Management of Pharmaceutical Waste</p>	<p>The draft Guidelines has put forward proposals for the safe storage, transportation, treatment and disposal of pharmaceutical waste in Kenya. Chemical wastes are among the waste categories</p>	<p>The Ministry of Health should finalize and implement the Guidelines as soon as possible.</p>

	covered in the draft Guidelines. These include laboratory reagents, film developer, expired disinfectants, solvents; waste with high content of heavy metals e.g. batteries, broken thermometers and blood pressure gauges. The draft Guidelines propose that all disposal of pharmaceutical waste (with the exception of returning to donor or manufacturer) shall be done under the supervision of a Pharmacy and Poisons Board Inspector and at NEMA approved pharmaceutical waste disposal facilities.	
Environmental Management and co-ordination Act	The Act gives powers to the Cabinet Secretary (Minister) responsible for environmental matters to make regulations prescribing the procedure and criteria for, <i>inter alia</i> , classification, registration, labeling, packaging, advertising, control of imports and exports, distribution, storage, transportation, handling and disposal of chemicals and hazardous materials, and restriction and banning of toxic and hazardous substances (which include MAPs). However, these regulations are yet to be put in place almost 2 decades after the Act came into force.	The Ministry of Environment and Forests, working in consultation with National Environment Management Authority, should hasten the completion of the draft Chemicals Management Regulations so as to establish an appropriate regulatory mechanism for MAPs in Kenya.
Environmental Impact Assessment and Audit Regulations	The Regulations require EIA for any new projects and activities likely to have an impact on the environment. Such activities which are relevant for the subject of mercury and MAPs include: extracting alluvial gold with use of mercury; introduction of new pesticides; large scale pest control programmes; widespread introduction of fertilizers; fertilizer manufacture or processing; sites for solid waste disposal; sites for toxic, hazardous and dangerous wastes; and installations for disposal of industrial wastes. For existing facilities, the Regulations require that the same must submit annual Environmental Audit reports that should	The Environmental Impact Assessment and Audit regulations provide important tools for regulatory agencies such as NEMA to regulate activities of new facilities and monitor the activities of existing ones, including those that may have mercury compounds as components in their production processes or products and equipment. To achieve the intended purpose, it is necessary to enhance NEMA's monitoring and enforcement capacity.

	contain, inter alia, relevant information about the past and present impacts of the project. However, NEMA lacks capacity for effective enforcement of the Regulations.	
Waste Management Regulations	Among the categories of wastes covered under these Regulations are hazardous and toxic wastes which include wastes containing mercury and mercury compounds. Besides requiring EIA approval for any activity likely to generate hazardous or toxic waste, the Regulations also cover in detail the manner of handling, storage, transportation and disposal of hazardous and toxic wastes. However, NEMA lacks adequate capacity to carry out effective surveillance and enforcement of the Regulations.	There is need to enhance the surveillance and enforcement capacity of NEMA in order to effectively implement the regulations.
Standards Act	A few Kenya Standards touching on mercury added products have been put in place namely: standards for clinical thermometers, dental mercury, fertilizers and soil conditioners, fluorescent lamps, mercury in toys, and thermometers for use with alcoholometers and alcohol hydrometers. However, there are still more MAPs for which standards need to be put in place.	KEBS and the National Standards Council should consider establishing Kenya Standards that cover all the MAPs subject to Article 4 of the Minamata Convention on Mercury as listed in Annex A (Part I and Part II)
Verification of Conformity to Kenya Standards of Imports Order, 2005	This Order is a subsidiary legislation under the Standards Act. Pursuant to the provisions of this Order, all importers of goods must ensure that the goods meet the relevant Kenya Standards or approved specifications. In line with the provisions of this Order all soaps and skin lightening creams containing mercury and its compounds are banned in Kenya. There is, however, an enforcement gap as these banned skin lightening creams are still prevalent in the Kenyan market, especially within the informal business sector.	KEBS and other relevant law enforcement agencies such as the Customs Services Department and the Kenya Police need to enhance surveillance and enforcement capacity in order to curtail the entry of the banned MAPs into the Kenyan market.

<p>Consumer Protection Act</p>	<p>This Act provides for the protection of the consumer and prevention unfair trade practices in consumer transactions. It re-emphasizes the right to goods and services of reasonable merchantable quality as enshrined in Kenya's Constitution. The quality envisioned here can be interpreted to be in terms of Kenya Standards on the quality of various goods and services.</p>	<p>The Act lays a legal basis for the protection of consumers against the harmful effects of any goods that do not meet Kenya quality standards, and these may include certain mercury added products that may be regulated, controlled or prohibited by law. Full implementation of its provisions may help in stemming MAPs that do not meet quality standards in Kenya.</p>
<p>Pest Control Products Act</p>	<p>The Act governs the manufacture, importation, exportation, distribution and use of products intended for the control of pests and of the organic function of plants and animals in Kenya. The Act provides the legal basis for the establishment of regulations to concerning the manufacture, importation, exportation, classification, registration, storage, distribution, display, packaging, labeling, advertising, and use of any pest control product in Kenya. All pest control products must meet safety, efficacy, quality and economic value aspects to qualify for registration in line with the provisions of the Regulations made under the Act.</p>	<p>Whereas the law has sufficient provisions to control mercury-added pest control products in Kenya, surveillance and enforcement capacity needs to be enhanced to ensure no such products enter Kenya's borders. The main challenge is in respect to Kenya's porous borders through which some of these products may be imported without detection by relevant regulatory agencies.</p>
<p>The Pest Control Products (Registration) Regulations, 1984</p>	<p>These Regulations are subsidiary legislation under the Pest Control Act and cover the manufacture, importation, exportation, classification, registration, storage, distribution, display, packaging, labeling, advertising, and use of any pest control product in Kenya. The Regulations give powers to the Pest Control Products Board to register, suspend or revoke registration of a pest control product, or prohibit/ban a pest</p>	

	control product on several grounds including, safety. In exercise of these powers, the Board has listed Mercury Compounds (used as fungicides and in seed treatment) among the banned products in Kenya.	
Health Act	The Act obligates the national government to provide guidelines for the procurement, distribution and management of health products and technologies including essential medicines, laboratory chemicals and reagents, and non-pharmaceuticals at all levels of the national health system. So far these guidelines have not been developed. As a result, there are no express controls on procurement of mercury based medicinal products and technologies in Kenya's health sector.	The Ministry of Health needs to develop clear guidelines for the procurement, distribution and management of health products and technologies including essential medicines, laboratory chemicals and reagents, and non-pharmaceuticals in order to provide express controls on procurement of mercury based medicinal products and technologies within Kenya's healthcare system.
Public Health Act	The Public Health Act aims at securing, protecting and maintaining the health of the public in Kenya. However, the Act does not have any specific provisions to protect the public from the effects of exposure to chemicals and chemical compounds such as mercury added products.	Future amendments to the Public Health Act should incorporate aspects on sound management of chemicals and chemical compounds such as mercury added products with a view to protecting the public from the effects of exposure to such chemicals. In addition the Ministry of Health should develop comprehensive internal guidelines on sound management of hazardous chemical wastes from the healthcare system as well as facility related systems and equipment.
The Kenya Medical Supplies Authority Act	The Act establishes KEMSA as a state corporation responsible for procurement, warehousing and distribution of drugs and medical supplies for prescribed public health programs, the national strategic stock reserve, prescribed essential health packages and national referral hospitals. The Act however does not define the procurement	The Ministry of Health and KEMSA should develop express procurement guidelines with regard to mercury based products and technologies within Kenya's healthcare system as a way of progressing the implementation of the provisions of the Minamata Convention on

	<p>policy/guideline that KEMSA should use in relation to hazardous chemicals such as mercury. As such no clear guidelines are in place with respect the procurement and distribution of mercury based products and technologies within Kenya’s healthcare system.</p>	<p>Mercury.</p>
<p>Animal Diseases Act</p>	<p>The Act grants powers to the Director of Veterinary Services to prohibit or regulate the importation, exportation, sale, distribution or use of any vaccines and other biological or chemical products intended to be used for the control of animal diseases in Kenya. Pursuant to this provision, the use of Chloramphenicol (a broad spectrum antibiotic) in food producing animals is prohibited. The pharmaceutical particulars of Chloramphenicol include the mercury compound <i>Phenylmercuric nitrate</i> as an excipient. However, this product does not appear in the customs list of prohibited items and may still enter the Kenyan market.</p>	<p>There is need for close collaboration between the Directorate of veterinary services and the Customs Services Department of KRA with a view to enforcing the ban on Chloramphenicol and any other mercury added products within the veterinary sector in Kenya.</p>
<p>Occupational Safety and Health Act</p>	<p>This Act governs the safety, health and welfare of workers and all persons lawfully present at workplaces in Kenya. It has provisions for the safe transportation, handling, use and disposal of chemicals and other hazardous substances in places of work. However, the Act does not define “chemicals and hazardous substances”. In addition, the Act does not make any express mention of mercury and mercury added products within the setting of places of work.</p>	<p>Future amendments to the Act should incorporate the definition of “chemicals and hazardous substances”, and if possible include mercury and mercury added products within the setting of places of work.</p>
<p>Factories and Other Places of Work (Hazardous Substances) Rules</p>	<p>These Rules are subsidiary legislation under the Occupational Safety and Health Act. The Rules require every employer to ensure that exposure of employees to hazardous substance does not exceed the exposure limits set out in the First Schedule to the</p>	<p>The Department of Occupational Safety and Health should develop express rules and/or guidelines regarding the use, handling and storage of mercury and mercury added products within places of</p>

	Rules. Among the substances listed in the schedule are mercury and mercury compounds. However, the Rules do not provide any guidelines on handling of mercury or mercury added products in places of work in order to minimize exposure.	work in order to minimize exposure.
Pharmacy and Poisons Act	This Act governs the control and regulation of the profession of pharmacy and the trade in drugs and poisons. The list of poisons that may be traded by dealers licensed under the Act include mercury compounds such as mercuric chloride, mercuric iodide, organic compounds of mercury, nitrates of mercury, and cyanides of mercury. However, mercury added products, i.e., mercury compounds as components in adhesives, anti-fouling compositions, builders' materials, ceramics, distempers, electrical valves, enamels, explosives, fillers, fireworks, fluorescent lamps, glazes, glue, inks, lacquer solvents, loading materials, matches, medicated soaps, motor fuels and lubricants, paints other than pharmaceutical paints, photographic paper, pigment, plastics, propellants, rubber, varnishes, tyrothricin, and framycetin are exempted from the Act and Rules.	Whereas the exempted mercury added products may not strictly be within the mandate of the Pharmacy and Poisons Act, there is need to regulate their manufacture, importation, handling, storage, distribution and use. In this regard, it is recommended that the same be covered within the framework of the draft Chemicals Management Regulations.
Pharmacy and Poisons (Control of Drugs) Rules	These Rules are subsidiary legislation under Pharmacy and Poisons Act and give power to Cabinet Secretary to prohibit or control the manufacture, sale, advertisement or possession of any secret, patent, proprietary or homoeopathic medicine, preparation or appliance. The list of prohibited products under these Rules at the moment does not include any medications or appliances with mercury components.	The list of prohibited and/or restricted products under these Rules should be updated to include mercury added products in line with the provisions of Article 4 and Annex A of the Minamata Convention on Mercury.

<i>Use of Poisonous Substances Act</i>	This Act seeks to control and regulate the use of a substance or a class of substances that, if used, would be likely to involve substantial risk of poisoning to persons. However, the Act does not specify the list of poisonous substances covered. In addition, the law does not establish any proper institutional framework for its implementation and enforcement.	This law is redundant and should be repealed so that all matters it is intended to cover should be left for coverage under the Pharmacies and Poisons Act and the proposed Chemicals Management Regulations
<i>Food, Drugs and Chemical Substances Act</i>	The Law prohibits the preparation, manufacturing, labeling, advertising, sale, importation, exportation or disposal of any food, drugs, chemical substances, cosmetics and devices other than in accordance with set national standards. The Act prohibits mercury content in all food products except for marine and fresh water animal products where a mercury exemption limit of 0.5 ppm applies.	The legal provisions relating to mercury in food products is clear but the enforcement mechanism may be inadequate hence the need to strengthen the capacity of relevant institutions to carry out surveillance and enforcement.
<i>Customs and Excise Act</i>	Whereas the principal mandate of KRA's Customs Service Department under the Act is tax administration and revenue collection, the Department also works with other government agencies to monitor and enforce prohibitions and/or restrictions of certain goods being imported into or exported from Kenya. As a result, the Customs and Excise Act in its schedules lists various restricted or prohibited products. Among the listed banned products are cosmetics containing mercury and mercury compounds.	Relevant government agencies need to work closely with KRA's Customs Service Department to monitor and enforce current and future prohibitions and/or restrictions of mercury added products in Kenya. In addition, the capacity of customs officials to detect these products should be enhanced.
<i>East Africa Community Customs Management Act, 2004</i>	This is a regional legislation passed by the EAC Legislative Assembly to actualize the EAC Customs Union. The Second Schedule of the Act lists generally prohibited and restricted goods for import into the EAC. The prohibited goods include all soaps and cosmetic products containing mercury,	

	mercury compounds as agricultural chemicals.	
County Governments Act	The County Governments Act is a legislation intended to give effect to Chapter Eleven of the Constitution of Kenya by providing for county governments' powers, functions and responsibilities to deliver services to the people. As per the Fourth Schedule of the Constitution, some of the functions of county governments in sectors that may involve mercury added products are: agriculture, health services, veterinary services, control of air pollution and other public nuisances, soil and water conservation, water and sanitation, waste management, trade development and regulation.	The provisions of the Act present county governments with an opportunity to put in place county legislation to control mercury added products in all the sectors in which they have jurisdiction, i.e. agriculture, health services, veterinary services, control of air pollution and other public nuisances, soil and water conservation, water and sanitation, waste management, trade development and regulation.
Draft National Policy on Chemicals Management	Among the areas prioritized in the draft Policy include the control and management of mercury. The draft Policy does not, however, mention mercury added products although it can be presumed under the general subject of mercury.	The draft National Chemicals management Policy should be updated to give more prominence to mercury and mercury added products in line with the provisions of the Minamata Convention.
Draft Chemicals Management Regulations	The draft regulations give sufficient prominence to restrictions on mercury, mercury compounds, mercury-added products and manufacturing processes using mercury or mercury compounds in line with the provisions of the Minamata Convention on Mercury.	The Ministry of Environment and Forests and NEMA should fast track the conclusion and passage into law of the draft regulations in order to set Kenya on the path to meeting the obligations under the Minamata Convention on Mercury.

Annex I

TERMS OF REFERENCE (TOR)

For

Individual Consultant to Conduct a Legal Gap Analysis Study on Policy and Legal Frameworks Related to Management and Control of Mercury Added Products in Kenya

The Project: Contribution towards early Ratification and Implementation of the Minamata Convention on mercury and towards phasing out mercury in Kenya

Implemented By

**Centre for Environment Justice and Development (CEJAD)
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June 2018

I. Background and Context

The Minamata Convention on Mercury is an international treaty intended to protect people and the environment from the harm caused by exposure to mercury. It is named after a city in Japan where inhabitants were poisoned by the release of mercury in wastewater from a chemical factory in the mid-20th century leading to crippling symptoms that became known as the Minamata disease. In accordance with Article 31, the Convention entered into force on **16th August 2017**, ninety days after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession. Kenya is signatory to the Minamata Convention on Mercury. However, Kenya has not ratified the Convention.

Mercury pollution is a global problem that requires global action as it is a highly toxic heavy metal which poses a global threat to human health and the environment. Historically, mercury-containing products and devices have been used in residential, commercial, industrial, marine and medical environments in countries around the world. Mercury is a good conductor of electricity, forms alloys with other metals, acts as a preservative, and because it is a liquid under standard conditions, it is sensitive to temperature and pressure. Its chemical and physical properties often continue to be utilized in a wide variety of products and applications.

Mercury is a chemical of global concern due to its long-range transport in the atmosphere, its persistence in the environment, its ability to bio accumulate in ecosystems and its significant negative effect on human health and the environment. Mercury from products and devices, and liquid mercury, can be released to the environment during the entire product life cycle including during production, transportation, manufacturing, use, storage and disposal. Once released, it can contribute to polluting the local and global environments. Mercury is transported around the globe through the environment, so emissions and releases of mercury can affect human health and environment even in remote locations. The purpose of restricting or banning mercury-added products is to eliminate non-essential uses of mercury in products, thereby reducing mercury releases to the environment.

Many countries and government jurisdictions within countries have successfully phased out most mercury-containing products and some of these cases are well documented. No country can control trans-boundary effects of mercury alone. It can be effectively tackled only through international cooperation as it moves with air and water, transcends political borders, and can be transported thousands of miles in the atmosphere.

Together with its various compounds, it has a range of severe health impacts, including damages to the central nervous system, thyroid, kidneys, lungs, immune system, eyes, gums and skin. Victims may suffer memory loss or language impairment, and the damage to the brain cannot be reversed. There is no known safe exposure level for elemental mercury in humans, and effects can be seen even at very low levels. Fetuses, new-born babies and children are amongst the most vulnerable and sensitive to the adverse effects of mercury.

The Minamata Convention on Mercury is an opportunity for the global community to address this mounting problem before it gets worse. The implementation of this international agreement will help reduce mercury pollution from the specific human activities responsible for the most significant mercury releases to the environment. It is anticipated that the Convention mandate to phase out mercury in many products will help foster competition among manufacturers and suppliers that will further promote innovation in mercury-free technologies to ultimately benefit consumers and the environment. With economies of scale, prices for high quality non-mercury devices should continue to drop, allowing demand for the alternatives to grow even more.

2. About the Project

The Centre for Environment Justice and Development (CEJAD), a national Nongovernmental Organization (NGO) in Kenya working on chemicals and waste management, funded by and in partnership with the European Environmental Bureau and the Zero Mercury Working Group (hereafter referred to as EEB/ZMWG) is implementing a project “Contribution towards early ratification and implementation of the Minamata Convention on Mercury and towards phasing out Mercury Added Products (MAPs) – Phase II in Kenya”.

The overall objective of the project is to contribute to the preparation for the ‘early ratification and implementation Minamata Convention on Mercury in Kenya, with a focus on the development and implementation of strategies for the MAP phase out provisions. Specifically, the project aim to strengthen legal frameworks for implementation of MAPs phase out in Kenya including monitoring of imported MAPs by relevant government agencies to control their entry into the Kenya, among others.

It’s against this background that CEJAD is seeking a qualified consultant to conduct a legal gaps analysis in Kenya, related to the phasing out of mercury-added products, as per Article 4 of the Minamata Convention. Once completed, it’s envisioned that this analysis will assist in filling in the identified gaps so that Kenya can comply with the obligations of the Convention. At the same time it will contribute to the development and implementation of a roadmap, following consultation with relevant authorities, to phase out mercury-containing products in Kenya.

3. Mercury-added products subject to this Request for Proposal (RFP)

According to the Minamata Convention, a mercury-added product is defined as a “product or product component that contains mercury or a mercury compound that was intentionally added” (Article 2.f). These products include fabricated and formulated mercury-added products. This definition is broad as it aims to cover all products where the mercury was added in the manufacturing process to provide a specific function or characteristic.

A fabricated product is a combination of individual components, one or more of which has mercury added, that combine to make a single unit. These equipment categories include: measuring devices, thermostats, switches and relays, dental amalgam, lamps, and batteries.

Table I: Fabricated Mercury-Containing Components and Products

Component or Product	Amount of Mercury in Individual Component or Product (grams)
Measuring devices	
Barometers	400 – 620
Sphygmomanometers	50 – 140
Manometers	30 – 75
Psychrometers	5 – 6
Thermometers	0.5 – 54
Switches & Relays:	
Flame Sensors	>1
Float Switches	0.1 – 70
Tilt Switches	0.05 – 5
Relays	0.005 - >1
Dental Amalgam	>0.1 – 1
Lamps:	
Fluorescent	<0.10
Compact Fluorescent	<0.01
High Intensity Discharge (metal halide, ceramic metal halide, mercury vapor, high pressure sodium)	<1
Mercury Short Arc	0.1 – 1
Button-cell Batteries	<0.05

Source: Extracted from Galligan *et al* (2003)

A formulated product is a chemical product, including, but not limited to, laboratory chemicals, cleaning products, cosmetics, pharmaceuticals, and coating materials that are sold as a consistent mixture of chemicals, acids, alkalis, bleach, stains, reagents, preservatives, fixatives, buffers and dyes. Formulation or re-formulation of these products is known to take place locally in Nigeria in both formal and informal settings. Some of these products are known to be in the market through regulated and unregulated (illegal) process.

Table 2: Formulated Mercury-Containing Products

Component or Product	Amount of Mercury in Individual Component or Product (ppm)
Preservatives & Reagents	>0 - >250
Mercury Compounds	>0 - >250

Source: Galligan *et al* (2003).

For the purpose of this study, the terms *product* and *component* is simply defined here.

Product: A product is predominantly sold to the consumer in its final product state. For example, a thermometer is sold to the consumer for temperature measuring purposes.

Component: A component is predominantly sold to an original equipment manufacturer to be incorporated within another product. For example, a tilt switch is sold to an automobile manufacturer to be incorporated into an automobile.

4. Overall Objective of the Consultancy

The overall objective of the consultancy is to conduct a desktop review and analysis of the existing policies, laws and regulations relevant to the management and control of the mercury added products as per article 4 and listed in Annex A of the Minamata Convention.

5. Scope of Work and Tasks

Specifically, the consultant is expected to:

1. Through a mapping exercise, collect, list, review and present an analysis of existing and proposed Kenya policies, laws and regulations for sound chemicals management, specifically mercury and mercury added products in Kenya
2. Evaluate and determine whether and how these policies, laws and regulations provide sufficient authority to comply with each of the obligations in Article 4 and Annex A of the Minamata Convention on Mercury.
3. Identify any and all gaps, fragmented and conflicting ones
4. Recommend policy options (e.g. revisions of existing legislation or developing a new framework) for the relevant government authorities to fill identified gaps in order to comply with the obligations of Parties under the Convention
5. Provide relevant examples where products have been banned in Kenya in the past, due to international obligations or otherwise, and where available, examples from other African countries that have banned mercury-containing products
6. Develop a report of the legal gap analysis study on Policies and Legal Frameworks Related to Management and Control of Mercury Added Products in Kenya

7. Participate and present the outcome of the work at a multi-stakeholder validation workshop to be organized by CEJAD in collaboration with EEB/ZMWG
8. Amend the final report, as needed, to reflect the input received from the multi-stakeholder workshop

6. Methodology

In conducting this legal gaps analysis, the consultant shall review all existing law, regulations, and authorities and conduct key informant interviews with selected stakeholders, as relevant. The consultant shall have the support of the Programmes Coordinator of CEJAD with consultation from the Ministry of Environment and Forestry, the Project Advisory Committee (PAC) and the EEB/ZMWG.

7. Expected Output/Deliverables

The expected outputs/deliverables from this assignment are;

1. Draft Report “Legal gap analysis of the Policies and Legal Frameworks Related to Management and Control of Mercury Added Products in Kenya” by 15 June, 2018.
2. Final Report “Legal gap analysis of the Policies and Legal Frameworks Related to Management and Control of Mercury Added Products in Kenya” with incorporated inputs and feedback from CEJAD, EEB/ZMWG project team and PAC.

Annex 2

SEMI STRUCTURED INTERVIEW FOR MAPs LEGAL GAP ANALYSIS – KENYA

(Questions were adjusted/customized at time of interview based on sector)

<p><u>MAPs in Kenya</u></p> <ul style="list-style-type: none"> ▪ What are some of the MAPs in use in Kenya? ▪ Are there records of stocks/stockpiles of the above? ▪ What are the MAPs currently restricted/prohibited in Kenya? 	<p><u>Current Policy/Legal Framework</u></p> <ul style="list-style-type: none"> ▪ Are there any existing policies/laws/regulations/standards/guidelines regarding the importation/exportation, sale, distribution, use and disposal of MAPs in Kenya? ▪ What is the current enforcement and coordination mechanism to ensure the restricted/banned MAPs do not enter the Kenyan market? ▪ What is the disposal mechanism for ceased MAPs at the points of entry/border points? ▪ Are there any enforcement challenges for your agency? If yes, which ones? ▪ Are there any planned policies/laws to regulate MAPs in Kenya?
<p><u>MAPs Alternatives</u></p> <ul style="list-style-type: none"> ▪ Are there alternatives in the Kenyan market for the MAPs currently in use in Kenya? Are they in use already? <i>((Ask based on sector))</i> ▪ What are some of the impediments to the uptake of the alternatives? 	<p><u>Ratification and Implementation of Minamata Convention</u></p> <ul style="list-style-type: none"> ▪ What is Kenya's progress towards ratification of the Minamata Convention on Mercury? ▪ Are there any plans by the Government to accelerate the adoption and phase-in of the alternatives in view of the impending phase-down and/or phase-out by 2020 of MAPs under article 4 of the Minamata Convention on Mercury? ▪ Any other comments?

Annex 3

LIST OF INTERVIEWED PERSONS

Name		Position	Institution
1.	Richard Mwendandu	Director – MEAs	Ministry of Environment and Forests
2.	John Mumbo	Head of Chemicals Unit	National Environment Management Authority
3.	Pauline Ngari	Chief Public Health Officer	Ministry of Health
4.	Tom Oduor	Chemist	Kenya Bureau of Standards
5.	Paul Ikmat	Chemist	Kenya Revenue Authority