zero Hg
mercury working group

Enforcement measures

to restrict high mercury cosmetic products under the Minamata Convention

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Executive Summary

By the end of 2020, the Minamata Convention on Mercury requires each Party to ban the manufacture, import or export of cosmetics containing over 1 ppm mercury, by taking appropriate measures. However, compliance with this requirement may present a challenge for Parties, as the sale of skin-lightening products is a fast growing multi-billion dollar industry, they are widely available, and research indicates that a certain percentage of these products contain dangerously high levels of mercury and other potentially hazardous substances.

In our companion report "Dangerous mercury-laden and often illegal skin lightening products: Readily available for (online) purchase"[1] extensive testing by the Zero Mercury Working Group (ZMWG) again confirms that local markets and also internet platforms, such as Amazon and eBay (along with many other online internet marketers worldwide), are selling toxic, dangerous and often illegal skin-lighteners that have been already identified by many governments around the world as over the legal limit. Further, e-commerce giants have failed to ensure that cosmetics sold through their sites directly or by third-party sellers are free of toxic and illegal substances like mercury.

Therefore, to address this growing challenge, coordinated compliance mechanisms are needed at the local, national, regional and global levels. The ultimate goal of this publication is to improve consumer protection by targeting unsafe products and accelerating their removal from commerce before they are sold to consumers.

This report presents elements for improving enforcement of the Minamata Convention provisions for banning cosmetic products with mercury levels over 1 ppm. It also presents a field survey of the systems and strategies in place in eight developing countries where the ZMWG has member organizations.

The analysis identified several key areas of activity that are important for successful implementation of the Minamata Convention provisions for controlling cosmetics containing over 1 ppm mercury:

- **Laws, regulations and supporting tools**. Laws and supporting policies should be enacted in line with the Minamata Convention restrictions on cosmetics. Supporting measures could include such provisions as ingredient lists, licensing systems, detention lists,[2] advisories and alert systems (e.g. EU RAPEX, ASEAN PMAS).
- **Division of responsibilities and mandates**. Roles, responsibilities, mandates and decision-making processes should be clearly defined in national law for all relevant stakeholders.
- **International collaboration**. Regional and international collaboration is essential for countries with limited resources to share costs and technical expertise, e.g., for market surveillance and enforcement, information-sharing, product inspection and analysis, and training. A regional alert system, for example, can be used to rapidly share information about non-compliant products among collaborating countries. Joint units for monitoring and tracing dangerous and non-compliant products sold online can inform the customs service, as well as consumers, regarding products that may be non-compliant.
- **Inspections, sanctions, penalties, voluntary agreements and screening tools**. For an enforcement scheme to be effective, there should be a system of regular inspections, sanctions and penalties for non-compliance. Customs services need access to basic monitoring equipment (e.g. XRF) and the training to effectively utilize them. Laboratory capacity for higher accuracy analytical work is also needed if legal measures are to be taken against importers.

[1] Report can be found at https://www.zeromercury.org/mercury-added-skin-lightening-creams-campaign/

[2] A "detention list" is a list of products that have been found to be non-compliant with national or international legislation. It could be used by the national customs service to stop the import of a listed product until the importer or supplier verifies that the product is in compliance.

- **Engagement with e-commerce platforms.** Channels of communication need to be established between governments and e-commerce platforms to inform them about national/regional labelling requirements, detention lists, communication means for posting alerts, etc. Effectively dealing with e-commerce, which is typically beyond the reach of national legislation, may require special measures such as voluntary agreements (e.g. EU Product Safety Pledge), or the ability to shut down web pages if other reasonable measures fail.
- **Consumer outreach and collaboration with civil society organizations (CSOs), market surveillance and testing mechanisms.** Well-informed consumers are key to combatting the marketing of toxic products. Information on the risks of certain product ingredients could be presented through health care providers, online advisories and national detention lists, along with information on how to submit complaints to the authorities. In particular, in low- and middle-income countries where scarce resources may limit the scope of the authorities, CSOs with access to reliable analytical instruments could support the authorities in the work of identifying non-compliant products.
- **Systems for sustainable financing**. Effective implementation of any international agreement requires dedicated funds. Many low- and middle-income countries still rely heavily on external funds to implement international agreements. In the long run, however, Parties will need to create conditions for raising the necessary funds in their own countries, to sustainably implement obligations required under the Minamata Convention. Industry is a potentially important partner in the "integrated approach," and may help to unlock new funds.
- **Harmonization of implementation and enforcement mechanisms**. In the medium to long term, in support of the Minamata Convention, countries should strive for better regional and/or global harmonization of legislation, enforcement measures, standards and communication systems preventing the marketing of unsafe products. Such harmonization will simplify and facilitate enforcement, which helps to ensure a level playing field among companies acting in both the traditional and online supply chains, while at the same time reducing product related risks to consumers.

1 Introduction

The primary aim of this report is to provide guidance for enforcing the ban on high mercury cosmetics under the Minamata Convention on Mercury. After 2020, most cosmetics must contain less than 1 ppm (µg/g) mercury under the Minamata Convention.[3]
However, compliance with this requirement may present a challenge for Parties, as mercury-added skin-lightening products are widely available on the market and their use continues to rise.[4, 5, 6] Therefore, to address this growing challenge, coordinated compliance mechanisms are needed at the local, national, regional and global levels.
To assist in this work, this report provides a menu of tools and measures that could potentially serve as examples for complying with the cosmetic provisions under the Minamata Convention. Successful compliance depends on a number of factors, but the basic elements include:

- Appropriate laws, regulations and policies that adhere to the Minamata Convention provisions through adoption of effective national legislation. These would also need to include supporting policies, strategies and enforceable legal mechanisms to address on-line sales.
- Clear divisions of responsibilities and effective coordination among enforcing ministries and governmental agencies.
- Regional and international cooperation.
- Assistance, penalties, inspection systems, etc. to discourage non-compliance.
- Consumer outreach and collaboration with civil society, including market surveillance and testing mechanisms.
- Sustainable financing of enforcement mechanisms.

These elements are further discussed in the following sections of the report.

2 Methodology

As part of the information gathering process, the Zero Mercury Working Group Network (ZMWG) completed the matrices shown in Annex A based on information gathered by partner non-governmental organizations (NGOs) from their respective governments. These included national and regional laws, regulations, and associated enforcement measures, in order to understand and record useful lessons from the experiences of various countries. The Annex A matrix was supplemented with some additional research findings that became available after analysis of the information collected.
The information collected from different countries was complemented by the collective knowledge and experiences of the ZMWG member organizations. Valuable information was also drawn from the experiences around the development of tools for the sound management of chemicals and waste.

[3] Minamata Convention (http://mercuryconvention.org/Portals/11/documents/Booklets/COP1%20version/Minamata-Convention-booklet-eng-full.pdf).
[4] The report Mercury-added skin-lightening creams: available, inexpensive and toxic (http://www.zeromercury.org/wp-content/uploads/2019/02/zmwg_skin_lightening_cream_report_final_nov_2018.pdf), and additional references therein.
[5] Dangerous, mercury laden and often illegal skin lightening products: Readily available for (online) purchase, ZMWG Report can be found at https://www.zeromercury.org/mercury-added-skin-lightening-creams-campaign/
[6] No One Knows How Many of the World's Skin-Lightening Creams Are Tainted With Mercury, *Bloomberg Business Week*, 28-08-2019.

3 Laws, regulations and supporting tools and measures

3.1 Need for a legal framework

Laws provide the authoritative basis to address an issue by defining its scope, principles on which a policy rests, and powers and responsibilities for relevant stakeholders. The first step is to ensure that legislation that complies with the Minamata Convention 1 ppm mercury limit for cosmetics, is put in place; it can then be complemented by a set of supporting measures. Adoption of international chemicals agreements should also be part of a larger approach to raise the overall profile for sound management of chemicals and waste in context of broader national legislation.[7]

As demonstrated in numerous Minamata Initial Assessments, a legal gap analysis should be conducted to determine how the relevant provisions would be integrated into national legislation. There are guidance documents to support such work, such as the United Nations Institute for Training and Research (UNITAR) National Chemicals Management Profile,[8] the Natural Resources Defense Council's training modules and its Guide to Checklist of Minamata Convention on Mercury Obligations Which May Require New Legal Authority,[9] the (ZMWG) Ratification and Implementation Manual[10] and the key elements outlined in the Legal and Institutional infrastructures for the sound management of chemicals and measures for Recovering costs of national Administrations (LIRA) Guidance.[11] A legal gap analysis ensures efficient use of resources and continuity where there are existing legislative provisions to build on, e.g., laws governing cosmetics, product safety or general restrictions on hazardous chemicals, but the details depend on the national context. Such legal reform work could also be supported by Civil Society Organizations (CSOs).[12]

[7] This could be in line with the 11 priority elements in the work with the United Nations chemicals strategy Strategic Approach to International Chemicals Management (SAICM). Putting the 11 core elements in place will also support a number of the targets of the global sustainable development goals of Agenda 2030. See UNITAR National Chemicals Profile (https://www.unitar.org/cwm/saicm/national-profile).

[8] See UNITAR National Chemicals Management Profile (https://www.unitar.org/cwm/saicm/national-profile).

[9] The Minamata Convention on Mercury: Contents, Guidance, and Resources (https://www.nrdc.org/resources/minamata-convention-mercury-contents-guidance-and-resources).

[10] Minamata Convention on Mercury Ratification and Implementation Manual (https://www.nrdc.org/sites/default/files/minamata-convention-on-mercury-manual.pdf).

[11] UNEP, LIRA Guidance on the Legal and Institutional Infrastructures and Measures for Recovering Costs of National Administration for Sound Management of Chemicals (http://wedocs.unep.org/bitstream/handle/20.500.11822/12224/LIRA_Guidance%20Report_PRESS.pdf?sequence=1&isAllowed=y).

[12] An example includes modifications to existing laws, such as modifications proposed by CSOs that were considered by relevant national agencies and ministries for adoption. Proposals for amendment of the Nigerian Cosmetics Regulations 2005 under the National Agency for Food and Drug Administration and Control Act, to include prohibitions of bleaching agents in the Cosmetics Regulation 2005 can be found at http://www.zeromercury.org/wp-content/uploads/2019/03/Nigeria-DraftProductsRegulationsTransmittalMemo-final-rev2.pdf. In Mauritius, the Consumer Protection Act is proposed to be amended as relevant (http://www.zeromercury.org/wp-content/uploads/2019/03/Mauritius_-_Products_Regulations_Transmittal_Memo_and_proposed_draft_laws-Final2.pdf).

A legal gap analysis will further need to look at harmonizing and/or amending related sectoral legislation to enable it to support the Convention provisions. Examples are laws and regulations to enable the work of the customs services to control illegal imports/exports, such as inspections and potential penalty/sanction mandates, as well as a law on mandatory ingredient lists for cosmetic products.
Legislators and implementing agencies can use a wide spectrum of tools to support implementation of laws, as well as to inform target groups. Some measures relevant to compliance with the Minamata Convention provisions for banning cosmetics over 1 ppm mercury may include:

Examples of laws under which cosmetics can be found

In **Kenya**, the Standards Act, chap. 496 and the Food, Drugs and Chemical Substances Act, chap. 254, prohibit the sale of cosmetics that may be hazardous to the user. In **Côte d'Ivoire**, decree 2015-288 on Cosmetics and Personal Care Products, Article 7, prohibits the manufacture of cosmetics with mercury and mercury-compounds. In **India**, relevant wording can be found in the Drugs and Cosmetics Act 1940, and In **Bangladesh** new specified Standard Guideline for Skin Creams was published under BDS 1382:2019 and it became mandatory according to SRO-275 and 276-Law/2019, which was adopted in September 2019. The law is already in action from 3rd November, 2019. In **Nepal**, the Council for Standardization (NCS) approved the Nepal Standard BS 2076 (2019) for Cosmetics on 3 July 2019, effective for all three sets of cosmetics (lipsticks, skin creams and skin lotions) imported, produced, sold and distributed in Nepal.

- Authorizations, restrictions, bans and labelling of ingredients;
- Supporting tools such as advisories, alert systems, detention lists and advertising restrictions.

3.2 Authorizations, restrictions, bans, labelling of ingredients

Regulatory provisions pertaining to chemicals could be linked to **lists of allowed, restricted, and/or banned ingredients,** and adopted into suitable legal text. Generally speaking, lists of **allowed** ingredients are the most costly to put in place and maintain, as they need to build upon systems for registration, evaluation and authorization of ingredients. Such systems may potentially be covered by cost-recovery mechanisms (see chapter 6 on sustainable financing mechanisms), but the national conditions for putting the mechanisms in place need to be thoroughly analyzed.
Measures **restricting or banning** certain ingredients also require a supporting evaluation system; however, as banned and restricted ingredients are less numerous, this approach may be more feasible for Parties with limited resources. One way to save resources is to adopt already existing lists of banned and restricted ingredients from other countries or regions, e.g. the European Union (EU) Cosmetics Regulation.[13] However, low and middle income countries may still struggle to secure the resources (funds, know-how, technical equipment, etc.) necessary to ensure compliance with the regulation of all chemicals on an adopted list.
Another, yet possibly narrower approach may be to base the restriction/ban lists on certain hazardous qualities of ingredients, e.g. carcinogenicity, mutagenicity, neurotoxicity, and so on, preferably according to the classification rules of the Globally Harmonized System (GHS). The Minamata Convention limit of 1 ppm for mercury in cosmetics can potentially be integrated in any of the above-mentioned models, or may already be included in a list adopted from another country. All countries referenced in this study have already adopted a 1 ppm upper limit for mercury in cosmetics into their national legislation. Some of them also have specific cosmetics legislation; others have general product and consumer safety legislation.

[13] EU Cosmetics Regulation (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:pdf)

Furthermore, laws may **require labelling of the ingredient lists on the packaging**. A number of the countries in this study (e.g. India[14] , Côte d'Ivoire[15], and Bangladesh[16]) also have requirements for cosmetic labelling. Ingredient lists are helpful to consumers, to inform their purchasing choices. Ingredient lists could serve also as a rough inspection tool, which can be used for initial visual scanning for banned or restricted ingredients in a product (see chapter 3.3 on supporting tools and measures). However, it should be kept in mind that oftentimes the ingredient lists may not be accurate and should always be complemented by inspections or other independent verification mechanisms. A set of model product labelling requirements may be seen in Table 1.

Table 1. Example of a set of model product labelling requirements

Element	Provisions
Identity information	Name of the product; Batch number; Name and address of the manufacturer and distributor; Country of origin
Ingredient list	Full ingredient list based on the most up-to-date edition of the INCI[17] from the Personal Care Products Council; Amount (or at a minimum, the list of ingredients by decreasing magnitude) of each ingredient present, in metric dosage unit
Content	The net content of the container by weight or volume in metric system
Dates	Date of manufacture; Best before/expiry date
User information	Any special storage conditions; Any special handling precautions

One way to improve the reliability of ingredient lists is to include **ingredient disclosure in a licensing system** (as in Uganda[18]), where manufacturers and importers are required to disclose the ingredient composition of the products that they either manufacture or place on the market, to a licensing agency or a non-governmental licenser commissioned by the government, in order to be licensed to operate. This approach could potentially encourage some companies to take more responsibility for the products they offer. Such a licensing system will, however, only improve reliability if supported by a verification mechanism with spot-checks (and associated laboratory analyses) done frequently enough to discourage submission of false information. A licensing system may also be used to help finance inspections and other product safety

[14] The Indian Drugs and Cosmetics Act (1940) has mandatory provisions for the manufacturers to disclose and label the ingredients of the cosmetics.
[15] In Côte d'Ivoire, Article 20 of the decree 2015-288, requests a qualitative and quantitative list of ingredients, as well as all excipients with known effects shall be listed on the cosmetics label.
[16] In Bangladesh, mandatory labelling for creams have been included in BDS 1382:2019 under packing and marking.
[17] The International Nomenclature of Cosmetic Ingredients (INCI) is available in full online to subscribers (http://webdictionary.personalcarecouncil.org/jsp/Home.jsp)
[18] In Uganda, different categories of trade licenses are issued under different laws and regulations. Licenses for imports and exports are governed by the External Trade Act, chap. 88 (https://ulii.org/ug/legislation/consolidated-act/88), while manufacturing and retail trade are licensed under the Trade Licensing Act, chap. 101 (https://ebiz.go.ug/wp-content/uploads/2016/01/trade-licensing-act-Chapter_101.pdf). For the purposes of ingredient disclosure, licensing manufacturers and importers is a higher priority than licensing retailers, since retailers may lack access to ingredient data and the resources required to license retailers may be substantial.

measures, as discussed in chapter 6 on sustainable financing mechanisms. Another country example of a process for setting up a licensing system is summarized in the box below.

When setting up licensing systems the process should consider including the following as, for example, in Côte d'Ivoire

All stakeholders who wish to manufacture, import or sell cosmetics should proceed as follows:

- Apply for a manufacture, import or distribution license for the products in question from the National Evaluation Comity for Trade with Authorization of Cosmetics and Personal Care Products.
- The application letter, should be accompanied by:
  - An administrative file;
  - A technical file specific to each category of cosmetics and personal care products;
  - Some samples from the batches to be licensed.
- After submission of all the documents and samples, the committee in charge of licensing the manufacturer, importer or retailer can:
  - Investigate the product manufacture process;
  - Consult with chosen experts for assays and collect their views;
  - Request additional information;
  - Send the products to the National Laboratory of Public Health to confirm that the control methods used by the manufacturer/importer/ retailer, and that are described in the application, follow regulation.

3.3 Supporting tools and measures

Effective information sharing systems may include a combination of advisories, alert systems and detention lists. These are key tools available to rapidly diffuse important product safety information to a wide network of stakeholders.
Advertising restrictions should also be considered, in combination with bans or restrictions for certain product categories.

3.3.1 Advisories

Advisories are recommendations or warnings issued by competent authorities to the public, e.g. in response to important product risk information, which may come from an alert system as described below. Advisories may thus be used as tools for public education about environmental and health issues and also to alert various levels of governments as to a potential hazard to be on the lookout for. The most effective channels for reaching out to consumers depend on the country context. In countries with good Internet coverage, for example, an online system may be sufficient, whereas in other contexts a cell phone app may be more appropriate. Utilization of health care centers may be another effective route for distributing information to sensitive and at-risk subpopulations, e.g., pregnant women and nursing mothers.

In the Philippines, the Food and Drug Administration (FDA) regularly publishes public advisories and lists of unauthorized products. Consumers may also verify if products are authorized by the FDA via the search engine embedded in the FDA website.[19] Enterprises are initially warned through public advisories to stop the distribution of unauthorized products. If outlets continue to sell unauthorized products, regulatory measures and sanctions are applied. The FDA also submits requests to local government units and law enforcement agencies to assist and support the ban of the identified products[20].

Development of advisories in the Philippines

Most of the advisories are based on results from post-marketing surveillance (PMS) activities, with spot checks. In addition, the FDA also accepts through their e-report facility information from private persons and non-governmental organizations (NGOs) who/that may have information regarding unauthorized products.

Local government units have the mandate to develop such national advisories (hence the call for local government units and law enforcement agencies to follow the advisories once published by the FDA).

In early 2019, the FDA issued Advisory No. 2019-074,[1] a public warning against cosmetic products containing mercury (Parley Beauty Cream and Parley Herbal Whitening Cream, respectively). The products were found to contain mercury through the FDA's post-marketing surveillance activities.

The FDA is also known to act on information from and actions taken by other countries. As an example, the FDA issued Advisory No. 2019-141[2] in response to an alert in the ASEAN Post-Marketing Alert System issued by Malaysia, which had identified cosmetic products that were not in compliance with the ASEAN Cosmetic Directive.

1. Food and Drug Administration (2019). FDA advisory no. 2019 -074. Retrieved from: https://www.fda.gov.ph/wp-content/uploads/2019/03/FDA-Advisory-No.-2019-074.pdf
2. Food and Drug Administration (2019). FDA advisory no. 2019-141. Retrieved from: https://www.fda.gov.ph/fda-advisory-no-2019-141-dissemination-of-asean-post-marketing-alert-system-pmas-report-on-adulterated-cosmetic-products-with-reference-no-8-9-2019-k/

[19] Philippine Food and Drug Administration (2019). FDA advisory 2019-043. Retrieved from: https://www.fda.gov.ph/wp-content/uploads/2019/06/FDA-Advisory-No.-2019-143.pdf

[20] An online reporting facility for such cases is also available (ww2.fda.gov.ph/ereport).

3.3.2 "Detention lists" and alert systems

Detention lists and alert systems are commonly used to support the implementation of regulations on hazardous products, including illegal high mercury skin-lightening products. A suspect product can be included in a list of prohibited products – a so-called "detention list" – and/or a warning or alert can be rapidly issued to customs services, importers, retailers and consumers, as relevant.

If a product has been found or suspected by a competent government agency to be non-compliant with national legislation, it could be added to a detention list (directly or via an alert system), to notify the customs service to stop imports of the product until the importer or supplier certifies that the product is in compliance. Any source of information, such as data from CSOs, could be brought to the attention of the authorities as the basis for further investigation by government agencies.

An alert system, on the other hand is a mechanism for reporting and rapid information sharing to all concerned stakeholders, sometimes including the public, about products suspected or found to be non-compliant, and what measures have been taken to address them. Ideally it should include:

Country example of the development of a national 'detention list':

The Uganda National Bureau of Standards (UNBS) made the decision to develop a list of prohibited products (a "detention list") after Post Marketing Surveillance activities had proven that some skin-lightening creams contained ingredients harmful to the skin and could lead to skin infections. The list was developed in consultation with the Ministry of Trade, Industry and Co-operatives, and the Kampala City Traders Association (Kacita) and Cosmetic Traders, in a bid to remove sub-standard cosmetics from the market, and to set appropriate standards for the sector. To that end, they agreed that some of the cosmetic products that contain hydroquinone and mercury should be banned from the Ugandan Market. The Uganda detention list can be found online at:

https://www.unbs.go.ug/attachments/alerts/4/list-of-prohibited-products.pdf

- A function that permits certain agencies to report non-compliance. This function should be open to competent government agencies, custom service and the police.
- A function for academia, industry, CSOs and others to report suspected non-compliance to competent government agencies.
- A function for rapidly issuing the alert to all concerned stakeholders. This function should be available to competent government agencies only.

An alert system is typically used to draw immediate attention to a non-compliant product, and inform relevant authorities enabling them to withdraw the product from the market or 'hold it in custody' until relevant information is provided by a testing lab or the manufacturer on its safety. Alert systems could also be used to alert retailers that the manufacturer or importer needs to certify that the product is in compliance with the law, or else it may be subject to withdrawal from the market. If a product has been reported to be non-compliant in other jurisdictions that have similar provisions in place, the alert system information could be shared among different levels of government as well as neighboring countries, and used accordingly.

Alert systems are already in place in some countries, but there is no "gold" standard. Often, the measures taken depend on several factors, e.g., on the details of national legislation requiring companies to verify compliance with the law, and legal provisions for restricting or withdrawing products from the market. In countries with sufficient and reliable Internet coverage, the alert system could take the form of an online system. Under other circumstances, other solutions may

be better, such as a cell phone app, or providing information for dissemination via health care providers.

In the near term, a national or regional alert system should be established, but in the medium to long term it would be essential to establish a global system under the auspices of an international organization such as the United Nations Environment Programme (UN Environment) or the World Health Organization (WHO), to which products found to be non-compliant with national and regional legislation could be reported into a database and posted on a publicly available website. A description of the sanctions or other measures taken could accompany the alert system as relevant. Such a database could alert competent authorities and customs services around the world to products that they may wish to investigate further if found within their respective jurisdictions, thereby saving time and costs for inspection activities. Since skin-lightening creams with more than 1 ppm mercury will be illegal after 2020, it is possible that unscrupulous manufacturers might change brand names and packaging design before then. A global database would make it easier to keep track of illegal products, and different versions of such products, that may be found in different markets.

Two current regional information sharing and alert systems are described below – the EU's RAPEX and the Association of Southeast Asian Nations (ASEAN) Post-Marketing Alert System.

3.3.3 EU Safety Gate Rapid Alert System (RAPEX)

A functional and effective regional information sharing system is the Safety Gate Rapid Alert System (RAPEX) of the EU.[21] The RAPEX information system was established under Article 12 of Directive 2001/95/EC on general product safety and its notification system.[22] It enables a quick exchange of information between EU/European Economic Area (EEA) member states and the European Commission about non-food products posing a potential risk to the health and safety of consumers.

RAPEX plays an important role in the area of product safety. It complements other actions taken both at national and at EU level to ensure a high level of product safety in the EU. RAPEX data helps to: (a) prevent and restrict the supply of dangerous products; (b) monitor the effectiveness and consistency of market surveillance and enforcement activities carried out by Member State authorities; (c) identify needs and provide a basis for action at EU level; and (d) facilitate consistent enforcement of the EU product safety requirements and therefore contribute to the smooth functioning of the single market.

The Commission maintains a web-based application for use as a communication tool for the purpose of RAPEX. Member States use this system to create and submit notifications through the RAPEX application, and the Commission uses it to validate and distribute the documents it receives. The Commission lays down the rules for granting access, and provides access to the system to all RAPEX Contact Points, competent national authorities and the relevant Commission departments. The Commission gives access to as many users as possible, taking into account their needs and technical limitations.

There are seven hazard categories covered by RAPEX, of which one is chemical hazards. In 2018, around 25% of the RAPEX alerts concerned chemical hazards.[23] A Member State submits a RAPEX notification only if it considers that the effects of the risk(s) posed by a product go or can go beyond its territory ("cross-border effects" or "international event"). National authorities in the member states are responsible for submitting appropriate information to the system, and alerts are automatically translated into 25 languages to ensure that appropriate action is taken as

[21] RAPEX (https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/index_en.htm)

[22] RAPEX Guidelines (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D0417&from=EN)

[23] RAPEX 2018 Annual Report (https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/reports/docs/RAPEX_2018_Report_en.pdf)

quickly as possible. RAPEX can also diffuse information reported by NGOs, but the authorities always have the ultimate responsibility to ensure that it is correct.
An alert always contains information about the product in question, such as the product category, manufacturer, country of origin, brand name, batch number or bar code, risk category, and a picture of the product. The information made available to the public is a summary of a notification and includes in particular the elements that allow for the identification of the product, as well as the information about risks associated with the product, and measures taken to prevent or restrict those risks.
To ensure efficient and effective follow-up, **best practice follow-up techniques** should be employed by national authorities, including: (a) regular and systematic spot-checks on the market; (b) cooperation with business associations; (c) publication of RAPEX data via the Internet or other electronic and paper media; and (d) regular checks by national authorities on the availability of products notified via RAPEX in e-commerce.
Preventive and restrictive measures can be taken in response to products posing a risk, either on the initiative of the economic operator who placed and/or distributed it on the market (i.e., "voluntary measures"), or as ordered by a member state authority competent to monitor the compliance of products with EU safety requirements (i.e., "compulsory measures").[24]
If a manufacturer or distributor finds out that one of their products is dangerous, they have to inform the competent national contact in charge of receiving and dealing with alerts of dangerous non-food consumer products according to Article 5(3) of the General Product Safety Directive (GPSD) (2001/95/EC).
If a consumer wants to report a dangerous product, they can contact their national product safety complaint service.[25]
Furthermore, if a consumer wants to be regularly updated about the RAPEX, they can subscribe to weekly reports.[26]
Since 2005, 46 cosmetic products were reported under RAPEX to contain high levels of mercury.[27]

[24] **(a) Voluntary measures:** (i) Preventive and restrictive measures adopted on a voluntary basis by an economic operator, i.e., without any intervention of an authority of a member state; (ii) recommendations and agreements with economic operators in their respective activities concluded by member state authorities; this includes agreements that are not in written form and result in preventive or restrictive action taken by economic operators in their respective activities in relation to products posing a serious risk that they put on the market. **(b) Compulsory measures:** Measures adopted or decided to be adopted by member state authorities, often in the form of an administrative decision, that oblige an economic operator to take preventive, corrective or restrictive measures in relation to a specific product they put on the market.
[25] National product safety complaint service (https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/docs/contact_points_consumers_en.pdf)
[26] https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/?event=main.listNotifications&lng=en
[27] https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/?event=main.search&lng=en#searchResults

More details can be found in the RAPEX Guidelines.[28]

Categories of measures taken in response to a RAPEX alert

Article 8(1)(b) to (f) of the GPSD provides a list of different categories of measures that may be applied when notifying RAPEX, including the following measures:

(a) marking a product with appropriate warnings on the risk(s) it may present;

(b) making the marketing of a product subject to prior conditions;

(c) warning consumers and end-users of the risks that could be posed by a product;

(d) temporary ban on the supply, offer to supply and display of a product;

(e) ban on the marketing of a product and any accompanying measures, i.e. measures required to ensure compliance with the ban;

(f) withdrawal of a product from the market;

(g) recall of a product from consumers;

(h) destruction of a withdrawn or recalled product.

For the purpose of RAPEX, the term "withdrawal" is used exclusively for measures aimed at preventing the distribution, display or offer of a product posing a risk to consumers or other end-users, while the term "recall" is used only for measures aimed at the return of a product that has already been made available to consumers or other end-users by a producer or distributor.

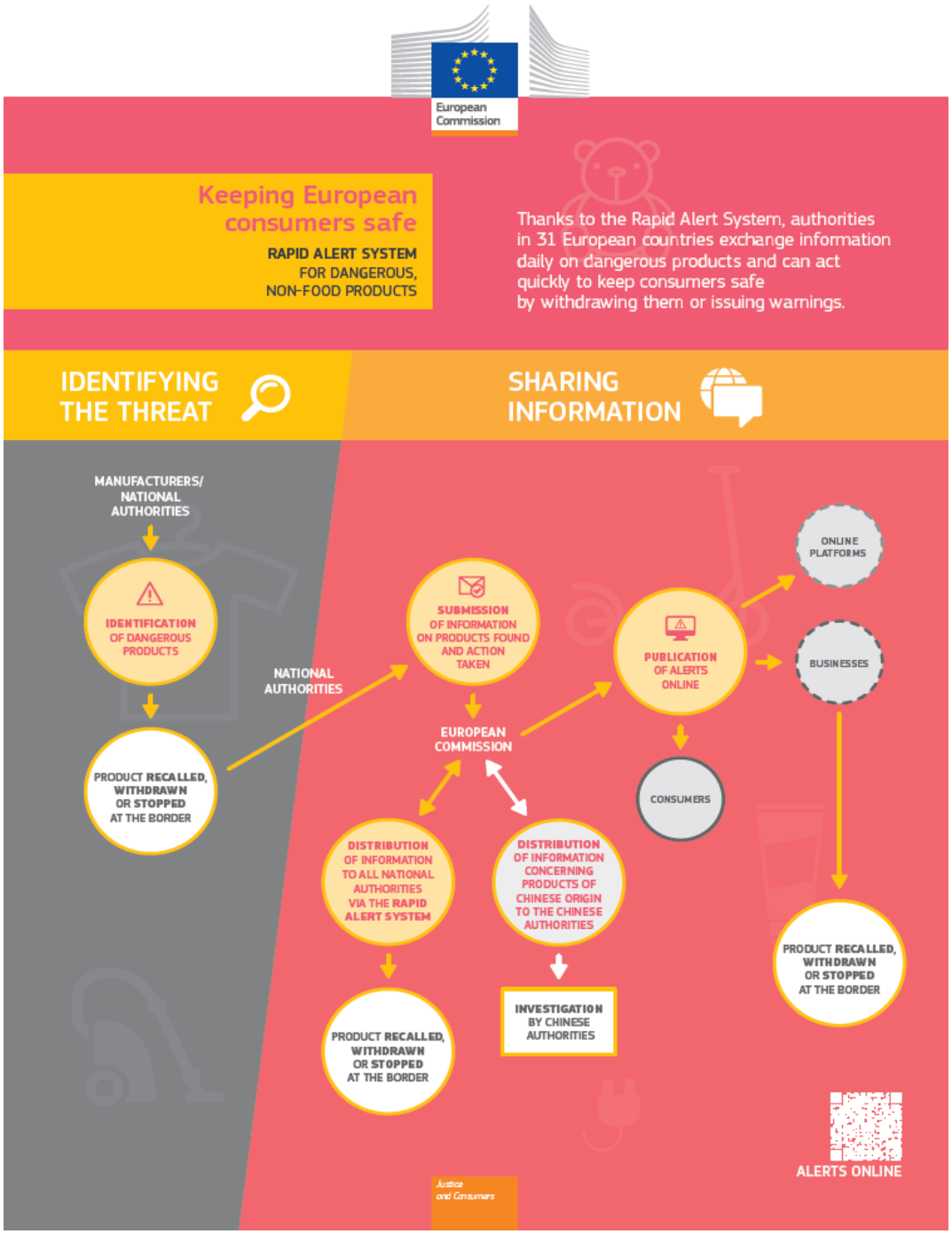
One of the biggest challenges for RAPEX is online sales platforms, for which legislation is still too weak. However, a way to address this may be through voluntary agreements between authorities and the online sales platforms (see also chapter 3.3.5 below). Another challenge is to encourage consumers to register their online purchases of certain products, so that they may be contacted by the authorities if a product needs to be recalled.

There are several models for funding alert systems. For example, market surveillance authorities may charge economic operators administrative fees (in addition to fines) for non-compliance with regulations. Those fees may be set at a level to cover the costs of coordination, testing, information sharing, withdrawing products from the market, monitoring to ensure offenders have taken corrective action, etc.[29]

[28] RAPEX Guidelines (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D0417&from=EN)

[29] Regulation of the European Parliament and of the Council laying down rules and procedures for compliance with and enforcement of Union harmonization legislation on products..., COM(2017) 795 final. See https://ec.europa.eu/transparency/regdoc/rep/1/2017/EN/COM-2017-795-F1-EN-MAIN-PART-1.PDF

Figure 1: Infographics and flow chart for actions and information between different actors in the RAPEX system (Source: https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/docs/rapex-poster-2017.pdf)



3.3.4 Association of Southeast Asian Nations Post-Marketing Alert System

The ASEAN (Brunei, Cambodia, Indonesia, Lao People's Democratic Republic, Malaysia, Myanmar, Philippines, Singapore, Thailand, Vietnam), has also put in place a regional information sharing and alert system on product safety, covering cosmetics, pharmaceutical products, dietary supplements, and related products such as traditional medicines. In the event that a safety concern arises in any ASEAN country, a PMAS coordinator from that country will notify the agency's International Affairs Office ensuring the information is distributed to all other ASEAN countries.

The PMAS will exchange information on:[30]

- Products for which registration has been cancelled, suspended, or withdrawn based on safety issues;
- Products recalled from the market due to quality defects with serious public health implications;
- Products found to be adulterated and associated with serious public health implications;
- Significant label changes, involving safety, that are initiated by the regulators;
- New restrictions on usage;
- Exchange of "Dear Healthcare Professional" letters, media releases related to drug safety, and Adverse Drug Reaction bulletin publications; and
- Adverse Event Reporting of cosmetic products.

Triggers for alerts come from inspection work, academic research, and relevant decisions taken by regulatory agencies or industry. The PMAS has harmonized definitions and terminology for key aspects of adverse event reporting, as well as harmonized mechanisms for reporting. Adverse events may be non-serious (i.e., neither lethal, life-threatening, disabling nor requiring hospitalization) but frequent enough to warrant reporting. In such a case, appropriate medical and scientific judgment is necessary to decide when the case should be reported to the competent authority.

The PMAS consists of a reporting function accessible to competent government authorities in the ASEAN member states and to the companies placing the relevant products on the market, as well as an alert function under the control of government authorities. Companies may voluntarily report their own products to the system based on information about adverse events. Consumer complaints may be a contributing factor to company reports to the PMAS, but must relate to actual adverse events. If the competent authority finds a case serious enough, they would then send an alert to the regional information sharing system, describing the product in question (such as product category, manufacturer, country of origin, brand name, name of company placing the product on the market, batch number and/or bar code, risk category, and picture of the product).

Country example

The ASEAN PMAS was adopted by the Philippines in 2013.[1]

It was developed by the ASEAN for its member countries and is a notification system where a PMAS coordinator notifies the ASEAN International Affairs Office about any posted alert, to ensure that the information is disseminated to other ASEAN countries.

Countries that have adopted the PMAS, such as the Philippines, then publish advisories warning about the product in question.

1. Albert, E. (2017). ASEAN: the association of Southeast Asian nations. Published by the Council on Foreign Relations. Retrieved from: https://www.cfr.org/backgrounder/asean-association-southeast-asian-nations

There are already practical examples of how the PMAS is useful for Minamata Convention compliance work. In June 2019, three cosmetic products with mercury above the permitted level, were found on sale in the region covered by the ASEAN by ongoing PMAS programs. The PMAS does not specify the exact amount of mercury found, but called for "withdrawal of products."[31]

[30] https://www.pacificbridgemedical.com/news-brief/philippines-adopts-harmonized-post-marketing-alert-system/
[31] https://chemicalwatch.com/78664/asean-finds-six-non-compliant-cosmetic-products-on-sale

3.3.5 Dealing with online commerce and extra-legal jurisdiction

3.3.5.1 Interactions with major e-commerce platforms

To address national provisions considered crucial for the safety of consumers and the environment, but recognizing that many suppliers are outside the jurisdiction of national legislation, voluntary agreements on mutual information-sharing and collaboration may be considered.

In the Philippines, besides issuing advisories against products, the FDA has also issued orders for domestic e-commerce platforms such as Lazada Philippines and Shopee Philippines (the two main sources of unauthorized drug-selling) to halt the sale of drug products that are not approved by the FDA. The crackdown has been largely successful, and most of the identified mercury-containing products have disappeared from these online platforms. However, some unauthorized products may still appear on these or other platforms such as the Facebook Marketplace.

Following a dialogue between the European Commission and four large e-commerce platforms (eBay, Amazon, Alibaba and WISH), a voluntary agreement known as the **"Product Safety Pledge"** was signed wherein the e-commerce platforms committed to collaborate with the EU enforcement authorities regarding product safety, as included in Annex B.[32] Under the agreement, these four e-commerce platforms committed:

- to provide contact points for the EU authorities;
- to closely monitor the RAPEX notifications and to take action within two days following a notification to remove a product from the marketplace;
- to inform sellers using their e-commerce platforms about the EU product safety legislation;
- to implement systems to remove from their e-commerce platforms any sellers that repeatedly break the law;
- to put in place systems for communicating to consumers about product withdrawals or corrective actions;
- to annually report to the European Commission on agreed key performance indicators.

3.3.5.2 The RAPEX-China agreement

Another example of a tool for dealing with suppliers outside of one's legal jurisdiction is the RAPEX-China agreement, which enables the European Commission to provide the Chinese authorities with information on dangerous consumer products originating in China, as notified by EU member states via the RAPEX.[33] As shown in Annex C, according to the agreement, the Chinese authorities are to investigate these notifications, and as feasible, adopt measures with regard to the products in question, which may prevent or restrict their further export to the EU. Since the Chinese authorities are not committed to impose any sanctions or other penalties upon receiving information from the EU, the RAPEX-China agreement may be considered to have less force than the EU agreement with the e-commerce platforms.

However, building upon the basic idea of the RAPEX-China agreement, similar agreements with key supplier countries for mercury-added skin-lightening creams could be explored. According to a ZMWG report published in 2018, the most likely countries of origin (as declared on the packaging) for skin-lightening creams with a high mercury content are Pakistan, China, Taiwan, the Philippines and South Korea.[34]

[32] Product safety pledge (https://ec.europa.eu/info/sites/info/files/voluntary_commitment_document_4signatures3-web.pdf)

[33] RAPEX-China (https://ec.europa.eu/info/policies/consumers/international-cooperation-product-safety/bilateral-cooperation_en).

[34] See the report, Mercury-added skin-lightening creams: available, inexpensive and toxic (http://www.zeromercury.org/wp-content/uploads/2019/02/zmwg_skin_lightening_cream_report_final_nov_2018.pdf).

3.3.5.3 Liability issues

Ideas on how to identify and deal with entities outside a country's legal jurisdiction may be inspired by the European Commission guidelines for market surveillance of products sold online.[35] Sellers based outside the EU who specifically target the EU market (e.g., as shown by the marketing language, prices in Euro and acceptance of Euro as payment) must comply with the provisions of the EU General Product Safety Directive (GPSD). If sellers do not target the EU market in this manner, they have no obligation to comply with the provisions of the Directive, even though EU consumers may buy the product from the same e-commerce platform.
Middlemen in the supply chain who store products for the EU market and/or who package the products and deliver them to final customers in the EU also need to fulfill the EU GPSD. If the middlemen attach their own trademark or other distinctive mark to the product, they are then considered to be the manufacturer. Middlemen with these functions usually have contracts as representatives of the suppliers; hence, from a legal perspective they represent the suppliers within the EU. Therefore, they must make sure that the products they deliver to EU customers fulfill all requirements for labelling and user security. In case a product needs to be withdrawn from the market, or corrective measures need to be taken, these middlemen are obliged to collaborate with the competent governmental authorities.
The service provider of an e-commerce platform has fewer obligations, as under the current EU legal regime the service provider is not required to control or gather safety information about every product that sellers place on their platform; the service provider is instead considered to passively host product information. The service provider can only be held liable if they know that information is incorrect and refrain to take action to correct it or to exclude the seller. The postal service, also an international service provider, operates in a slightly different environment. Because postal services must guarantee the confidentiality of correspondence and of the postal items they deliver, in principle they are not liable for the items they deliver, but must cooperate with police and customs services if inspections are necessary.

3.3.6 Advertising restrictions

An "**advertisement**" is a form of communication through the media about products, services or ideas paid for by a sponsor. It is used to encourage, persuade or manipulate consumers to continue with an existing habit/consumption pattern, or to take new actions. Advertising restrictions can support product bans and restrictions by obstructing the usually most important and efficient method for manufacturers, distributors and retailers to reach out to potential customers. At the same time, advertising restrictions send a clear signal to consumers that a specific product category is hazardous and should be avoided.
Some of the countries that provided data for this study have advertising restrictions:
In **India**, The Drugs and Cosmetics Act (1940) has provisions and guidelines for advertising and regulations on various products including cosmetics. The Advertising Standards Council of India (ASCI) issued advertising guidelines for skin-lightening creams in 2014, but the main objective of the guidelines is to stop the dissemination of information that promotes and sustains discrimination on the basis of color, race, caste, etc., and it does not talk about the use of mercury in skin whitening products.[36]
In **Côte d'Ivoire**, decree 2015-288 on cosmetics and personal care products includes specific provisions related to skin-lightening products. Article 10 of this decree prohibits the advertisement of skin-lightening products with mercury and mercury-compounds.
In **Nigeria**, regulations apply to all advertisements and promotion of cosmetic products manufactured, imported, exported, sold, distributed or used in Nigeria. No person shall advertise

[35] Commission notice on the market surveillance of products sold online (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52017XC0801(01)&from=EN)
[36] ASCI Guidelines for skin-lightening products (https://www.ascionline.org/download.php?f=images/pdf/press-release-on-asci-sets-up-new-guidelines-for-the-fairness-products-category-2-.pdf).

a cosmetic product unless (1) the product has been registered by the Nigerian Agency of the Federal Ministry of Health; or (2) the advertisement has the approval of the Agency.

4 Mandates and division of responsibilities

Implementation of regulations governing sound management of chemicals and waste is typically a shared responsibility of various stakeholders, in particular public authorities and industry. These roles, responsibilities, mandates and decision-making authority must be clearly defined in a primary law. Further details relating to specific stakeholders can be defined in sector specific regulations. This will help to avoid overlap and duplication of work, or unclear division of tasks, as well as helping to allocate the cost of implementation.

Due to the cross-sectoral dimension of chemicals management – mercury not being an exception – many ministries or authorities may have to be involved in the enforcement of the provisions in a primary law. Stakeholders that may be involved include sectoral authorities, provincial/local authorities (often the implementing bodies in federal states), ministries in charge of finance and development planning, customs services, police and the national focal point for the Minamata Convention. Therefore, it is very helpful to establish a lead ministry, or an executive inter-ministerial body, to coordinate the work.

An approach promoted by the WHO and the UN Environment Programme is a strategic alliance between the ministries responsible for health and environment, which could chair an inter-ministerial advisory group.[37] The lead ministry should normally have executive powers, including the power to issue regulations and standards/quality marks, carry out inspection work, be involved in international collaborations (see chapter 4.1) to promote implementation of international agreements, collect data and maintain information-sharing systems (see chapter 3), and charge fees for services provided (see chapter 6). An inter-ministerial advisory group may have the same powers, or may simply have an advisory and coordinating role, although such a group must have a clear legal basis that sets out the mandates and division of responsibilities, how the participants are appointed and based on what qualifications.

The role of the customs service is generally limited to spot checks and inspections at border crossings, whereas other authorities such as the police can do spot checks and inspections once products have entered the domestic market.

Among the countries reviewed in the information gathering process for this report, Kenya, – a member of the East African Community (EAC) – appears to have functioning systems for division of responsibilities and mandates in place. Customs service, police and inter-agency collaboration are defined and mandated in the national legislation. Furthermore, among other elements, regional harmonization of product, inspection and test methodology standards in the EAC is already a reality, or in progress, as discussed in the following chapter. Such cooperation agreements are often wider, e.g. for chemicals and waste and include cosmetic products.

Both the 2017-18 and 2019 ZMWG market surveys of skin-lightening creams suggest that these national and regional coordination mechanisms are effective, as no mercury-added skin-lightening creams were found during spot checks in Kenya and Uganda in 2017 and 2018; in 2019 one cream purchased in Kenya from the Internet had high mercury and only two in Uganda purchased from the local market.[38, 39] However, the number of samples was limited and may not have fully captured the situation in the informal commercial sector.

Country examples of the allocation of responsibilities for the sound management of chemicals and waste are presented in Annex D.

[37] Further information is available, e.g., on the WHO website (https://www.who.int/heli/en/).

[38] See the report ‚Mercury-added skin-lightening creams: available, inexpensive and toxic (http://www.zeromercury.org/wp-content/uploads/2019/02/zmwg_skin_lightening_cream_report_final_nov_2018.pdf).

[39] Dangerous, mercury laden and often illegal skin lightening products: Readily available for (online) purchase, ZMWG Report can be found at https://www.zeromercury.org/mercury-added-skin-lightening-creams-campaign/

4.1 International collaboration

Collaboration with other countries in achieving sound management of chemicals and waste, including implementation of international agreements, can help to optimize the need for special skills as well as limited resources. Furthermore, international collaboration to harmonize laws and supporting regulations simplifies procedures for import and export, creates a more level playing field for companies, and can eliminate double standards that are now a disadvantage for consumer safety. In the end, the economic benefits of improved management of chemicals and waste come from 1) lowering the risks and related healthcare costs for society, and 2) reduced costs related to impaired ecosystem functions and their need for remediation.[40]

In countries and regions with limited financial and technical resources, regional cooperation around test hubs and research is highly advisable. Due to the efficiencies afforded by regional collaboration, domestic resources that might have been allocated to purchase expensive analytical equipment and to hire and train operational staff can be freed up to support more local inspection work.

The **EAC** (Burundi, Kenya, Rwanda, Tanzania and Uganda) already has this kind of collaboration in place, governed by the EAC Protocol on Environmental and Natural Resources Management, article 28, for the management of chemicals and waste. Cosmetics are covered by this article, which provides that the Partner States:

- develop and harmonize policies, laws and strategies to protect human health and the environment against the adverse effects of toxic chemicals and products containing toxic chemicals;
- develop measures to control illegal trafficking of chemicals scientifically proven to be hazardous; toxic or persistent in the environment;
- adopt common measures for importation, transportation, use, storage and disposal of chemicals; chemical products, and products containing or made with chemicals;
- promote collaborative research and assessment on levels of chemical contamination, impacts to human health and the environment, technologies for decontamination and remediation of contaminated sites, and on the development of feasible chemical substitutes and biological and botanical alternatives;
- cooperate in the exchange of technical information on new developments occurring in the sub-region or region regarding chemicals issues, and strengthen capacity for chemical analysis; and
- encourage collaboration in the implementation of international agreements on the use and handling of chemicals.

This collaboration, which has already helped customs services and other implementation and enforcement authorities in the region to tighten control of skin-lightening products in the market, is one element of the long-term ambition for regional harmonization of laws and policies. The banned skin-lightening products have virtually disappeared from the legal markets in the countries participating in the EAC, except from online sales platforms.

Customs services of the EAC member states carry out joint inspection work at border crossings. These countries also jointly invest in training, research and analytical capacities. The management of the EAC Customs Union is governed under the EAC Management Act 2004, which provides that each Partner State's Directorate of Customs should collaborate in the initiation and implementation of policies on customs and related trade matters in the Community.[41]

[40] See the report, Cost of inaction on the sound management of chemicals (http://wedocs.unep.org/bitstream/handle/20.500.11822/8412/-Costs%20of%20inaction%20on%20the%20sound%20management%20of%20chemicals-2013Report_Cost_of_Inaction_Feb2013.pdf?sequence=3&isAllowed=y).

[41] East African Community Customs Management Act 2004 (http://www.kenyalaw.org/kl/fileadmin/pdfdownloads/EALA_Legislation/East_African_Community_Customs_Management_Act_2004.pdf

The following key actors take part in the EAC governing and implementing structure of the Protocol on Environmental and Natural Resources Management for chemicals and waste:

1) The EAC Council that oversees the regional work;
2) A regional committee known as the East African Standards Committee for harmonization of products, inspection and methodology and standards relating to conformity with the standards, as well as monitoring and reporting of the work progress to the Council;
3) A supporting office to the Committee that provides administrative and logistical support, and identifies and addresses regional capacity building needs related to the standards;
4) National agencies that are the implementing agencies of the standards, and that also provide information to companies and the public about the standards; and
5) National inspection agencies, certifying agencies and accredited laboratories to support the national implementation work. The details are laid out in the 2006 EAC Standardization, Quality Assurance, Metrology and Testing (SQMT) Act.[1]

1. http://www.eac-quality.net/fileadmin/eac_quality/user_documents/3_pdf/EAC_SQMT_Act__2006_Scan_.pdf

The Second Schedule of the East Africa Community Customs Management Act (EACCMA, 2004) lists generally prohibited and restricted goods for import into the EAC. The prohibited goods include agricultural chemicals, as well as all soaps and cosmetic products containing mercury or mercury compounds. Kenya and Uganda provide examples of the implementation of this act.

- In implementing the EACCMA, the Kenya Revenue Authority (KRA) together with a multi-agency team (the Kenya Bureau of Standards, the Anti counterfeit Agency, the National Environment Management Authority and national police) enforces border control measures to prevent entry of illicit items through the borders such as those prohibited under the EACCMA. Since the East Africa standards are harmonized across the region, market surveillance and quality assurance controls are carried out by all countries.
- In Uganda, similar activities help to prevent prohibited creams on the Uganda detention list (e.g., Mekako creams and lotions, Jaribu, Princess Patra, among others) from entering the country. These creams used to come from the Democratic Republic of Congo.

Harmonized policies and tools to control illegal trafficking of prohibited products within the Partner States include:

- EACCMA and the East African Community Common External Tariff (EAC CET).
- The Harmonized Systems (HS) Handbook for Customs Administration in the East African Region.[42]

Regional strategies to reinforce these EAC policies include:

- Build the knowledge and skills of customs officials and customs clearing agents with regard to the proper classification of goods, and the uniform and correct application of the Harmonized System.

[42] Harmonized System (HS) Handbook for Customs Administration in the East African Region (https://www.kra.go.ke/images/publications/1_HS-Handbook-Final-Nov-2012.cleaned.pdf).

- Share enforcement information between the Partner States, including information on bans on certain goods, changes in duty rates, increases/or exemptions of taxes on certain goods, etc.
- Encourage other regional information sharing. The secretariat of the EAC Customs Union releases an online periodic gazette on pertinent issues to the Partner States, and operates a listserve for enforcement agencies of the Partner States.

Although the Partner States of the EAC have agreed to standardize their trade information and documentation in accordance with internationally accepted standards using electronic data processing, many areas (including border posts) within these countries are not yet connected to the Internet, and therefore information sharing is more challenging.
The EAC Customs Union started when three member states (Kenya, Uganda and Tanzania) achieved the first regional integration milestone, and signed a pact that came into force in 2005 to establish free trade (or zero duty imposed) on goods and services traded amongst themselves. They also agreed on a CET, whereby imports from countries outside the EAC zone are subject to the same tariff when sold to any EAC Partner State.[43] The system appears to be working well, with the following outputs so far:

- EAC Customs Valuation Manual – a document that provides guidelines on how to implement and uniformly interpret EAC Customs valuation provisions within the Community;
- One Stop Border Posts that have already been articulated within the auspices of the Community Law;
- Interconnectivity of customs systems to facilitate a seamless flow of information between customs stations and a payment system to manage financial transfers between EAC Partner States.

The Southern African Development Community (SADC) and the Economic Community of West African States (ECOWAS) also have cooperation agreements in place, but they are not yet fully functional for various reasons. It is hoped that the information and ideas in this report will help both regional organizations to improve (see Annex E).
As discussed above, the **ASEAN**[44] is a regional grouping that aims to promote economic, political, and security cooperation among its ten member countries. The ASEAN was started in response to growing economic interactions in the early 90s and aims to strengthen its member countries through cooperative policies and programs.[45] As described above, the ASEAN Post Market Alert System contributes to regional cooperation (see also Annex E).
The **EU** also encourages extensive regional cooperation, so even for countries with greater resources there is much to gain from coordination and optimization of resources in a regional perspective. One example of regional cooperation in the EU of relevance to the Minamata Convention provisions for mercury-added products is the RAPEX register (described in section 3.3.3). This and other systems for sharing information on consumer products identified as hazardous, e.g. due to their chemical composition, can greatly support the work of customs services and other agencies responsible for monitoring and inspection, as well as to alert importers, retailers, and consumers.

[43] See the Protocol on the Establishment of the East African Customs Union at https://www.ifrc.org/Global/Publications/IDRL/regional/Protocol%20on%20the%20Establishment%20of%20the%20East%20African%20Customs%20Union.pdf
[44] Albert, E. (2017). ASEAN: the association of Southeast Asian nations. Published by the Council on Foreign Relations. Retrieved from: https://www.cfr.org/backgrounder/asean-association-southeast-asian-nations
[45] Haas, D. (1994). Out of the others shadows: ASEAN moves towards greater regional cooperation in the face of the EC and NAFTA. Retrieved from: https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1475&context=auilr

5 Inspections, sanctions, voluntary agreements, screening tools

A system to address non-compliance with laws must be in place in order to ensure that the legal system is credible and respected. The system may include educational elements to promote compliance, and an enforcement framework that punishes non-compliance. Educational elements may be particularly useful at the outset for small and medium sized companies that have limited technical capacity.

5.1 Inspections

The effectiveness of inspections depends upon the mandate of the inspectors, their qualifications and the frequency of inspections. It is very import to clearly define the mandate and obligations, as well as qualifications, of inspectors in appropriate legislation. Among other legal requirements, the inspectors should be allowed to enter and inspect premises or storage facilities, search vehicles, persons and containers, take samples and seize equipment, take photographs, ask for information and evidence, and issue orders and/or apply sanctions (often with the assistance of the police). Inspections are generally most effective if unannounced, and they should ideally be permitted to include large, medium, and small companies, formal and informal sectors, while also allowing for frequent spot checks. In the end inspections are limited mostly by the budget available. Shared regional facilities (such as for chemical analyses) may be a cost-effective approach.

Inspection activities targeting companies involved in e-commerce are more complicated, as the companies offering the products may be outside a country's legal jurisdiction. Some of the more standard measures used by inspection and enforcement authorities are less effective in such cases. The Swedish Chemicals Agency (KemI) – the authority in Sweden charged with market surveillance and inspection powers – carried out a compliance study in 2018 for products bought online, and identified the following challenges:[46]

- **Finding the manufacturer's name and contact information**: To track down the original manufacturer may be the most challenging part of the investigation, especially when labelling (if any) omits the name and contact information of the supplier. Potential sources of information, if product labels are absent, include the Internet service provider, domain name registries, payment service providers, and other intermediary service providers.
- **Obtaining samples of products for investigation**: The products of interest may not be readily available in the country, so international collaboration may then be necessary. An EU specific issue is that authorities in some EU member states are not allowed to buy products (e.g. for testing purposes) anonymously, which may tip off the supplier that they are being scrutinized. Online information or offers may be quickly altered or removed from the Internet, which inspectors need to take into account.
- **Obtaining a response to communications:** During its 2018 compliance study, KemI's experience was that several of the contacted companies outside the EU did not respond to KemI's notification, request for further information, and demand to remove the product from the web. In such cases, the corresponding inspection and enforcement authority in the jurisdiction where the company is registered should be informed, so that they can support and advance the case. Cooperation between market surveillance authorities and customs between countries is very important to effectively control and stop shipments of products at the border. Therefore it is highly advisable to have

[46] Enforcement of e-commerce 2018 (https://www.kemi.se/global/tillsyns-pm/2019/enforcement-3-19-enforcement-of-e-commerce-2018.pdf).

appropriate laws in place that give the authorities the power, as a last resort, to block and shut web pages that sell non-compliant products.

- **Setting requirements for action in response to decisions**: This takes place through dialogue with the country in which the targeted company is based.
- **Deciding on sanctions and fees**: This takes place through dialogue with the country in which the targeted company is based.
- **Notifying prosecutors**: This takes place through dialogue with the country in which the targeted company is based.

5.2 Penalties and sanctions

Penalties must be designed carefully. They should be severe enough to discourage the offender from breaking the law; e.g., fines should at least be higher than the cost of compliance and revocation of a license. Moreover fines should generally increase progressively with the number of offences. A fine, jail sentence, or withdrawal of a license to operate are some of the typical penalties that may be applied as punishment.

A fine may be based on a "flat" system, with the same fine for all offenders, or it may be progressive, e.g., based on the annual turnover of a company. A fine based on turnover, while punitive, better protects a company that has a low annual turnover and small profit margin, and also discourages larger companies with better profit margins to break the law. Moreover, as mentioned previously, fines are a source of income that can help to support routine screening and inspections.

Whichever sanction system or combination of systems is chosen, it must be supported by screening and inspections, so that companies understand they are taking a risk of being penalized if they do not comply with regulations.

Some examples of countries' inspections, penalties, sanctions and related tools are summarized in the box below. Others may be seen in Annex F.

Country examples of inspection and sanction regulations and procedures

Kenya, South Africa, and Uganda all have legislation and systems in place for inspections and sanctions. The presence of illegal products on the market is regularly controlled. If illegal products are found, they are removed from the market – in the case of Uganda, they are sent back to the country of origin or destroyed within 21 days – and sanctions are imposed on importers or retailers. Sanctions may include fines, cancellation of trade licenses or even prison.

In **Kenya** the Standards Act Cap 496 stipulates that all importers of goods must ensure that they meet the relevant Kenya standards or approved specifications. The act clearly defines the appointment procedure, mandate and liability of inspectors, provides for penalties, and gives the legal basis for the police to provide support to inspectors in connection with inspections.

The **Uganda** National Bureau of Standards (UNBS) Imports Inspection and Clearance Regulations, 2015, provides for periodic spot-checks in retail outlets, seizure of prohibited products, reprimands, fines, arrests and/or cancellation of trade licenses, and warnings to the general public. A renowned cosmetics dealer has been charged for the illegal use of the UNBS Quality Mark. UNBS has banned more than 50 cosmetic products that contain mercury and hydroquinone.

The **Uganda** Specific Goods (Conveyance) Act Cap 349 LOU provides for the control of conveyance of certain goods to and from neighboring countries including Kenya, Rwanda, the Democratic Republic of Congo and Sudan. The Uganda Revenue Authority (URA) impounded 622 cartons of cosmetics containing hydroquinone from DR Congo valued at SHS 120m.

In **Uganda**, failure by an importer to obtain a Certificate of Conformity from a Pre-export Verification of Conformity (PvoC) service provider results in a penalty and a destination inspection being applied. Consignments that do not meet the standards of the PVoC will either be returned to the country of origin or destroyed at the exporter's expense.

In **Cote d'Ivoire**, in addition to penal prosecutions, the different ministries in charge of the application of decree 2015-288 on cosmetics and personal care products (Health, Trade and Industry) can order the closure of factories, shops or facilities where cosmetics are found with hydroquinone content higher than 2%, or any mercury content.

- A fine going from 50,000 CFA (USD 100) to 350,000 CFA (USD 700) will be issued to anyone producing, advertising or selling prohibited cosmetics.
- A temporary or definitive withdrawal of the license can be ordered by the jurisdiction in which the seizure occurred.
- Anyone who produces for sale cosmetics for skin bleaching or lightening will be fined anywhere from 50,000 CFA (USD 100) to 350,000 CFA (USD 700). All of the prohibited products will be confiscated and destroyed.

In South Africa, the Department of Environment, Forestry, and Fisheries (DEFF) has a dedicated unit known as Compliance and Enforcement, that ensures that chemicals and waste regulations are complied with. In the Foodstuffs, Cosmetics and Disinfectants Act (no. 54 of 1972), the Regulations Relating to the Labelling, Advertising and Composition of Cosmetics stipulate that offenders are subject to fines and/or imprisonment that increases in severity in case of a second or third conviction. National notification or detention lists of withdrawn products are published in Government Gazettes and/or by relevant Government Departments.

In **South Africa**, there are standards or limits under the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act no. 54 of 1972), Regulations Relating to the Labelling, Advertising and Composition of Cosmetics. *Penalties*: (1) Any person convicted of an offence under, or failure to comply with these regulations, is liable (a) on a first conviction, to a fine or to imprisonment for a period not exceeding six months, or to both a fine and such imprisonment; (b) on a second conviction, to a fine or to imprisonment for a period not exceeding twelve months, or to both a fine and such imprisonment; (c) on a third or subsequent conviction, to a fine or to imprisonment for a period not exceeding twenty-four months, or to both a fine and such imprisonment.

In **Bangladesh**, The Bangladesh Standards and Testing Institution (BSTI) Act, 2018 specifies inspection, penalties, sanctions and related tools already in action.

Penalties for sale, distribution and commercial advertisement of prohibited products or prohibited or restricted export of products: If any person contravenes the provisions of any notification under section 20 or of any licence issued thereunder, he shall, without prejudice to any confiscation or penalty to which he may be liable under the provisions of the Customs Act, 1969 (IV of 1969), as applied by section 20(3), be punishable with imprisonment for a term which may extend to 11[four years, or with fine which may extend to one lakh taka but shall not be less than ten thousand taka], or with both. Any person who contravenes the provisions of any notification under section 21 shall be punished with imprisonment for a term which may extend to four years, or with fine which may extend to two lakh taka but shall not be less than fifty thousand taka, or with both.

Penalty for obstructing Inspector in discharge of his functions: Any person who voluntarily obstructs, or gives false information to, any Inspector in the discharge of his public functions shall be punished with imprisonment for a term which may extend to one year, or with fine which may extend to fifty thousand taka but shall not be less than ten thousand taka, or with both.

In the **Philippines**, those found to be in violation of RA 9711 and RA 3720 (otherwise known as the Food, Drug, and Cosmetics Act) are subjected to 1) cancellation of the authority given by FDA, 2) a fine of P50,000 to P500,000, with an additional fine of P1,000 per each additional day of violation, 3) imprisonment, and/or 4) the destruction of said products in violation (reference: Congress of the Philippines (n.d.), Republic act 3720. Retrieved from: http://www.lawphil.net/statutes/repacts/ra1963/ra_3720_1963.html)

In **India**, there are a number of provisions for penalties for contraventions of the rules and regulations. These include a penalty for non-disclosure of the name of the manufacturer(s), a penalty for not keeping documents, etc., and for non-disclosure of information, a penalty for the use of a Government Analyst's report for advertising, a penalty for manufacture, sale, etc., of cosmetics in contravention of this Chapter, etc. The penalty includes imprisonment and a fine as well. However, there is very little information in the public domain on specific actions taken under these clauses, hence it would be useful if all such information were in the public domain. It would help the consumers' right to know regarding products that do not comply with the rules and regulations.

5.3 Screening

Initial screening for ingredients that are banned or restricted can be done from product labelling, which is why mandatory labelling is helpful for customs control. However, ingredient lists alone are not sufficient, as there may be non-compliance with the labelling requirements. Spot checks including actual analyses of the chemical contents of products should, therefore, also play a role in inspection schemes.

An affordable, portable instrument that can greatly facilitate screening of mercury-added cosmetics is X-ray fluorescence (XRF), which is capable of real-time readings of samples.[47] In a study published in 2018, ZMWG concluded that XRF provided reasonably accurate readings for

[47] X-ray fluorescence is a non-destructive analytical technique used to determine the elemental composition of materials. XRF analyzers determine the chemistry of a sample by measuring the fluorescent (or secondary) X-rays emitted from a sample when it is excited by a primary X-ray source.

mercury in skin-lightening creams in comparison with more sophisticated analytical instruments.[48] Thus, XRFs allow for efficient and cost-effective screening. The Minamata Convention limit of 1 ppm mercury content for skin-lightening creams overlaps the detection limit[49] of many XRFs. If XRF readings are just above 1 ppm, therefore, a confirming laboratory analysis is highly recommended because readings close to the detection limit of the instrument may be less accurate. A more sophisticated analysis should also be carried out by an accredited laboratory when a legal case is filed against a manufacturer, importer or retailer based on a spot check.

XRFs are already used by many customs services and other authorities with inspection mandates. Each country should assess how to maximize access to XRFs at relevant entry points to establish a credible deterrent, taking into account available resources, and capacity for training the border agents.

Figure 1: An example of an XRF – an instrument for real-time, non-destructive readings of mercury contents in ppm, in various materials, including cosmetics.

Some examples of country surveillance and screening procedures are presented in the box below.

In **Bangladesh**, In BDS 1382:2019, BSTI has already established standard procedures for surveillance and screening. Mandatory inspection and testing method has been included in BSTI Act 2018 and BDS 1382:2019 respectively

In the **Philippines**, based on procurement request documents, the Department of Environment and Natural Resources (DENR) is in possession of one MA 3000 Mercury Analyzer in the EMB-Inorganics Laboratory Unit (Source: DENR (2019). Request for quotation. Retrieved from: https://emb.gov.ph/wp-content/uploads/2019/07/RFQ-PR-NO.2019-0801-ERLSD-MERCURY-ANALYZER-PM-237000-2nd.pdf). For cosmetic products, the FDA has set up testing and quality assurance laboratories in Cebu (Visayas), Davao (Mindanao), and Subic (Luzon), according to the Department of Health (2011, Department circular no. 2011 – 0101. Retrieved from: https://www.wipo.int/edocs/lexdocs/laws/en/ph/ph080en.pdf).

Certain products are required to undergo clinical trials. Once reaching the market, products must be monitored via the PMS system. For identification of potentially hazardous products, the FDA conducts its own research through the three testing facilities, and through its e-report facility.

In **South Africa** there is equipment for carrying out both cold vapor atomic absorption spectroscopy (CVAAS) and XRF testing for mercury.

In **Nigeria** the National Agency for Food and Drug Administration and Control (NAFDAC) has a mercury analyzer installed.

In **Uganda** a suitable laboratory is available to confirm the presence of mercury or other harmful substances in creams. The UNBS has a Testing Department that offers analytical laboratory services, and they confirm that their sister agencies in the region have similarly well uipped laboratories manned by competent and highly qualified staff. Additional information on EAC Testing Departments can be found at: <http://www.eac-quality.net/better-business-with-quality/technical-regulations/assessment/unbs-testing-department.html>

[48] See the report, Mercury-added skin-lightening creams: available, inexpensive and toxic (http://www.zeromercury.org/wp-content/uploads/2019/02/zmwg_skin_lightening_cream_report_final_nov_2018.pdf).

[49] The detection limit is the lowest quantity of a chemical that can be distinguished from the absence of that chemical (a blank value) with a stated confidence level, generally 99%.

5.4 Informing consumers for better market surveillance

National authorities have an obligation to help consumers reduce product related risks to their health and the environment. At the same time, informed consumers can be encouraged to contribute to improved market surveillance.

Better informed consumers make better informed decisions that reduce the health, safety and other risks associated with some consumer products. When consumers buy products such as cosmetics online, however, where the cheap prices are especially tempting, they are likely to have access to less product information than usual. Among other things, consumers should be reasonably informed about the national and regional legal requirements that are in place to minimize risks, especially legal labelling requirements.

In particular when shopping online, consumers should be encouraged to check if the required information is visible, e.g., warnings and traceability information such as the address and contact information of the manufacturer as well as the importer, where applicable. To minimize any risks associated with online purchases, consumers should know how to consult national, regional or global notification and recall lists, such as the RAPEX in the EU, or the Organisation for Economic Co-operation and Development (OECD) global recall list.[50]

Consumers should also be educated about where to find information on submitting complaints, and they should know how to report any safety problems or other issues to authorities. They should also be informed of their rights as consumers when products are recalled. Authorities' websites could provide concise and up-to-date information about product safety laws and the rights of consumers, along with the rights and obligations of companies. This information could take the form of advisories with associated information on legislation and alert lists.

CSOs may be enlisted to assist with compliance checks, based on their own consumer safety data. CSOs sometimes have access to analytical equipment similar to that of the inspectors, such as XRFs, and they sometimes send samples to accredited laboratories for more detailed analysis. Although they should not be considered partners in formal inspection schemes, CSOs may still be a valuable source of complementary information upon which the inspectors can take further action. In countries where resources are limited, this may be a particularly valuable option.

6 Sustainable financing

6.1 Key funding sources

A prerequisite for effective implementation of any international agreement is the allocation of dedicated funds in the national budget and planning process. Through sustainable and integrated financing, countries could be able to establish a functional and durable legal and institutional framework for the sound management of chemicals. This is one of 11 core priorities of the Strategic Approach to International Chemicals Management (SAICM)[51] mentioned in Section 3.1. Implementation of the Chemicals Conventions, including the Minamata Convention, is another of these core priorities of SAICM.

Many low- and middle-income countries still rely heavily on external funds to implement international agreements. There are, for example, the Special Programme,[52] the Global Environmental Facility (GEF),[53] as well as other bilateral and multilateral mechanisms that can support the sound management of chemicals. However, the general trend is that international donors are increasingly restricting access to new funds for this purpose. The so called "integrated

[50] OECD global recall list (https://globalrecalls.oecd.org/)
[51] See Section IV, p. 8, of the UNITAR National Chemicals Management Profile (https://www.unitar.org/cwm/saicm/national-profile)
[52] Special Programme (https://www.unenvironment.org/explore-topics/chemicals-waste/what-we-do/special-programme)
[53] Global Environmental Facility (https://www.thegef.org/)

approach to financing of sound management of chemicals and waste,"[54] in which external funds are one component, is likely to remain important for low- and middle-income countries for the foreseeable future. In the long run, however, Parties will need to create conditions for raising the necessary funds in their own countries, to sustainably implement obligations required under the Minamata Convention. Industry is a potentially important partner in the "integrated approach," and may help to unlock new funds.

To facilitate the development of domestic funding, UNEP developed the LIRA Guidance, previously mentioned in Section 3.1.[55] This guidance document is now part of the Inter-Organization Programme for the Sound Management of Chemicals (IOMC) toolkit, and outlines in significant detail how to develop a legal and institutional framework such as that required to support the sound management of chemicals, including how to finance the necessary reforms and operations through cost-recovery mechanisms. The development of such domestic resources is crucial to reduce the dependency of many countries on external funding sources. The box below, along with the following sections of this report, provide a number of country examples for securing resources in support of an institutional framework for the sound management of chemicals. Some of those examples could contribute to a more sustainable financial system to support such work.

6.2 Cost-recovery mechanisms

Cost-recovery mechanisms require a legal basis and an institutional organization that oversees effective implementation. It must be carefully considered which ministries or agencies have the responsibility to develop and implement the legal basis and instruments. Division of responsibilities within the system must be absolutely clear, and there must be a formal set of sanctions and penalties for late payments and non-compliance.

Examples of cost-recovery instruments are:

- fees for placing chemicals on the market (registration, evaluation, authorization or licensing), and
- fees for inspection and verification activities.

The fees may be one-off fees, or recurring maintenance fees for periodic renewal of registrations and licenses. Further details and suggestions are included in the LIRA Guidance.

Key aspects to consider when designing a cost-recovery mechanism include: 1) the number of companies, such as manufacturers and importers, that can be taxed; 2) how the fee is to be determined, which may depend on the annual turnover of a company and its profit margin; and 3) the expected operational cost of the cost-recovery mechanism, which depends on, e.g., what verification, inspection and other administrative activities are necessary. These aspects would need to be evaluated per the country situation, and set accordingly. Ideally, the fees should also be high enough to provide some surplus to support certain tangential costs such as inspection activities for cosmetics that are marketed illegally, which cannot be directly taxed.

[54] Integrated approach to the financing of chemicals and waste (https://www.unenvironment.org/explore-topics/chemicals-waste/what-we-do/policy-and-governance/sdgs-and-mainstreaming/integrated)

[55] See LIRA Guidance on the Legal and Institutional Infrastructures and Measures for Recovering Costs of National Administration for Sound Management of Chemicals (http://wedocs.unep.org/bitstream/handle/20.500.11822/12224/LIRA_Guidance%20Report_PRESS.pdf?sequence=1&isAllowed=y)

In **Uganda**, for improving regulations for businesses (and citizens), enforcement and delivery of regulations, and inspections in particular, the following resources need to be in place:

1. Accredited agents (both international and national)
2. Competent human resources to enforce the regulations.
3. Laws and regulations that protect health and the environment.
4. Financial resources to facilitate monitoring, enforcement and inspection.

Financial resources are secured from different sources in Uganda. For implementing the PCoC program, financial support is provided by the World Bank. Monitoring, enforcement and inspection at the national level is financed by the government of Uganda.
In **Côte d'Ivoire,** there is a specific allocation in the national budget for the functioning of certain enforcement measures, but not for surveillance of compliance with the laws implementing the various chemicals conventions.
In **India,** the government collects taxes that they use to monitor products as part of good governance.
In **South Africa,** the DEFF has a dedicated Unit called Compliance and Enforcement, which ensures compliance with chemicals and waste legislation. This Unit receives an annual budget.
In the **Philippines**, FDA funding comes primarily from its authority to collect, retain and utilize fees, fines and royalties under laws such as Republic Act 9502, or the Universally Accessible Cheaper and Quality Medicines Act of 2008, or other acts primarily enforced by the FDA (Source: Department of Health (2011). Department circular no. 2011 – 0101. Retrieved from: https://www.wipo.int/edocs/lexdocs/laws/en/ph/ph080en.pdf).

An example of a product-specific cost-recovery instrument is fees collected for licenses for manufacturers and importers of cosmetics. Such a fee is usually split into sub-fees: a one-time application fee; a fee for renewal when the license expires; and an annual turnover fee. To facilitate any calculation involving turnover, it is suggested that data about the annual manufacturing/import volumes for the products covered by the license should be provided by the applicant as one of the requirements for being awarded a license. Such data can also be valuable for a national inventory for keeping track of what cosmetic products enter the national market, as well as helping in the planning of inspection activities. The criteria for a product specific license should include the technical competence of the licensee in order to ensure that the company is competent to manufacture/import the cosmetics, and it should also require a complete list of all ingredients, as well as requirements for labelling ingredients. These kinds of requirements foster producer responsibility.
A more substantial source of income is a cost-recovery instrument that covers the placing of chemicals on the market, but this comes with considerably larger operational and maintenance costs, as it builds upon a registration-evaluation-authorization system. This kind of instrument not only requires more qualified staff, but also takes time to put into full operation. Countries with scarce resources should not immediately invest in a full-scale cost-recovery system for placing chemicals on the market, but may consider doing it for chemicals in certain well-defined hazard categories, such as carcinogens, mutagens and neurotoxic chemicals.
It is important that these cost-recovery mechanisms should be used solely to fund sound management of chemicals and waste, and not be viewed as a source of additional income to the general government budget. This is because they close the loop between the administrative costs and delivery of services to the beneficiaries (companies and the public), and are justified by the "polluter pays principle."[56] Designed intelligently, cost-recovery mechanisms can largely pay for the sound management of chemicals. With such a mechanism, funds could be allocated to

[56] Polluter pays principle (https://www.oecd-ilibrary.org/docserver/9789264044845-en.pdf?expires=1567510211&id=id&accname=guest&checksum=F5A4A4A99EB2871B1A036B0791125409)

Minamata Convention implementation, including intensified inspection activities to identify illegal skin-bleaching creams and their supply chains.
One region already working extensively with cost-recovery mechanisms is the European Union. The EU has perhaps the most ambitious chemicals regulation at present, and its operation is largely financed by industry through cost recovery mechanisms. In this regard, other countries could learn from the EU about how to deal with cost-recovery challenges and take advantage of opportunities as relevant.

In **Kenya** all companies - manufacturers, retailers and importers - must pay a fee to be registered, and have a certificate of incorporation from the register of companies in the office of the Attorney General. There are various licenses to be purchased as well. For example a company will need an Environmental Impact Assessment (EIA) license from National Environment Management Authority (NEMA) if it is newly registered, or if it is conducting an annual environmental audit. For importers, clearing and forwarding agents pay a fee to register with KRA, and when goods are imported, they must be cleared by registered agents.

7 Conclusions

This report outlines some of the key elements necessary to successfully identify and restrict the use of hazardous substances in cosmetics, especially for implementation of international agreements such as the Minamata Convention. While it should not be considered as comprehensive guidance on how to approach the task, key elements are presented and some successfully used tools are suggested. However, each country has its own unique context in terms of existing laws and policies on which to build, including some legal gaps, not to mention varying governing structures with different agencies and different mandates and responsibilities. Consequently, each country needs to carry out its own analysis to identify the best way forward. The report should be seen as a useful resource for tackling this complex task in a systematic way.
Since the trade in mercury-added skin-lightening products is international, and after 2020 it will be (if not mostly already) an illegal market, international collaboration and harmonization around inspection work and alert systems are highly recommended. All countries would use their limited resources more efficiently by sharing product and enforcement information to the extent possible.
Absolutely essential to successful implementation of a viable program for sound chemicals management is to develop a (preferably sustainable) funding mechanism. The Special Programme, GEF and other bilateral and multilateral financing mechanisms should be willing to support the development of national plans for cost-recovery systems, where feasible, in order to minimize future dependency on external funds.

Annex A—Information gathering

When mapping good practices for law enforcement and their key elements, as well as regional initiatives, ask the following questions to your relevant enforcement authorities:

a) Is there a dedicated competent agency responsible for enforcing compliance with chemical conventions, including the Minamata Convention?
b) Is there a specific allocation in the national budget to surveillance of law compliance in relation to the Minamata Convention, and if so, how is this financed (cost internalization or externalization)?
c) Is there a system for spot checks, and if so, is there a system according to which the sampling done, and how frequent are the spot checks?
d) What equipment for verifying mercury content is used, what detection limits do the instruments in question have, and how many pieces of them are available nationally for the responsible agency?
e) Is there a standard mark of quality that is available, of the national authority, for compliance monitoring?
f) Are there any follow up activities to check if the products were withdrawn from the market, if they were found in at a retailer in the national market?
g) Are there any attempts to track down the suppliers and manufacturers of the creams, and if so what methods are used?
h) Is there coordination with other countries in the region in enforcing the Minamata provisions on mercury added cosmetics, and if so, how in practice is it organized and are the methods harmonized between the collaborating countries?
i) Are there national or regional notification or detention lists, and if so, is the information available to importers, retailers and buyers, and if so, how is this information available?

Matrix A: Enforcement elements for specific laws and regulations.

Country/region	**Law/regulation number or name of law governing use, manufacture, import and export of skin-lightening cosmetics**	**Describe key/critical elements behind successful enforcement (see the questions a-f in the previous page)**

Matrix B: Enforcement elements in regional initiatives to crack down illegal creams

Region	**Describe key/critical elements behind successful enforcement**

Annex B—Product safety pledge by online marketers

EU voluntary agreement with e-commerce platforms

Product Safety Pledge

Voluntary commitment of online marketplaces with respect to the safety of non-food consumer products sold online by third party sellers

Consumer non-food products placed on the EU market must be safe, regardless of whether they are sold online or in brick-and-mortar shops. Online sales in the EU represented 20% of the total sales in 2016(1), and this percentage is expected to increase in the coming years. E-commerce marketplaces may facilitate economic growth by enabling sellers to access new countries and to reach new customers. As such, this may encourage trade between Member States and the free movement of goods in the Single Market. This in turn promotes further harmonisation of standards and improvement of the functioning of mutual recognition. Online intermediaries are also in a novel position where they can trace products more easily, as well as develop a strong post-sale connection to customers. At the same time they are well placed to play an important role in product safety, due to the significant amount of products sold through their websites.

This initiative sets up areas where online intermediaries voluntarily agree to take specific actions with respect to the safety of non-food consumer products sold online by third parties on their marketplaces, to the extent reasonably and commercially practicable and in regular dialogue with the relevant authorities. The ultimate goal is to improve the detection of unsafe products marketed in the EU before they are sold to consumers or as soon thereafter as possible, and to improve consumer protection. These commitments will go beyond what is already established in the EU legislation, including those on product safety.

This voluntary commitment does not cover technical compliance matters not posing serious risks to the health and safety of consumers.

(1) Source: Eurostat (http://ec.europa.eu/eurostat/statistics-explained/index.php/E-commerce_statistics)

Areas for voluntary commitment of online marketplaces with respect to the safety of non-food consumer products sold online by third party sellers

1. Consult information on recalled/dangerous products available on RAPEX ([2]) and also from other sources, such as from enforcement authorities. Take appropriate action ([3]) in respect to products concerned, when they can be identified.
2. Provide specific single contact points for EU Member State authorities for the notifications on dangerous products ("notice") and for the facilitation of communication on product safety issues.
3. Cooperate with EU Member State authorities in identifying, as far as possible, the supply chain of dangerous products by responding to data requests should relevant information not be publicly available.
4. Have an internal mechanism for notice and take-down procedure for dangerous products. This should include commitments from the marketplace's side on the procedure they will follow when notices are given by authorities and other actors.
5. React within two working days to government notices made to the single contact points to remove identified listings offering unsafe products for sale in the EU. Inform the authorities on the action taken ([4]).
6. Provide a clear way for customers to notify dangerous product listings. Such notices are treated expeditiously and appropriate response is given within five working days.
7. Provide information/training to sellers on compliance with EU product safety legislation, require sellers to comply with the law, and provide sellers with the link to the list of EU product safety legislation.
8. Cooperate with EU Member State authorities and sellers to inform consumers ([5]) about relevant recalls or corrective actions.
9. Cooperate with authorities and set up a process aimed at proactively removing banned product groups as appropriate.
10. Put in place measures to act against repeat offenders offering dangerous products in cooperation with authorities.
11. Take measures aimed at preventing the reappearance of dangerous product listings already removed.
12. Explore the potential use of new technologies and innovation to improve the detection of unsafe products.

Signatory online intermediaries will report to the European Commission on the actions taken to implement the above voluntary commitment every six month following its signature. This will be done via the below key performance indicators (KPIs), as well as qualitative information about the progress on the areas of the voluntary commitment, which will be provided to the European Commission in an aggregated format compiled by a third party combining the inputs of all signatories. This is to ensure the confidentiality of submissions and a neutral non-discriminatory evaluation process.

([2]) https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/index_en.htm

([3]) This could include, among other things, removal of product listings, blocking the sale of product into the EU and/or informing consumers and sellers, as appropriate.

([4]) When specialized reporting tools are used in cooperation with authorities, the communication policy may differ.

([5]) This may also include informing sellers and requesting them to contact concerned buyers

KPIs:

1. % of identified products listings removed within 2 working days based on governmental notices provided to the established single contact points;
2. % of identified products listings removed within 2 working days found through monitoring of public recall websites such as RAPEX.

It is the understanding of all parties that the above voluntary commitment should serve as contribution to EU product safety discussions with Online Intermediaries.

This voluntary commitment is not legally binding and does not now nor in the future create any contractual or pre-contractual obligations under any law or legal system. Nothing in this voluntary commitment shall be construed as creating any liability, rights, waiver of any rights or obligations for any parties or as releasing any parties from their legal obligations. This voluntary commitment shall not be construed in any way as replacing, extending or interpreting the existing legal framework. This voluntary commitment is not to be used as, or form part of, evidence in any legal proceedings.

List of signatories: Brussels, 25.6.2018

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Head of Government Relations
Alibaba Group

James Waterworth
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Annex C—The EU's RAPEX-China Agreement

JOINT STATEMENT ON THE EXTENSION OF THE MEMORANDUM OF UNDERSTANDING ON ADMINISTRATIVE COOPERATION ARRANGEMENTS BETWEEN DG SANCO AND AQSIQ

The existing policy and regulatory dialogue between the European Commission's Directorate-General for Health and Consumer Protection (DG SANCO) and the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China (AQSIQ) is based on the Memorandum of Understanding on Administrative Co-operation Arrangements signed in February 2006 which was first signed on 16 January 2006.

As of 1 March 2010, DG SANCO is the department responsible for the legislation of medical devices and cosmetics in the EU. The legislative unit "Cosmetics and Medical Devices", formally in the European Commission's Directorate-General Enterprise and Industry (DG ENTR), is now part of DG SANCO.

The Working Groups on Medical Devices and Cosmetics, established under the Consultation Mechanism on Industrial Products and WTO/TBT between DG ENTR and AQSIQ, have proven to be an excellent basis for regulatory dialogues on medical devices and cosmetics.

With regard to the reattribution of responsibilities in the European Commission concerning medical devices and cosmetics, the two Sides have decided that the existing Working Groups on Medical Devices and Cosmetics under the DG ENTR-AQSIQ Consultation Mechanism on Industrial Products and WTO/TBT shall, from now on, continue under the Memorandum of Understanding on Administrative Co-operation Arrangements between DG SANCO and AQSIQ.

Therefore, the two Sides have decided to extend accordingly the Annex 1 to the Memorandum of Understanding as attached.
The Joint Statement is signed in Beijing on 27 October 2010 in the English and Chinese languages.

For the Directorate-General
Health and Consumers
of the European Commission

John Dalli
Commissioner

For the General Administration of Quality
Supervision, Inspection and Quarantine
of the People's Republic of China

Zhi Shuping
Minister of AQSIQ

ANNEX 1

GENERAL PRODUCT SAFETY

Cooperation framework

In order to protect and achieve a high level of health and safety of consumers the Sides intend to cooperate in the area of non-food consumer product safety, within the scope of their mandate, authority and responsibilities and on the basis of applicable laws and regulations of the EU and China respectively.

As far as necessary for achieving the objectives of this Memorandum, the Directorate-General Health and Consumers of the European Commission will in particular liaise, and where appropriate co-ordinate, with the market surveillance and other enforcement authorities of the EU Member States, the European Standardisation Organisations and the other competent European Commission departments, to facilitate contacts and cooperation with their Chinese counterparts. Similarly, AQSIQ will in particular liaise, and when appropriate co-ordinate with local CIQs and other enforcement authorities, relevant Chinese Industry Organisations and Standardisation Organisations, to facilitate contacts and cooperation with their European counterparts. The mentioned organisations, as well as other relevant stakeholders such as business representatives, consumer associations or individual experts may be involved in joint meetings under this Memorandum if agreed by both Sides.

For consumer products which are not under the competence of one of the Sides, this Side will facilitate contacts between the other Side and the authorities or departments competent for such products.

The co-operation under this Memorandum includes:

- **Exchange of scientific, technical and regulatory information, including in particular;**
  - Exchange of information on significant emerging health and safety issues;
  - Exchange of general information on market surveillance, border control and enforcement activities;
  - Exchange of information on risk assessment and product testing methods and practices;
- **Collaboration regarding specific products constituting a risk for consumer health or safety, as relevant under the "RAPEX-China" system, including in particular;**
  - Exchange of information on unsafe products originating from the other Sides' jurisdiction, including product details, measures taken, risk descriptions (with test reports and certificates) and the identity of economic operators ensuring the confidentiality of such information.

- Quarterly reports detailing the activities undertaken by AQSIQ on the basis of the information provided by DG SANCO and regular responses by DG SANCO to AQSIQ regarding its questions and/or concerns;

- Co-operation in case of major withdrawal/recall operations of mutual interest in a form to be agreed on a case by case basis;

- Regular meetings of the RAPEX-China Working Group to discuss the operation, results and improvements of the "RAPEX-China" system.

- **Cooperation regarding other relevant consumer product safety issues, including in particular:**

  - Regular meetings of the Consumer Products/Market Surveillance Working Group to discuss issues of mutual interest;

  - Jointly organised seminars on Market Surveillance for Consumer products when mutually agreed;

  - Regular meetings of the Cosmetics Working Group to discuss issues of mutual interest;

  - Regular meeting of the Medical Devices Working Group to discuss issues of mutual interest;

  - Cooperation in facilitating consumer product traceability;

  - Exchange of information on standardisation activities and applicable standards, cooperation in comparatively assessing relevant product safety standards, making efforts together for coordination of international standardisation ;

  - Providing training for relevant technical and regulatory experts, including the exchanges of officials to facilitate understanding of the Sides' legislative framework and procedures;

  - Other joint activities such as joint enforcement actions regarding certain high risk products when both sides agree.

- **Meetings**

  - The regular meetings of the RAPEX-China Working Group are held in Europe to facilitate participation by representatives of market surveillance authorities and other relevant European organisations, unless differently agreed by both Sides.

  - The regular meetings of the Consumer Products/Market Surveillance Working Group are held in China to facilitate participation by representatives of local CIQs and other relevant Chinese organisations, unless differently agreed by both Sides.

  - The regular meetings of the Cosmetics Working Group and Medical Devices Working Group are held alternatively in China or in the EU, unless differently agreed by both Sides.

  - The aim is to undertake at least one meeting of each of the Working Groups per year.

– Other Working Groups may be established if agreed by both Sides.

- **Confidentiality**

Confidentiality of the information on unsafe products exchanged in the context of the RAPEX-China system shall not prevent its dissemination to the competent authorities relevant for ensuring the effectiveness of market monitoring and surveillance activities (i.e. CIQs and relevant local governmental authorities in China and market surveillance and customs authorities in Member States of the EU and EFTA/EEA countries, etc.) and the companies subject to investigation. The authorities receiving information covered by confidentiality shall ensure its protection. Information on unsafe products covered by confidentiality, obtained by one Side under this Memorandum can not be disclosed to the general public or other authorities, unless this has been previously approved by the other Side that provided this information.

– Information other than on unsafe products exchanged under this Memorandum is not subject to confidentiality unless specifically requested by one of the Sides.

- **Contact Points**

– Contact points for the purposes of the different working groups of this cooperation framework will be appointed.

– Contact points will facilitate the practical application of the MoU and the rapid exchange of information in emergency cases, for example during major consumer product recall campaigns.

Annex D—Division of government responsibilities

Division of responsibilities for dealing with hazardous substances in products

In **Kenya,** different government agencies have different mandates. However, there is lead agency, for example, National Environment Management Authority (NEMA) on environment, and Kenya Bureau of Standards (KEBS) on standards. While each organization will take the lead/responsibility based on its mandates, these organizations work through a multi-agency team comprising relevant government departments.

Under the Customs and Excise Act Chap.472, the Customs Service works with other government agencies to monitor and enforce prohibitions and/or restrictions on certain goods imported into or exported from the country. Among the listed banned products are cosmetics containing mercury and mercury compounds[57].

The KEBS, working with other law enforcement agencies such as the Police, conducts regular market surveillance activities to ensure that products in the Kenyan market comply with the requirements set out in the approved specifications and do not endanger health, safety or the environment.

Market surveillance is conducted in compliance with Article 46 (1) (a), (b) and (c) of the Constitution of Kenya, Revision 2010. Market surveillance is also anchored in the Standards Act and related Regulations (in terms of enforcement of Sections 9, 10 and 12 of the Standards Act and Legal Notice No. 78 of 15th July 2005).

As a result of ongoing East African regional harmonization of Standardization, Metrology and Conformity Assessment services (SMCA) procedures and regulations, market surveillance in the East African Community is buttressed by Section 6 of the EAC SQMT (Standardization, Quality Assurance, Metrology and Testing) Regulations, 2013.

In Uganda, the Ugandan Bureau of Standards (UNBS) is responsible for standardization, Quality Assurance, Metrology and Laboratory Testing (SQMT). Its mandate is to formulate, promote and enforce national standards to enhance the competitiveness of Ugandan products, promote fair trade and protect consumers. The Uganda Revenue Authority (URA) is responsible for assessing and collecting specified revenue, to administer and enforce the laws relating to such revenue and to provide for related matters. Its mandate is to assess, collect and account for central government tax revenue and to provide advice to government on matters of policy relating to all revenue sources.

The enforcement officers need to know the mandatory requirements for customs clearance of goods entering the country, the categories of restricted goods and the list of goods prohibited from entering the country.

The system was developed from a product conformity assessment programme for the control of certain categories of imported consumer goods to ensure that all consignments of regulated products demonstrate compliance with the applicable Ugandan technical regulations and mandatory standards or approved equivalents. The UNBS contracted three international companies: GS, Intertek and Bureau Veritas to implement the programme. The aim of the program is to establish a quality import inspection regime that is in harmony with member states of the East African Community. The programme is working, and Intertek Country Offices issue Certificates of Conformity (CoC). The programme is funded by the World Bank. See https://www.cma-cgm.com/static/eCommerce/Attachments/Uganda%20111115.pdf

In **Côte d'Ivoire**, the agencies competent to enforce chemicals conventions are the National Programme for Chemicals Management, which follows all the legal obligations, and the Anti-Pollution Center in charge of performance tests for control and/or confirmation of product contents.

[57] Source: www.kebs.org

For cosmetics compliance with national regulations, the National Directorate of Quality and Standardization is in charge of enforcement. There is also the National Committee for Control and Evaluation of Cosmetics established by decree 2015-288 on cosmetics and personal care.

In **Nigeria**, the National Environmental Standards and Regulations Enforcement Agency (NESREA) and the National Agency for Food and Drug Administration and control (NAFDAC) are responsible for enforcement. NAFDAC includes a task force on counterfeiting, non-compliance and a post-marketing surveillance system. Cost is internalized. NESREA also has a unit of compliance monitoring.
In **South Africa**, there is no dedicated agency responsible for managing chemicals Multilateral Environmental Agreements (MEAs), but the Department of Environment, Forestry, and Fisheries (DEFF) has a unit called Compliance and Enforcement that ensures that chemicals and waste regulations are complied with. This unit also ensures compliance with MEAs (including the Minamata Convention) that have been ratified by South Africa.
In **India**, under the Drugs and Cosmetic Act (1940) the Food and Drug State Authority (FDSA) randomly checks samples of cosmetics from the marketplace. The Bureau of India Standards (BIS) and FDSA are the competent authorities to regulate mercury content in cosmetics as per the provisions of the Drugs and Cosmetic Act 1940. There are detailed criteria for the sampling methodology, samples are then sent to a recognized laboratory for analysis and a system is in place to check if non-compliant products have been withdrawn from the market. On the other hand, no agency has yet been given responsibility to enforce compliance with chemical conventions including the Minamata Convention. In 2016, Maharashtra state food and drugs authority reported mercury in some of the samples of a skin whitening cream and asked the manufacturer to withdraw the stock.[58]

In the **Philippines**, the FDA is the primary agency responsible for enforcing laws related to mercury-containing cosmetic products. However, local government units (LGUs, referring to the smallest administrative branches in the Philippines) are given the responsibility of complying with FDA standards by virtue of the Local Government Code.[59] As such, some LGUs may have differing programs (separate from FDA-led programs) and levels of success depending on their actions. Key issues include the lack of cooperation between national agencies. As discussed earlier, the FDA has stated that it lacks the capacity to dispose of confiscated mercury-containing products, as disposal falls under the jurisdiction of the Department of Environment and Natural Resources (DENR). Official mandates and policies must be pushed to ensure that maximum cooperation between agencies is established.

[58] https://www.business-standard.com/article/companies/l-oreal-may-face-action-for-further-violation-fda-116100701297_1.html , https://economictimes.indiatimes.com/industry/cons-products/fmcg/loreal-rejects-maharashtra-fdas-mercury-claims/articleshow/54518934.cms?from=mdr https://indianexpress.com/article/india/india-news-india/tests-show-mercury-in-loreal-products-maharashtra-fda-3048779/

[59] Philippine Government. The local government code of 1991. Retrieved from: https://www.officialgazette.gov.ph/downloads/1991/10oct/19911010-RA-7160-CCA.pdf

Annex E—International collaboration

International collaboration on health and environmental risks of cosmetics
Kenya and the EAC - East Africa Community Customs Management Act, 2004 (EACCMA)

- 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, as well as mercury compounds used as agricultural chemicals.
- The EACCMA, 2004, prevents prohibited and restricted goods including all soaps and cosmetic products containing mercury and mercury compounds from being imported into East Africa Community.
- The Kenya Revenue Authority (KRA), together with a multi-agency team (Kenya Bureau of Standards, Anti-Counterfeit Agency, National Environment Management Authority and national police) enforces border control measures to ensure non entry of illicit items such as those prohibited under the EACCMA.

Uganda and the EAC - The East African Community Protocol on Environmental and Natural Resources Management, Article 28 Management of Chemicals, provides that:

- Partner States develop and harmonize policies, laws, and strategies to protect human health and the environment against the adverse effects of toxic chemicals and products containing toxic chemicals;
- The Partner States develop measures to control illegal trafficking of chemicals proven scientifically to be hazardous, toxic, or persistent in the environment;
- Partner States adopt common measures for importation, transportation, use, storage and disposal of chemicals and chemical products and products containing or made with chemicals;
- Promote collaborative research and scientific assessment of chemical contamination, impacts on human health and the environment, technologies for decontamination and remediation of contaminated sites, and development of feasible chemical substitutes and biological and botanical alternatives;
- Cooperate in exchange of technical information to enhance skills in new developments occurring the subregion or region regarding issues of chemicals, and strengthen capacity for chemical analysis;
- Encourage collaborative initiatives in the implementation of international agreements on the use and handling of chemicals.

Follow-up Activities

- Through the implementation of the East African Protocol, the prohibited products have been removed from the market in one or more member states in the East African region;
- Some prohibited creams on the Uganda detention list are no longer on the market. These used to enter the country from the Democratic Republic of Congo. According to retailers in Kampala, these brands are no longer available.

EAC harmonized customs

- The East African Community has a harmonized system at customs to check all goods imported and exported;
- Analytical laboratories are available in all of the East African countries to confirm the presence of mercury or other harmful substances in creams.

Other EAC strategies and activities

- Capacity building for Customs officials and Customs Clearing Agents regarding knowledge and skills on the proper classification of goods, as well as the uniform and correct application of the Harmonized System;
- Sharing of information between the EAC member states, including bans on certain goods, changes in duty rates, increases and exemptions of taxes on certain goods, etc.;
- The secretariat of East African Customs Union publishes an online periodic gazette on pertinent issues for the member states, and maintains a listserve of the enforcement agencies of each member state (see: https://www.pwc.com/rw/en/assets/pdf/tax-alert-eac-customs.pdf)

EAC analytical services and joint monitoring

- The Uganda UNBS has a Testing Department that offers analytical services (Lab), and confirms that their sister agencies in the region have similar well equipped laboratories manned by competent and highly qualified staff. Additional information on EAC Testing Departments can be found on this link: https://www.unbs.go.ug/content.php?src=what-is-testing?&pg=content
- There is joint monitoring by national enforcement agencies (National Bureau of Standards and Revenue Authority) in each country in the region for prohibited products available on media platforms. Harmonized policies and strategies to control illegal trafficking of prohibited products within the member states include:
    - The EACCMA (2004)
    - The EAC CET
    - The Harmonized Systems (HS) Handbook for Customs Administration in the East African Region: https://www.kra.go.ke/images/publications/1_HS-Handbook-Final-Nov-2012.cleaned.pdf

The **Southern African Development Community** (SADC) has a regional Protocol on Environmental Management for Sustainable Development, which was signed by President Zuma on 18 August 2014 at the 34th SADC Summit, held in Victoria Falls, Zimbabwe.

- The overall objective of the Protocol is to promote sustainable utilization and transboundary management of the environment, which is of interest to SADC Member States.
- The Protocol covers a wide range of environmental issues including climate change, waste and pollution, chemicals management (including mercury), biodiversity and natural heritage, sustainable land management, marine and inland water resources, as well as cross cutting issues such as gender, science and technology, and trade and investment.

South Africa ratified the Minamata Convention only in early 2019. However, it is envisaged that regional coordination regarding the Convention will be fostered through the SADC Protocol on Environmental Management for Sustainable Development, under the chemicals focal area.

At present most of the regional cooperation activities undertaken by the **Economic Community of West African States** (ECOWAS) involve standards harmonization. Since Côte d'Ivoire enacted its regulation on cosmetics, standards have been developed to enforce that regulation in the country, especially with regard to hydroquinone content, but also with regard to the 1 ppm permissible level of mercury in skin-lightening creams. In the interest of harmonization, Côte d'Ivoire proposed its standards on cosmetics to be adopted by the 15 countries at ECOWAS level. However, for political reasons the sub-commission for standardization has not met since 2017. Therefore, the process of sub-regional harmonization of standards on cosmetics is pending.

The **Association of Southeast Asian Nations** (ASEAN)[60] is a regional grouping that aims to promote economic, political, and security cooperation among its ten member countries. The ASEAN was started in response to growing economic interactions in the early '90s, and aims to strengthen its member countries through cooperative policies and programs.[61] Funding for the ASEAN comes from the contributions of its member countries and other partners. An example of an enduring regional project is the ASEAN Infrastructure Fund that is co-financed by the Asian Development Bank.[62] The ASEAN is chaired by a different country each year, with its own chairmanship theme. For 2019, Thailand heads the ASEAN with the theme, "Advancing Partnerships for Sustainability."[63]

The **Philippines** adheres to the ASEAN Cosmetics Directive. The country also adheres to the International Conference on Harmonization (ICH) Safety and Efficacy Guidelines,[64] and is one of the lead countries (along with Thailand) for these guidelines, which are established to ensure standardized safety and efficacy standards across ASEAN member countries.

ICH standards are globally applicable guidelines that define mercury limits in medicinal products, among other things.[65] These standards are consistent with the Minamata provisions.

The FDA is also known to incorporate developments from other countries. As an example, the FDA issued Advisory No. 2019-141[66] as a response to the ASEAN Post-Marketing Alert System published by Malaysia, which identified cosmetic products that are not consistent with the ASEAN Cosmetic Directive.

Annex F—Product inspections and sanctions

From a range of countries the following information has been collected on regulations and procedures for product inspections and sanctions.

In **Cote d'Ivoire**, based on the regulation adopted in 2015 prohibiting the use, manufacture, import and export of mercury-containing creams, the Ministry of Trade sends every month its inspectors into the field especially to control the different cosmetics found on markets. Checks are only performed when a suspected product is identified or when there has been a scandal generated by such a product.

According to the decree 2015-288 on cosmetics and personal care products, inspection is carried out by pharmacist investigators plus accredited agents from the Ministries in charge of trade and industry. Inspections and controls are carried out for manufacturing conditions, packaging and storage of ingredients as well as final products.

Practically, the inspectors arrive at a market, storage facility or factory to control the facilities and collect samples for further analysis. An inspection report is prepared and submitted to the Ministries of Trade, Industry and Health through the National Committee of Evaluation and Control of Products. However, the minimal logistics infrastructure hardly permits the work to be carried out properly. The budget dedicated for inspection and control activities is limited and

[60] Albert, E. (2017). ASEAN: the association of Southeast Asian nations. Published by the Council on Foreign Relations. Retrieved from: https://www.cfr.org/backgrounder/asean-association-southeast-asian-nations

[61] Haas, D. (1994). Out of the others shadows: ASEAN moves towards greater regional cooperation in the face of the EC and NAFTA. Retrieved from: https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1475&context=auilr

[62] Asian Development Bank (n.d.). ASEAN infrastructure fund. Retrieved from: https://www.adb.org/site/funds/funds/asean-infrastructure-fund

[63] ASEAN (2019). ASEAN chair. Retrieved from: https://asean.org/asean/asean-chair/t

[64] Food and Drug Administration (n.d.). Adoption of the international conference on harmonization (ICH) safety and efficacy guidelines. Retrieved from: https://webcache.googleusercontent.com/search?q=cache:mUpMbTLXdYUJ:https://ww2.fda.gov.ph/index.php/issuances-2/pharml-1/pharml-fda-circular/99525-fda-circular-no-2013-018+&cd=14&hl=en&ct=clnk&gl=ph

[65] King, A. (2015). Low level mercury in drugs safe but EU needs to set limits says Polish researchers. Retrieved from: https://www.in-pharmatechnologist.com/Article/2015/09/07/Low-level-mercury-in-drugs-safe-but-EU-needs-to-set-limits-say-Polish-researchers

[66] Food and Drug Administration (2019). FDA advisory no. 2019-141. Retrieved from: https://www.fda.gov.ph/fda-advisory-no-2019-141-dissemination-of-asean-post-marketing-alert-system-pmas-report-on-adulterated-cosmetic-products-with-reference-no-8-9-2019-k/

there is no clear definition of how the budget should be used, or its source. Generally, inspections are carried out in response to an emergency situation.

In **South Africa**, Medicines Control Council (MCC) South Africa developed some decades ago an expert-manned regulatory authority that is internationally recognized under the Department of Health. The MCC provides a safety net for both the government and the public to ensure that standards and norms are met as prescribed by the Medicines and Related Substances Act. The structure mainly does coordination using a variety of experts; the Act governs manufacture, distribution, sale, and marketing of medicines. Using the expertise of independent experts, it evaluates data sets submitted to it for purposes of registration**.**

In **Uganda**, the customs clearing office checks the PVoC (Pre-export verification of conformity) certificate, issued by an authorized agent, for imports to Uganda. Compliance with PVoC requirements are necessary in addition to any other import processes. The PVoC Standards Programme is a conformity assessment and verification procedure applied to specific Goods/Products at the respective exporting countries, to ensure their compliance with the applicable Ugandan Technical Regulations and Mandatory Standards.

In **Kenya**, there is an inspection structure in place, a fully-fledged department of market surveillance at KEBs, which receives budgetary allocation and staff. According to KEBs, their inspectors carry out market surveillance where they visit random shops disguised as customers, and buy samples for testing.

In **Bangladesh**, according to Section 22 in BSTI Ordinance 2018, subject to any regulations made under this Ordinance, an Inspector shall have power- (a) To inspect any operation carried on in connection with any article or process in relation to which the Standard Mark has been used; (b) to take samples of any article, or of any material or substance used in any article or process, in relation to which the Standard Mark has been used; and (c) to search, size and investigate in respect of an offence under this Ordinance as a Police officer of the rank or Sub-Inspector. (d) to exercise such other powers as may be prescribed.

In **India**, the state FDA randomly checks the samples of cosmetics from the market. There are also detailed criteria for sampling methodology. They send the samples to a recognized laboratory for analysis. As per the relevant provisions of the act and rules, there is a formal structure and system in place to inspect products following detailed procedures and guidelines.

In the **Philippines**, the Chemical Control Order (CCO) for Mercury and Mercury Compounds[67] states that premises using, storing, or treating mercury and mercury compounds, or mercury-containing wastes should adhere to Department Administrative Orders 34, 35, 14, and 14a. These standards cover water and air quality.

The CCO does not provide specific standards for mercury products, but states in Section 7 that international standards such as the World Health Organization (WHO) standards may be used in the absence of local criteria. In 2011, the Philippines imposed a national regulatory limit of 1 mg/kg for mercury in skin lightening products.[68] Aside from these regulatory limits, the FDA also uses the ASEAN Cosmetic Directive as basis for standards.[69]

Before entering the market, skin-lightening products are subjected to clinical trials as outlined in Bureau Circular No. 05 s. 1997.[70] This includes clinical pharmacology studies (Phase I, II, and III) and an additional Phase IV testing (under FDA Administrative Order No. 67 s. 1989) for products

[67] DENR (1997). Chemical control order for mercury and mercury compounds. Retrieved from: http://119.92.161.2/portal/Portals/15/DAO%201997-38.pdf

[68] World Health Organization (2011). Mercury in skin lightening products. Retrieved from: https://www.who.int/ipcs/assessment/public_health/mercury_flyer.pdf?ua=1

[69] Food and Drug Administration (2019). FDA advisory 2019-074. Retrieved from: https://www.fda.gov.ph/wp-content/uploads/2019/03/FDA-Advisory-No.-2019-074.pdf

[70] Food and Drug Administration (1997). Bureau circular no. 05 s. 1997. Retrieved from: https://ww2.fda.gov.ph/attachments/article/15912/bc%205%20s%201997.pdf

classified as monitored-release, aka new chemicals or structural modifications to existing approved products.[71]

Under Republic Act No. 9711,[72] manufacturers, distributors, advertisers, and/or agents may be subjected to product confiscation, seizure, or the suspension, and revocation of FDA authorization (discussed in-depth additional question #4). The Act also states that actions may be filed by petitioners or the FDA themselves to pursue legal action against violators.

At the consultative meeting for the project proposal on mercury for the Global Environmental Facility (GEF) 7 cycle, representatives from the FDA have noted that they have conducted numerous seizures of mercury-containing products in 2019, with the main concern being the disposal of said products. Based on numerous advisories cited in this document, the FDA uses PMS activities to track these entities down as well as through reports received by the administration.

The FDA conducts post-marketing surveillance (PMS) activities where marketing authorization holders (MAH) are required to establish PMS systems for every product in the market, which shall be translated into a product Risk Management Plan (RMP).[73] RMPs are required to adhere to guidelines such as:

- ICH Harmonised Tripartite Guideline;
- The European Medicines Agency's (EMA) Guideline on Risk Management Systems for Medicinal Products for Human Use;
- EMA's guideline on Good Pharmacological Practices Module V;
- EMA's volume 9a of the Rules Governing Medicinal Products in the European Union;
- The US FDA Amendments Act of 2007, and Guidance for Industry Format and Content for Risk Evaluation and Mitigation Strategies (REMS), REMS Assessment, and Proposed REMS modifications.

In early 2019, the FDA issued Advisory No. 2019-074,[74] a public warning against cosmetic products containing mercury (Parley Beauty Cream and Parley Herbal Whitening Cream, respectively). The products were found to contain mercury through the FDA's post-marketing surveillance activities. Establishments are initially warned through public advisories to stop the distribution of unauthorized products. Regulatory actions and sanctions are pursued when establishments are proven to continue selling unauthorized products. The FDA also submits requests to local government units and law enforcement agencies to assist and support the ban of said products. An online reporting facility for such cases is available at <ww2.fda.gov.ph/ereport>.

In Kenya, the Kenyan Standards Act clearly defines the appointment procedure, mandate and liability of inspectors, penalties, as well as provide the legal basis for inspectors to obtain support from the police in connection with inspections.[75] All of the mentioned elements in the law are important for functional inspection work.

The standards [Standards Act chap. 496] stipulate that all importers of goods must ensure that they meet the relevant Kenya Standards or approved specifications.

According to the KEBS, the standards act requires that goods entering the country must meet quality requirements, as stated in the cosmetics standards and labelling standards. The cosmetics standards contain a requirement for lists of ingredients, so KEBS ensures a product does not have harmful ingredients.

As per the standards, lab tests are done from time to time. KEBS has inspectors, so this test is done on suspicious products, especially those products that are not labelled properly or at all.

[71] Food and Drug Administration (2018). FDA circular no. 2018-012. Retrieved from: https://ww2.fda.gov.ph/index.php/issuances-2/pharml-1/pharml-fda-circular/525777-fda-circular-no-2018-012

[72] Department of Health (2011). Department circular no. 2011 – 0101. Retrieved from: https://www.wipo.int/edocs/lexdocs/laws/en/ph/ph080en.pdf

[73] Food and Drug Administration (2018). FDA circular no. 2018-012. Retrieved from: https://ww2.fda.gov.ph/index.php/issuances-2/pharml-1/pharml-fda-circular/525777-fda-circular-no-2018-012

[74] Food and Drug Administration (2019). FDA advisory no. 2019 -074. Retrieved from: https://www.fda.gov.ph/wp-content/uploads/2019/03/FDA-Advisory-No.-2019-074.pdf

[75] Kenya Standards Act (https://www.aca.go.ke/images/downloads/standards-act.pdf).

Also, there is quality assurance according to the Law of Kenya and the quality imports order no.78 of July, 2005, legal notice no.127 of June 2018, and Verification of conformity to Kenya standards of imports order, 2005. In line with the provisions of this order, all soaps and skin lightening creams containing mercury and its compounds are banned in Kenya. For enforcement, the inspectors visit facilities manufacturing products and inspect the products at manufacturing point and also stores of raw materials, which the companies must give list of. Random inspection is done and if the products are not labelled or hidden in containers, especially at import, these are taken for lab tests. There are raw material standards.

The Pre-shipment Inspection and verification of conformity (via a certificate of conformity), which is done by KEBS licensed inspectors at the port of origin, ensures that all goods coming to Kenya are tested.

One challenge has been low fines, as stipulated in the standards act, but there are efforts to revise and increase fines for those found culpable.

UNBS Imports Inspection and Clearance Regulations, 2015, in Uganda

This regulation provides for;

1. Periodic spot-check by enforcement officials from both UNBS and the URA to look out for the prohibited products in retail shops / outlets;
2. Seizure of the prohibited products if found, and either shipped back to countries of origin or destroyed within 21 days;
3. Reprimand, fines, arrests and or cancellation of trade licenses of importers / retailers of prohibited creams;
4. Warning / cautioning the general public to desist from the purchase and use of the prohibited cosmetics through different media platforms.

The law enforcement agencies (UNBS and URA) have implemented the provisions of the regulation 2, 3 and 4 above.

Enforcement - UNBS orders harmful cosmetics off the market

Hydroquinone and Mercury, which are common active ingredients were found in a number of skin care products designed specifically to lighten or bleach the skin[76]

Effective from 31 March 2020, the UNBS will not permit any trader to sell cosmetic products containing mercury or hydroquinone. The agency says it will implement the law and arrest all persons found to be distributing the harmful products after this date[77].

URA impounds Shs120m cosmetics from DR Congo

The URA has impounded 622 cartons of cosmetics containing hydroquinone from DR Congo valued at Shs120m.

URA's acting Assistant Commissioner Enforcement said the cosmetics were intercepted at Kagamba in Kanungu District at about midnight after a tip-off, impounded and brought to URA headquarters in Kampala[78].

[76] UNBS maintains ban on cosmetics containing mercury and hydroquinone **(**https://www.monitor.co.ug /News/National/UNBS-maintains-ban-cosmetics-containing-mercury-hydroquinone/688334-5245358-glyff9z/index.html)

[77] https://www.monitor.co.ug/Business/Markets/UNBS-orders-harmful-cosmetics-off-market/688606-3083634-format-xhtml-mepudm/index.html , https://www.monitor.co.ug/News/National/UNBS-bans-cosmetics-containing-mercury/688334-3127660-jsketb/index.html

[78] URA impounds Shs120m cosmetics from DR Congo (https://www.monitor.co.ug/Business/Commodities/URA-impounds-Shs120m-cosmetics-DR-Congo/688610-3805294-68w5wa/index.html **)**

The **Public Health Act Chap 281 LOU** provides for prevention of diseases to the public arising from poor sanitation, pollution of the environment and consumer products that contain hazardous chemicals.

Follow-up activities:
UNBS and URA enforcement officers have implemented all the provisions of the regulation. They have seized the prohibited creams and lotions found in retail shops, arrested and fined the sellers of these products, warned the general public on buying these products through the media, print and electronic media platforms.
The specific Goods (Conveyance) Act Cap349 LOU provides for the control of conveyance of certain goods to and from neighboring countries in the region, including Kenya, Rwanda, the Democratic Republic of Congo and Sudan.