



MERCURY-ADDED SKIN-LIGHTENING CREAMS

Available, inexpensive and toxic

November 2018



Swedish Society
for Nature Conservation



BIODIVERSITY RESEARCH INSTITUTE
innovative wildlife science

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Executive summary

The toxic trade of often illegal mercury-added skin-lightening products is a global crisis expected to only worsen with skyrocketing demand, especially in Asia, the Middle East and Africa.¹ Consistent with other research, a new Zero Mercury Working Group (ZMWG) study indicates that a significant percentage of skin-lightening creams sold worldwide contains dangerous levels of mercury.

In 2017 and 2018, 338 skin-lightening creams from 22 countries were collected by seventeen of our non-governmental organization (NGO) partners from around the world and tested for mercury. 34 creams (10% of the samples) had mercury concentrations ranging from 93 - 16,353 parts per million (ppm). These levels significantly exceeded not only the legal standard established by countries that regulate these products, but also the provisions set forth in the Minamata Convention disallowing after 2020 the “manufacture, import or export” of cosmetics with a mercury content above 1ppm.²

In Bangladesh, almost 50% of the creams sampled and tested had mercury content exceeding 1ppm. In the Dominican Republic and Indonesia it reached 33% and 31% respectively. In Mauritius one out of 15 creams was found to contain more than 1ppm (7%). 19% of the Philippines’ samples exceeded 1ppm mercury content, while the Thai samples reached 63%. Finally, in Trinidad and Tobago, 20% of the samples tested also exceeded the Minamata Convention limits. Sampling was carried out following established protocol in 2017 and further streamlined in 2018.

Mercury is well known to international agencies as toxic and a risk to human health. Regular use of skin bleaching or skin-lightening creams and soaps containing mercury can lead to rashes, skin discoloration and blotching. Long-term exposure can have serious health consequences, including damage to the skin, eyes, lungs, kidneys, digestive, immune and nervous systems.³

Out of the 22 countries where sampling took place, 15 have legislation or other requirements consistent with the Minamata Convention provisions. Out of the 7 countries where high mercury samples were found, only 4 have legal requirements prohibiting creams with more than 1ppm mercury content.

Our research demonstrates that hazardous substance restrictions and accompanying risk communication strategies in many countries are incomplete and/or inadequately enforced, thereby raising the risk of health effects, primarily to women.

As countries strive to comply with the 1ppm mercury content cutoff provision pertaining to cosmetics in the Minamata Convention on Mercury, a range of measures are available to reduce exposure to mercury from skin lighteners, including renewed opportunities for collaboration with all levels of government and civil society:

- 1) **New laws or regulations.** The Minamata Convention’s ban on the manufacture, import and export of mercury-added skin products after 2020 may result in adoption of new national legislation and enforcement programs. Local ordinances can also play an effective role in targeting specific venues of production and sales, raising awareness and promoting measures that can protect consumers.
- 2) **Better enforcement.** Government officials, and in particular customs officers, should be provided with the training and resources to control their national market and intercept cosmetics that violate the Convention, as most may be imported. Several relatively simple and efficient screening technologies can be used to screen products for mercury. The report presents measurement protocols for the X-ray fluorescence (XRF) spectrometer or analyzer,

an affordable screening instrument already in use by many customs services and government authorities for doing compliance checks.

- 3) **Non-discriminatory advertising.** Many of the social pressures that underlie the widespread use of skin-lightening products are amplified by the media. Countries should adopt advertising guidelines that ensure advertisers do not reinforce negative social stereotyping on the basis of skin color, akin to those adopted by the Advertising Standards Council of India (ASCI) in 2014.
- 4) **Harmonization of enforcement efforts.** With an increasingly global supply chain, and widespread sales over the internet, governments should coordinate efforts by posting and maintaining a continuously updated list of illegal products. Such up-to-date postings on UN agency and Interpol websites would greatly assist regulators around the world, as well as civil society, to identify illegal products in the marketplace.
- 5) **Targeted monitoring of the marketplace.** To the extent possible, monitoring of the marketplace should be conducted to investigate and prevent the proliferation of hazardous or illegal domestic and cross boundary trading practices. Market surveillance should target especially internet sales as well as small stores that sell creams to specific ethnic groups or immigrant communities.
- 6) **Accurate labeling.** To discourage the marketing of unregulated products, all cosmetics should be labelled according to national regulations, with accurate information on the ingredients, producer, address and country of manufacture. Sellers should also provide documentation verifying that products meet all relevant regulations, and that the labeling language is understandable in the destination country.
- 7) **Education.** While the deeply rooted practice of skin-lightening will not change rapidly, mercury exposure via cosmetics poses serious health but also environmental and indoor air quality risks. Governments, health practitioners and community leaders should initiate culturally-appropriate campaigns about potential risks to people who use skin-lighteners.
- 8) **Popular enforcement.** Civil society groups are well placed to identify suspect products in the marketplace, especially with the use of XRFs or similar screening tools.

The following tables list the 34 skin-care products containing excessive mercury identified in seven countries during research in 2017 and 2018:

Skin care products with excessive mercury content (purchased in 2017)

Country of purchase	Country of manufacture	Brand name	Mercury [ppm]
Bangladesh	Pakistan	New Face Whitening Cream	16,000
Bangladesh	Not indicated	Noor Herbal Beauty Cream	16,000
Bangladesh	Bangladesh	Lata Herbal Skin Bright Cream	8,500
Bangladesh	Pakistan	Chandni Whitening Cream	6,800
Bangladesh	Pakistan	White Pearl Plus Cleanser Cream	93
Dominican Republic	Dominican Republic	Crema Blanqueadora Whitening Cream Lisso	260
Mauritius	Pakistan	Chandni Whitening Cream	14,000
Philippines	China	Jiaoli Miraculous Night Cream	1,200
Philippines	Hong Kong	Glutathione Grapeseed Extract Whitening / Anti-Aging Night	750
Philippines	China	Jiaoli Miraculous Day Cream	500
Trinidad/ Tobago	Jamaica	Non-Oily Deluxe Silken Bleaching Cream	8,300

Note: Mercury content analysed by Enthalpy Analytical Laboratories (California, USA) using Cold Vapor Atomic Absorption Spectroscopy (CVAAS).

Skin care products with excessive mercury content (purchased in 2018)

Country of purchase	Country of manufacture	Brand name	Mercury [ppm]
Indonesia	Not indicated	Collagen Plus Vit E Night Cream	7,111 ^a
Indonesia	Philippines	RDL Whitening Treatment Night Cream 8 Days Treatment	5,958 ^a
Indonesia	Malaysia	Temulawak Cream (Night Cream)	3,059 ^a
Indonesia	Not indicated	Natural 99 Vitamin E Plus	2,018 ^a
Philippines	Pakistan	Goree Beauty Cream	10,576 ^a
Philippines	China	Jiaoli Day Cream	1,693 ^a
Philippines	Hong Kong	Gemli Glutathione Grapeseed Extract (Day Cream)	1,565 ^a
Philippines	China	Jiaoli Night Cream	365 ^a
Bangladesh	Pakistan	Goree Beauty Cream with Lycopene	16,353 ^a
Bangladesh	Pakistan	Due Beauty Cream	11,940 ^a
Bangladesh	Taiwan	Huayenong - Bird's Nest Cosmetology	10,749 ^a
Bangladesh	Pakistan	Golden Pearl Beauty Cream	9,648 ^a
Bangladesh	Pakistan	Faiza Beauty Cream	9,053 ^a
Bangladesh	Taiwan	Egg White and Cherry 7 Days Specific Eliminating Freckle Whitening Cream	5,271 ^a
Bangladesh	Taiwan	Green Tea Whitening Anti-freckle Cream	5,068 ^a
Bangladesh	China, via Malaysia	Temulawak New Beauty White Cream (Night Cream)	1,884 ^a
Bangladesh	Pakistan	Hoor! Whitening Cream	1,083 ^a
Bangladesh	China	Jiaulihuc Hunsu Jioli Miraculous Day and Night Cream	711 ^a

Note: Mercury content analyzed by Quality Assurance & Control Systems Laboratory (Greece) using Hydride Atomic Absorption Spectroscopy (HAAS).

Country of purchase	Country of manufacture	Brand name	Mercury [ppm]
Thailand	Thailand	Cleome White	8,300 ^b
Thailand	Thailand	O White Whitening Cream Premium Package	7,300 ^b
Thailand	Thailand	White Rose Whitening	6,500 ^b
Thailand		Whitening Pearl and Snow Lotus Cream	4,300 ^b
Thailand	South Korea	Whitening Ginseng and Pearl Cream	2,100 ^b

Note:^b Mercury content analysed by Enthelpy Analytical Laboratories (California, USA) using Cold Vapor Atomic Absorption Spectroscopy (CVAAS).

Some of the high mercury creams identified during our study



1 Introduction

1.1 Background and aim

The use of skin-lightening creams and soaps is prevalent around the globe.⁴ Demand is skyrocketing, especially in Asia, the Middle East and Africa, with sales of \$17.9 billion in 2017, and projected to reach \$31.2 billion by 2024, according to Global Industry Analysts.¹ Depending on the active ingredients, skin-lightening formulations can cause a number of direct and indirect skin disorders, as well as other serious health effects.

Many users of these products live in regions of the world with high UV light^a exposure.^{5, 6} Often overlooked, or unknown to consumers, is the increased risk of skin cancers in lightened skin. Many active ingredients in commercially available formulations specifically target the production of the pigment melanin in the skin cells, effectively destroying the natural ability of the skin to protect itself from UV light.^{7, 8, 9, 10, 11} Skin-lightening products are often used without medical supervision, and often for prolonged periods of time on large areas of the body. In the tropics these factors may be compounded by hot and humid conditions, favoring increased absorption of some active ingredients.¹²

Mercury is often added as an active ingredient in skin-lightening products, and is the only heavy metal addressed at global level, via the Minamata Convention on Mercury (see below). According to the World Health Organization, after skin rashes, skin discoloration and scarring, the main adverse effect from inorganic mercury contained in skin-lightening products is kidney damage. Other health effects may include “anxiety, depression or psychosis and peripheral neuropathy.”^b Annex K provides further detail on the health effects of mercury as an active ingredient.

Mercury is a unique metal that can be both liquid and gaseous at room temperature, which makes it a pollutant prone to long-range atmospheric transport and global distribution.^{13, 14, 15} Furthermore, it can be transformed by bacteria into organic forms that accumulate in living organisms and biomagnify^c in ecosystem food webs.^{d, 13} Because of this, and the high toxicity of mercury, the international community in 2010 initiated negotiations on a global mercury treaty to ban and regulate the use of mercury. The negotiations were finalized in 2013 with the adoption of the Minamata Convention on Mercury, which entered into force on 16 August 2017.²

Article 4 of the Minamata Convention addresses “mercury added products.” The manufacture, import and export of products listed in Annex A of the Minamata Convention, including cosmetics with more than 1 part per million (1ppm, or 1 µg/g) mercury, are banned after 2020.²

With this report, we have highlighted the toxic trade and risky and often illegal use of mercury as an active ingredient in skin-lightening products. The basic aim of this study was to take a current

^a Ultraviolet light is high in energy and damages the structural components of exposed skin cells, including the DNA.

^b “Peripheral neuropathy” (PN) is damage to or disease affecting nerves, which may impair sensation, movement, gland or organ function, or other aspects of health, depending on the type of nerve affected.

^c “Biomagnify” implies that each organism in a food web acquires the accumulated burden of a chemical from its food source (plants or prey organisms), so that the concentration of the chemical increases in the food web from plants, grazers and lower level predators, to top predators at the top of the food web.

^d A food web is basically a diagram of who eats what in an ecological system or community. Humans are usually at the top of the food web.

“snapshot” of how frequently, and in what concentrations, mercury is used as an active ingredient in skin-lightening creams in a number of countries around the world. In 2017 and 2018, 338 samples were collected by our NGO partners from both formal and informal markets, and the samples were screened and analyzed, as described below. It is anticipated that this study will be followed by a similar analysis of skin-lightening creams in 2020.

1.2 Relevant national legislation

For countries where samples were collected, relevant legislation has been summarized with respect to use, manufacture, import, and export of skin-lightening cosmetics. Laws/regulations conforming to the Minamata Convention requirements (i.e., less than 1ppm mercury content) were noted, as well as laws/regulations governing ingredient lists for cosmetics and personal hygiene products.

The relevant legislation, and more detailed analysis can be found in Annex G including the following key observations:

- From the 22 countries where samples were collected, 15 were found to have legislation covering skin-lightening creams, and 14 of these appear to have a ban (via law or otherwise) on mercury content above 1ppm.
- Out of the 7 countries where high mercury samples were found, 4 have legal or other requirements prohibiting creams with more than 1ppm mercury content.
- Furthermore, over 50% of the countries sampled appear to have some requirements for ingredient labels.

1.3 Sampling and analysis

The sampling and analysis methodologies used in this research were based on earlier laboratory work and practices, as well as relevant work and experiences of civil society organizations. A Lumex RA 915+, a Jerome J405, as well as different XRF models were used for screening the collected samples for mercury content. Samples with more than 1ppm of mercury were further analyzed by accredited laboratories, for more accurate mercury readings, according to standardized test methods.

The following analytical methods were used:

- Analysis for total mercury, using the direct combustion/trapping atomic absorption (AA) method on a Milestone DMA 80, by the Biodiversity Research Institute Laboratory (BRI).
- Cold Vapor Atomic Absorption Spectroscopy by Enthalpy Analytical, an accredited USA-based lab.
- Hydride Atomic Absorption Spectroscopy, by accredited laboratory Quality Assurance & Control Systems (QACS lab) based in Greece.

The cost of analysis differs from one laboratory to another, and the quotes for this study ranged from USD 50–150 per sample. Further details are provided in Annexes A, D, E and L.

2 Results

2.1 Findings in 2017

In the first round of sampling in 2017, 240 samples were collected by NGOs^e in 19 countries: (Bangladesh (12); Barbados (1); Belgium (11); Dominican Republic (3); Gabon (9), Ghana (15); Grenada (1); India (15); Côte d'Ivoire (17); Kenya (15); Mauritius (15); Nigeria (15); the Philippines (17); South Africa (10); Sri Lanka (17) Tanzania (22); Trinidad and Tobago (5); Uganda (14); and the USA (26).

Some creams were duplicates even though collected in different countries, indicating the prevalence of companies selling in multiple continents. The majority of the creams contained no detectable mercury, but Annex H provides the complete results of the Milestone DMA-80 analysis of creams with detectable mercury levels.

More than 90 creams from 15 countries had detectable mercury concentrations below 1ppm. 12 creams had mercury levels above the maximum detection capability of the Milestone DMA-80 instrument. The BRI lab diluted the high-mercury creams, but the levels still exceeded the range of the instrument. Ultimately, mercury readings for these samples were measured using a Lumex R 915+ and a Niton XRF-model XL3t 955 by Thermofisher, and in 2018 the mercury content of those samples was further confirmed by the USA-based accredited laboratory Enthalpy Analytical, according to the EPA standard 7471A (see Table 1 below).

^e Environment and Social Development Organization (ESDO), Bangladesh; European Environmental Bureau (EEB), the EU; Friends of the Nation (FoN), Ghana; Toxics Link (TL), India; BaliFokus, Indonesia; Centre Africaine Santé Environnement (CASE), Côte d'Ivoire; Centre for Environment Justice and Development (CEJAD), Kenya; Center for Public Health and Environmental Development (CEPHED), Nepal; Pesticide Action Network Mauritius (PANeM), Mauritius; Sustainable Research and Action for Environmental Development (SRADev), Nigeria; Ban Toxics (BT), the Philippines; groundwork South Africa (gW), South Africa; Agenda for Environment and Responsible Development (AGENDA), Tanzania; EARTH Thailand, Thailand; National Association of Professional Environmentalists (NAPE), Uganda; Biodiversity Research Institute (BRI), USA; Mercury Policy Project (MPP), USA.

Table 1. Creams purchased in 2017 exceeding 1ppm mercury content

Country of purchase	Country of manufacture	Manufacturer	Brand name	Lumex (in air ng/m3)	Jerome (in air, µg/m3)	XRF-Hg screening (ppm)	Enthalpy THg (ppm)
Bangladesh	Not indicated	Not decipherable	New Face Whitening Cream		20	25,519	16,000
Bangladesh	Not indicated	Kaw Cosmetics	Noor Herbal Beauty Cream		10	16,242	16,000
Bangladesh	Bangladesh	Lata Herbal Co.	Lata Herbal Skin Bright Cream		35	8,943	8,500
Bangladesh	Not indicated	Not decipherable	Chandni Whitening Cream		30	10,473	6,800
Bangladesh	Pakistan	White Pearl	White Pearl Plus Cleanser Cream		6		93
Dominican Republic	Dominican Republic	Laboratorios LISSO, S.R.L.	Crema Blanqueadora Whitening Cream Lisso	1000		416	260
Mauritius	Pakistan	SJ Enterprises	Chandni Whitening Cream	12000	71	28,718	14,000
Philippines	Hong Kong	Gemli	Glutathione Grapeseed Extract Whitening / Anti-Aging Night	1400		2,144	750
Philippines	China	Not indicated	Jiaoli Miraculous Day Cream	4000		2,021	500
Philippines	China	Not indicated	Jiaoli Miraculous Night Cream	6400		4,222	1,200
Trinidad/ Tobago	Jamaica	E.W. Abrachaus and Sons Ltd	Non-Oily Deluxe Silken Bleaching Cream	2200		29,539	8,300

Note: Creams screened by BRI in 2017 with Lumex, or Jerome, or XRF, and analyzed in 2018 by Enthalpy Analytical with cold vapor atomic absorption spectroscopy. The readings from the screening instruments are also shown.

2.2 Findings in 2018

98 samples were collected in 9 countries in 2018, including most of those where creams with a mercury content of at least 1ppm were found during the first sampling round,^f, including Bangladesh (20), and the Philippines (20). In addition, samples were collected from India (8), Indonesia (13), Kenya (9), Nepal (10), Nigeria (10), and Thailand (8).

Skin-lightening creams purchased in India, Indonesia and the Philippines were screened for mercury in August 2018 by Ban Toxics (BT) in Quezon City, the Philippines, using an Olympus Innov-X Delta Professional DS 2000 XRF. Four of the 13 samples from Indonesia, and four of the 20 samples from the Philippines contained mercury levels above 1ppm, while none of the Indian samples contained detectable mercury. The results of the analysis of samples with detectable mercury may be seen in Annex I, and the samples with mercury above 1ppm are included in Table 2 below.

Skin-lightening creams purchased in Bangladesh, Kenya, Nepal and Nigeria were screened in September 2018 by the Centre Africaine Santé Environnement (CASE-Côte d'Ivoire) and the European Environmental Bureau (EEB), with assistance from the French XRF provider Fondis, in Brussels, Belgium, using a Niton XL3t-970 GOLDD+ Analyser SDD XRF. Ten of the samples from Bangladesh had mercury concentrations exceeding 1ppm, while none of the samples from Kenya, Nepal or Nigeria contained detectable mercury. The results of the analysis of samples with detectable mercury levels may be seen in Annex J, and the samples with mercury above 1ppm are included in Table 2 below.

As above, the high mercury content samples from Bangladesh, the Philippines and Indonesia were sent to a specialized lab (in this case, the Greek Lab QACS) for further analysis.

^f Although high mercury creams were found in 2017 in Mauritius, Dominican Republic and Trinidad and Tobago, they were not included in the 2018 sampling round.

Table 2. Creams purchased in 2018 exceeding 1ppm mercury content

Country of purchase	Country of manufacture	Manufacturer	Brand name	Innov-X Delta Professional DS 2000 XRF THg (ppm)	QACS (ppm)
Indonesia	Not indicated		Collagen Plus Vit E Night Cream	7,276±80	7,111
Indonesia	Philippines		RDL Whitening Treatment Night Cream 8 Days Treatment	3,319±37	5,958
Indonesia	Malaysia		Temulawak Cream (Night Cream)	3,892±71	3,059
Indonesia	Not indicated		Natural 99 Vitamin E Plus	1,000±19	2,018
Philippines	Pakistan		Goree Beauty Cream	22,133±0.1	10,576
Philippines	China		Jiaoli Day Cream	3,156±56	1,693
Philippines	Hong Kong		Gemli Glutathione Grapeseed Extract (Day Cream)	6,52±18	1,565
Philippines	China		Jiaoli Night Cream	269±11	365
Bangladesh	Pakistan	H Pharmacy	Goree Beauty Cream with Lycopene	9,356±62	16,353
Bangladesh	Pakistan	Kreative Cosmetics Private LTD	Due Beauty Cream	8,185±112	11,940
Bangladesh	Taiwan	Bird's Nest Cosmetology	Huayenong - Bird's Nest Cosmetology	6,515±42	10,749
Bangladesh	Pakistan	Golden Pearl Cosmetics	Golden Pearl Beauty Cream	10,567±107	9,648
Bangladesh	Pakistan	Poonia Brothers	Faiza Beauty Cream	4,636±43	9,053
Bangladesh	Taiwan	Spring International Cosmetic Group Company	Egg White and Cherry 7 Days Specific Eliminating Freckle Whitening Cream	4,371±31	5,271
Bangladesh	Taiwan	Hua Thu Li	Green Tea Whitening Anti-freckle Cream	4,870±32	5,068
Bangladesh	China, via Malaysia	Guangzhou Tengzhang International Trade Co. Ltd	Temulawak New Beauty White Cream (Night Cream)	12,73±13	1,884
Bangladesh	Pakistan	Hamza Company	Hoor! Whitening Cream	16,72±18	1,083
Bangladesh	China	Hearben Gelidai Jiabao Cosmetics	Jiaulihuic Hunsu Jioli Miraculous Day and Night Cream	732±9	711

Note: Creams analyzed in 2018 with the Innov-X Delta Professional DS 2000 XRF, and Niton XL3t-970 GOLDD+ Analyser SDD, as well as by QACS using cold vapor atomic absorption spectroscopy.

In 2018, eight skin-lightening creams purchased from Thailand were screened with the Lumex 915+; five were found to have relatively high mercury concentrations and were sent to the USA – based Enthalpy Analytical lab, which confirmed high levels of mercury, above 1ppm. The Thai creams corresponded to a selection of creams in the Minnesota Pollution Control Agency and Minnesota Department of Health (USA)⁸ lists of potentially harmful cosmetics. Enthalpy Analytical prepared and analyzed the samples according to the EPA 7471A standard and identified the creams in Table 3 below containing mercury exceeding 1ppm.

Table 3. Thai creams purchased in 2018 exceeding 1ppm mercury content

Country of purchase	Country of manufacture	Manufacturer	Brand name	Lumex (ng/m ³ air)	THg (ppm)
Thailand	Thailand	Inter Progress Cosmetic	Cleome White	1,750	8,300
Thailand	Thailand	OK Cosmetics Limited Partnership	O White Whitening Cream Premium Package	2,200	7,300
Thailand	Thailand	Lola rose Cosmetics company	White Rose Whitening	500	6,500
Thailand			Whitening Pearl and Snow Lotus Cream	1,040	4,300
Thailand	South Korea		Whitening Ginseng and Pearl Cream	575	2,100

Note: Creams analyzed in 2018 by Enthalpy Analytical using cold vapor atomic absorption spectroscopy.

3 Discussion

3.1 Results of analysis

This study demonstrates that mercury is still prevalent as an ingredient in many skin-bleaching creams, despite bans in a number of countries included in the study. In total, 338 samples from 22 countries were analyzed, of which 34 in 7 countries (10 % of the samples) had mercury concentrations exceeding the limit of 1ppm set forth in the Minamata Convention.

The overall percentage of 10% is slightly higher than other findings in the literature where sampling covers several countries simultaneously, but it is relatively low when compared with studies focusing on an individual country, where the percentage of creams exceeding 1ppm mercury often ranges from 20-60% (see Annex F). Nevertheless, such outcomes are problematic

⁸ <http://www.health.state.mn.us/topics/skin/> ; also see: <http://www.health.state.mn.us/topics/skin/testedprds.pdf>

from an environmental and human health point of view. Furthermore, it should be kept in mind that most of our samples from 2018 were initially screened with XRF instruments, which have a level of detection (LOD) sensitivity of around 5ppm, implying that we may not have identified some creams containing more than 1ppm but less than 5ppm mercury.

As also discussed below, the sampling methodology can influence the results. More generic sampling in 2017 led to a somewhat lower percentage of high mercury creams identified, whereas a more streamlined and focused approach in 2018 led to significantly higher results.

Summarizing the statistics by country: In Bangladesh almost 50% of the creams sampled and tested had mercury content exceeding the Minamata limit of 1ppm. In the Dominican Republic 33% of samples had mercury above 1ppm, whereas in Indonesia it was 31%. In Mauritius only one out of 15 creams (7%) was found to contain more than 1ppm. 19% of the Philippines' samples exceeded 1ppm mercury content, while the Thai samples reached 63%. Finally, in Trinidad and Tobago, 20% of the samples tested also exceeded the Minamata limit.

Overall, the mercury concentrations in these products ranged from 93 ppm to over 16,000 ppm, exceeding not only the legal standard established by many countries, but also the provision set forth in the Minamata Convention disallowing after 2020 the "manufacture, import or export" of cosmetics with a mercury content above 1ppm.²

Most of the creams are marketed for women, although during the 2017 sampling BRI noted that three creams appeared to target men. Although assumed in the past to be an issue only of interest to women, skin lightening appears to be a practice that is also increasing among men.^{16,}

¹⁷

3.2 Sampling methods

Relatively few high-mercury samples were detected in the 2017 sampling round, focusing mainly on the formal market. The initial percentage of high mercury creams detected was around 4.5 % (11 out of 240 creams), in five countries.

As a result, the 2018 sampling was further streamlined, with investigations focusing on the informal market, and reorienting the sampling effort to countries where high-mercury samples were more often found in the first sampling round. We also focused more on countries where high-mercury creams had already been identified by authorities in national import detention lists, or through government testing. Consequently the creams with high mercury content reached 23% (23 out of 98) in the 2018 sample.

2018 sampling efforts also targeted smaller stores and markets, which are also found in higher-income countries with sizeable immigrant communities. And the 2018 sampling also focused on imports from countries where high-mercury creams had been found in 2017 or in previous investigations, such as creams coming from Bangladesh, China, Indonesia, Malaysia, the Philippines, Pakistan, Thailand, Jamaica, the Dominican Republic and Trinidad and Tobago.^{5,6, 18,}

^{19, 20}

This approach was intended to help identify previously unknown products with a potentially high mercury content, as well as to inform companies and authorities about products that should be

withdrawn from the market, while raising public awareness so consumers can better avoid them. No samples from Latin America were included in this study, so those regions should be a higher priority in future studies. Finally, sampling efforts should also regularly include especially the larger internet sales operators.

3.3 Screening tools

As mentioned previously, the purchased creams were first screened with a portable instrument in order to identify those with high mercury levels. Then the high mercury creams were subjected to more accurate mercury analysis using standardized sample preparations and more sensitive instruments. Screening was used not only to limit the number of creams requiring expensive laboratory analysis, but also to protect sensitive laboratory instruments from contamination.

Three different instruments were used for the screening process:

- A Lumex 915+, 2004 model, which measures mercury in the air in ng/m^3 ;



- A Jerome 405, 2009 model, which also measures mercury in the air in $\mu\text{g}/\text{m}^3$;



- Two types of XRF instruments measuring mercury directly in ppm.



Referring to Table 1 above, the comparative readings of the various screening instruments, and the more precise results of the laboratory analysis, it can be concluded that in general, Lumex readings above 1000 ng/m³ appear to indicate that the mercury content of a cream is greater than 1ppm.

One major difference is that the Lumex and Jerome instruments analyze the concentration of mercury vapor in the air, while the lab methods analyze the mercury concentration of the cream itself.

Given that the XRF instrument measures the mercury concentration, it appears to be a more accurate instrument for screening. It was observed that XRF readings are closer to the more sophisticated laboratory results, yet do not necessarily correlate fully. Nevertheless, XRF measurements showing high mercury concentrations were fully confirmed by the subsequent laboratory analysis.

All three instruments are quite easy to use, and with a day's training and practice they may be used by customs officers or others, even by persons who may be less experienced or non-technical. The purchase cost of the XRF is higher than a Lumex, but as noted above, it tends to provide a more accurate reading of the concentration of mercury in a cream. Also the XRF can be used to measure many other elements, whereas the Lumex is mercury-specific. The Jerome instrument is the least expensive, as well as being more compact and lightweight.

3.4 Countries of purchase and countries of manufacture

High-mercury creams in this study were purchased in Bangladesh, the Dominican Republic, Indonesia, Mauritius, the Philippines, Thailand and Trinidad and Tobago. We had previously seen evidence of mercury-containing skin-lightening creams for sale and/or manufactured in Bangladesh, the Dominican Republic and the Philippines.^{8, 21, 22}

Based upon the labeling on the packages of the creams (which may not always be accurate), all high-mercury products found in this study appeared to originate in China, the Dominican Republic, Hong Kong, Jamaica, Malaysia, South Korea, Taiwan, Pakistan and the Philippines. According to the labeling, ten of the high-mercury samples were manufactured in Pakistan; six in China; three in Taiwan; three in Thailand; two in Hong Kong and one each in Malaysia, the Philippines, the Dominican Republic, Jamaica and South Korea. Six did not indicate the country of manufacture.

4 Conclusions and recommendations

Consistent with many other studies (see Annex F), our spot check sampling confirms the likelihood that a significant percentage of skin-lightening creams sold worldwide contain dangerous and often illegal levels of mercury. In light of the increasing demand and the large range of skin-lightening products available, more regulations, guidelines and programs are needed to curtail this global crisis, along with better enforcement and the use of effective risk communication strategies.

As a first step, of course, the 34 creams found to exceed the 1ppm mercury limit should immediately be removed from the market.

With the Minamata Convention's provisions on cosmetics soon to enter into force, a range of measures are emerging to end mercury use in these products, and to reduce the health risks of skin lighteners, including promising opportunities for collaboration between various levels of government and civil society:

- 1) Efforts to control often illegally imported cosmetics and track down manufacturers and distributors of high mercury containing cosmetics must be scaled up as sales increasingly shift to the informal economy or illegal markets. The Minamata Convention's ban on the manufacture, import and export of mercury-added skin-lightening products after 2020 will result in new national legislation and enforcement programs for many countries. Local ordinances can play an effective role in targeting specific venues of production and sales, raising awareness and promoting measures that can protect consumers. Comprehensive national legislation with a supportive enforcement mechanism is also critical and several governments, such as Singapore and local councils in the U.K. have made great strides in this area.^h Coordinated and enhanced enforcement by related government agencies, including those responsible for industry and commerce, quality and inspection of consumer goods, and health are necessary to effectively enforce these laws and regulations, as well as meeting international obligations under the Minamata Convention.
- 2) As most cosmetics are imported, reinforced border controls can help reduce the entry of hazardous products into the market, while identifying the responsible importers. Government officials, and especially customs officers, should be provided with the training and resources to monitor the national market and seize cosmetics that violate the Convention, as most may be imported. Several relatively simple and efficient screening technologies can be used to screen products for mercury. The X-ray fluorescence (XRF) spectrometer or analyzer, for example, is an affordable screening instrument already in use by many customs services and government authorities for carrying out compliance checks. This instrument can quickly and easily detect mercury as well as other metals in consumer goods.
- 3) According to a recent NGO study in Pakistan, the social pressures for acquiring a lighter complexion are often reinforced and amplified by television shows, advertisements and the internet. A majority of dermatologists interviewed stated that such programs and

^h For example, anyone convicted of marketing illegal health products in Singapore may be jailed for up to three years and/or fined up to \$100,000. HSA, Singapore's enforcement agency, conducts outreach through the media and takes enforcement action on an on-going basis. Singapore also engages with Operation Pangea, a global operation of 126 countries coordinated by Interpol, to disrupt the sale of illegal health products online by monitoring the internet infrastructure, electronic payments and delivery services.

advertisements should be banned.¹⁷ National guidelines for non-discriminatory advertising should be adopted and vigorously monitored in order to ensure that the media do “not reinforce negative social stereotyping on the basis of skin colour”, as stated in the guidelines adopted by the Advertising Standards Council of India (ASCI) in 2014.²³

- 4) Governments at all levels should develop continuously updated listings of illegal products, as well as contributing to a global listing, posted prominently on websites of UN agencies and Interpol, in coordination with the Minamata Convention Secretariat. With an increasingly global supply chain, and widespread sales over the internet, it is too easy for illegal products to be marketed. Such up-to-date postings would greatly assist regulators around the world, as well as civil society, to identify illegal products in the marketplace. These lists would provide specific information on unpermitted products, including (as available) such details as: the brand name of the product; a photo; information on where the product was purchased; the levels of mercury detected; and the regulatory agency that tested the product. These lists could serve multiple functions, including informing consumers, businesses, civil society and governments around the world about hazardous or illegal products, and requiring sellers to respect the list of banned products.
- 5) To discourage unregulated products from entering a country, all cosmetics should be labelled consistent with national regulations, which should require an accurate and complete list of the ingredients as well as current information on the manufacturer, including the address and country of production. Sellers should also provide documentation verifying that products meet all relevant regulations, and that all labeling is in a language comprehensible in the destination country.ⁱ
- 6) Retailers, including physical stores, e-shops and internet websites should be obliged to remove hazardous or illegal products from sale. To the extent possible, monitoring of the marketplace should be conducted to investigate and prevent the proliferation of hazardous or illegal domestic and cross-boundary trading practices. Our study revealed that cosmetics containing mercury are sold through a variety of pathways. Market surveillance should target especially internet sales and small stores that receive creams from certain countries or regions, and/or sell skin-lightening products to specific ethnic groups or immigrant communities.
- 7) Local ordinances could play an effective role in raising awareness and promoting measures that can protect consumers, while galvanizing and reinforcing collaboration between local, state, county and national authorities and be of interest globally via UN website links. For example, the environmental group EcoWaste is asking the Quezon City council in the Philippines to approve an ordinance to protect consumers from hazardous skin-lightening creams. The ordinance, supported by the Food and Drug Agency (FDA), would require strict compliance by business of cosmetics containing mercury more than the 1ppm limit established by the FDA and consistent with the Association of Southeast Nations (ASEAN) Cosmetic Directive.²⁴

ⁱ For example, cosmetics that have secured the required market authorization from the Philippines Food and Drug Authority (FDA) are presumed not to contain mercury above the threshold limit and are safer to use. According to the FDA, “notified cosmetic products have the following written in English: a) product name, b) ingredients, c) net content, d) instruction on the use of the products, e) batch number, f) special precautions if any, and g) country of manufacturer/importer”. Similarly, for a recent enforcement UK local council action, see: <https://www.asianimage.co.uk/news/16992052.trader-who-sold-illegal-cosmetics-on-ebay-is-sentenced-after-council-investigation/>

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- 8) There is a clear and ongoing need for more effective public outreach and communication concerning the risks of toxic cosmetics and consumer rights. While the deeply rooted practice of skin lightening will not change rapidly, mercury exposure from cosmetics poses serious health and environmental risks. Governments, health practitioners and community leaders should initiate culturally-appropriate campaigns about potential risks to people who use skin-lighteners. Research has confirmed that many consumers are not aware of the risks and that low income citizens are most likely to buy the products that are least expensive, which are often those that may be more hazardous. In particular, outreach efforts should target women and girls, who are still the largest user groups, as well as their families. Since these products are typically used indoors every day, they may easily contaminate the home environment and may pose a risk to young children and pregnant women.
- 9) Finally, civil society groups are well placed to identify suspect products in the marketplace, especially with the use of XRFs or similar screening tools and the benefit of continuously updated government detention lists of illegal and unpermitted skin-lightening creams.

Annex A: General methodology

The sampling and analysis methodologies build on earlier scientific work and practices, as well as relevant work by and experiences of civil society organizations. Skin-lightening cream sampling followed a common protocol, which was used by all participants. A Lumex RA 915+, as well as different XRF models were used for screening the collected samples for mercury content. Samples with more than 1 ppm of mercury were further analyzed according to standardized tests methods for more accurate mercury readings.

Sampling

In 2017, the NGO partners of Zero Mercury Working Group were asked to follow certain protocols with instructions for sampling and handling the creams prior to the analyses (see Annexes B and C-1). Step one was to identify popular brands of skin-lightening creams in the respective countries. Some of the NGOs already had a good understanding of the market and purchased the samples; others had to do a quick survey based on interviews with vendors in formal and informal markets, and/or students and employees at universities (see the protocol in Annex B). Creams that were not close to their expiration date were preferentially selected, and the ingredient list or user instructions were reviewed for indications of possible mercury content. The samples were stored in cool and dark places, away from living areas, before being shipped to the USA for the initial screening to determine their mercury content.

A total of 240 skin-lightening creams were collected by the participating NGOs in 19 countries in 2017 (Bangladesh (12); Barbados (1); Belgium (11); Dominican republic (3); Gabon (9); Ghana (15); Grenada (1); India (15); Côte d'Ivoire (17); Kenya (15); Mauritius (15); Nigeria (15); the Philippines (17); South Africa (10); Sri Lanka (17) Tanzania (22); Trinidad and Tobago (5); Uganda (14); and the USA (26)).

In 2018, the protocol for the second round of sampling was modified (see Annex C-2), since few creams with high mercury content were found in the 2017 spot checks focused on formal market purchases. Based upon our literature review, we suspected that high-mercury creams are more common in informal markets, so we also instructed NGOs to look for creams listed in government detention lists for high mercury content.

98 samples were collected in 9 countries in 2018, including those where creams with a mercury content of at least 1ppm were found in the first sampling round,^j including Bangladesh (20) and the Philippines (20). In addition, samples were collected from India (8), Indonesia (13), Kenya (9), Nepal (10), Nigeria (10), and Thailand (7).

Sample preparation and determination of mercury content

Samples from the first sampling round were shipped between February and July 2017 to Biodiversity Research Institute (BRI) in Portland, Maine, USA.

To avoid internal mercury contamination of BRI's analysis instrument, a Milestone DMA 80, all creams were first screened to identify products with very high mercury levels. This was done using a portable mercury analyzer Lumex RA 915, 2004 model, or Jerome J405, or a Niton XRF-model XL3t by Thermofisher. It was determined by BRI that only 12 creams were not able to be analyzed using the DMA 80.

^j Although high mercury creams were found in 2017 in Mauritius, Dominican Republic and Trinidad and Tobago, these countries were not included in the 2018 sampling round for technical reasons.

The samples were analyzed for total mercury using the direct combustion/trapping atomic absorption (AA) method on a Milestone DMA 80. This approach has been incorporated by the U.S. Environmental Protection Agency (EPA) in the EPA Method 7473. A blank and two calibration standards (CE-464 and DOLT-5) were used for calibration, one for each of the two detector cells. The instrument response was evaluated immediately following calibration, and thereafter following every 10 samples, and at the end of each analytical run by analyzing two certified reference materials and a control blank. Mercury concentrations are expressed in ppm per wet weight.

10 high-mercury products were sent to the accredited USA-based lab Enthalpy Analytical for accurate mercury determinations. Analyses were carried out using Cold Method Atomic Spectroscopy. The samples were prepared, diluted, and analyzed according to the EPA 7471A standard for metals.^k The dilution takes place after the acid digestion of the samples and is done with a 5% solution of HNO₃.

The 2018 collected samples were screened with XRFs, in a timely and cost effective manner. An XRF Innov-X Delta Professional DS 2000 was used to screen the samples from India, Indonesia and the Philippines. The measurement of mercury in skin-lightening cream was done using the consumer product mode of the instrument. Each sample was tested three times, for 30 seconds, and the average of the three readings calculated. The Limit of Detection (LOD) was 1-2ppm (see annex D).

The 2018 samples from Bangladesh, India, Kenya, Nigeria, and Nepal were screened using a Niton XL 3t-970 GOLDD+ Analyser. The sample preparation was done with sample cup using a film of polypropylene (TF 240 255). The sample cups were filled to about 2 cm depth. The diameter of the cup was 3 cm, but the window of analysis was 8 mm. Depending on their consistency, the creams were stirred with a plastic spoon or shaken. After the cream was placed in the cup, the cup was tapped gently to ensure the cream was evenly distributed. The analytical mode used was "cosmetics, semi-solid" (which uses a combination of the algorithm of the soil and plastic mode). Time of analysis was 60 seconds and each sample was read once. The Limit of Detection (LOD) was 5ppm (see annex E).

The above screening indicated that 4 samples from the Philippines, 4 from Indonesia and 10 samples from Bangladesh contained high levels of mercury. These were then sent for further analysis to the accredited laboratory Quality Assurance & Control Systems (QACS lab) in Greece. Analyses were carried out using Hydride Atomic Absorption Spectroscopy, and the samples were prepared, diluted and analyzed according to the standard ACM THA 05.^l (Annex L provides further detail on the procedures).

^k EPA 7471A standard (<https://www.epa.gov/sites/production/files/2015-07/documents/epa-7471b.pdf>).

^l ACM THA 05(<https://www.asean.org/storage/images/archive/MRA-Cosmetic/Doc-3.pdf>)

Annex B: Brand survey instructions



Brand survey for skin-lightening creams

Purpose

This questionnaire should facilitate a quick mapping of the most popular brands of skin-lightening creams in your national market.

Questions to vendors/shop owners in the formal market

Ask in at least 10 shops in the same town/city.

1. Which brands of skin-lightening-creams are top ten sellers?

Take note of the country of origin of the product, if this information is available.

Questions to vendors/shop owners in the informal market

Ask in at least 10 shops in the same town/city.

1. Which brands of skin-lightening-creams are top ten sellers?

Take note of the country of origin of the product, if this information is available.

Questions to users of skin-lightening products

Ask at least 20 college/university students/employees.

1. Which brands of skin-lightening creams are the top 5 most popular among your friends and relatives?
2. Where is the respective product usually bought – from the informal market, e.g. from street hawkers, or from the formal market?

Timeframe

The survey is expected to be completed for the next work group call the week starting with June the 5th.

Log matrixes

See the appendix 1 (for vendors/shop owners) and 2 (and students/employees)

Appendix 1: Log matrix for information from vendors/shop owners

- Log the source of information.
- Log the brand name.
- Log the origin of the product (domestic or imported). This information can be filled in when you buy the product and can check the country of origin.
- Log in which market (formal or informal) that the product is sold. If it is sold in both markets, write "both" in the matrix.

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Source of information	Brand	Domestic or imported product?	Formal or informal market setting?
Vendors/shop owners			Formal
Vendors/shop owners			Formal
Vendors/shop owners			Formal

Appendix 2: Log matrix for information from students/employees

- Log the source of information.
- Log the brand name.
- Log the origin of the product (domestic or imported). This information can be filled in when you buy the product and can check the country of origin.
- Log in which market (formal or informal) that the product is sold. If it is sold in both markets, write "both" in the matrix.

Student/employee 1	Brand	Domestic or imported product?	Formal or informal market setting?
Student/employee 2	Brand	Domestic or imported product?	Formal or informal market setting?

Repeat box as relevant

Annex C: Sampling instructions

Annex C-1: 2017 sampling instructions



Instructions for sampling of skin-lightening creams (2017)

Each organization participating in this ZMWG study buys up to 15 skin-lightening creams, to be sent to Biodiversity Research Institute (BRI) (<http://www.briloon.org/>) for analysis of their mercury content. Please carefully read and follow the below instructions for selecting, handling, packaging and shipping the products.

Criteria for selecting the brands:

- 1) Do the brand survey based on the instructions in the distributed questionnaire, if you feel that this step is necessary. The purpose of the survey is to find out the top ten most popular skin-lightening cream brands in your respective countries. The questionnaire contains three target groups for the questions: vendors/shop owners in the formal market, vendors/shop owners in the informal market, and college/university students/staff. In case you already feel confident that you know which brands are popular, or can find out directly in connection with the purchase of the products, you can skip the brand survey. Preferably select branded products, which could indicate larger manufacturing volumes. In low-income settings in Africa, e.g., it is common that single individuals manufacture and sell cosmetic products. Do not buy the latter kind of products. The markets where you most commonly find skin-lightening products may differ between countries. In many countries they are mainly found in informal market settings, but it cannot be ruled out that mercury containing creams are also found in formal markets. The survey will help you decide, unless you already know based on experience.
- 2) Select creams that are not too close to their expiration dates, providing that the date is printed on the package. Old products exposed to heat may potentially have lost mercury.

Criteria for selecting the brands: ingredient lists

- 3) Check if there is an ingredient list on the package. If so, look for the following kinds of ingredients that are the most common mercury compounds used for skin lightening:
 - **Mercury (I) chloride** (also called **calomel**, or mercuric chloride (I)) (with the chemical formula Hg_2Cl_2)
 - **Mercury (II) chloride** (also called mercuric chloride (II)) (with the chemical formula HgCl_2)
 - **Mercury (I) iodide** (also called **red mercury**, or mercuric iodide (I)) (with the chemical formula Hg_2I_2)
 - **Mercury (II) iodide** (also called **red mercury**, or mercury diiodide, or mercuric iodide (II)) (with the chemical formula HgI_2)
 - **Mercury (I) oxide** (also called mercuric oxide (I)) or hydragyri oxydum rubrum (with the chemical formula Hg_2O)
 - **Mercury (II) oxide** (also called mercuric oxide (II)) or hydragyri oxydum rubrum (with the chemical formula HgO)

- **Mercuric amidochloride** (also called ammoniated mercury) (with the chemical formula HgNH_2Cl)

The following organic mercury compounds are used as preservatives in cosmetics, and probably not for bleaching, but are listed here, in case you anyway would find them in the ingredient lists:

- **Thiomersal** (also known under the brand name **Merthiolate**, or Ethyl(2-mercaptobenzoato-(2-)-O,S) mercurate(1-) sodium, or Mercury((o-carboxyphenyl)thio)ethyl sodium salt)
- **Phenylmercury acetate** (also called Phenylmercurio acetate)
- **Mercury (II) acetate** (also called mercuric acetate, or mercuriacetate) (with the chemical formula $\text{Hg}(\text{O}_2\text{CCH}_3)_2$)

Any other compound with the name "mercury" in it and not listed here but in the ingredient lists should of course also catch your attention.

Furthermore, directions to avoid contact with silver, gold, aluminum, jewelry, and rubber, may also indicate the presence of mercury.

Companies that sell products containing mercury, do not always list it as an ingredient. In a study from South Africa in 2012, it was found that nearly half of the skin-lightening products examined contained mercury but had no indication of that on the package.^m Furthermore, studies have shown that active bleaching ingredients are often combined in a product. E.g., according to another South African study, combinations of ultrapotent steroids, hydroquinone and mercury are common.ⁿ Since hydroquinone is still permitted as a skin-lightening agent in many countries, it cannot be ruled out that products with hydroquinone listed as an ingredient on the product packages also contain unlisted mercury, as the latter is banned in cosmetics in concentrations exceeding 1ppm in a number of countries.

Handling and storing of the purchased products

- 4) Log the name of the product, the producer, if there is any indication of possible mercury content (e.g. from the ingredient list), the place where you bought the product (i.e. note the name of the store and address), and take photos of the product and its ingredient list (if it has a list). Please use the format of the matrix in the appendix 1 for logging the information.
- 5) Do not store the purchased products in hot conditions, as this may enhance breakdown of some mercury compounds, with subsequent loss of the mercury. Try to find the coolest place in the house, but do not store the product near food, e.g. in the fridge.
- 6) Do not remove the package materials around the products. Do not open the tube/box. They need to be delivered intact to BRI.

Legal requirements and marketing of skin-lightening products

- 7) Also review if there is a legal requirement in your country:
 - a. to regulate the use, manufacture, import and export of such cosmetics.
 - b. to have ingredient lists on cosmetics and personal hygiene products, and how the requirement is formulated.

^m Dlova, N.C., Hendricks, N.D., Martincgh, B.S., 2012. Skin-lightening creams used in Durban, South Africa. *International Journal of Dermatology* 51, 51-53.

ⁿ Maneli, M.H., Wiesner, L., Tinguely, C., Davids, L.M., Spengane, Z., Smith, P., van Wyk, J.C., Jardine, A., Khumalo, N.P., 2016. Combinations of potent topical steroids, mercury and hydroquinone are common in internationally manufactured skin-lightening products: a spectroscopic study. *Clinical and Experimental Dermatology* 41, 196-201.

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- c. If your country already has banned skin-lightening products with 1ppm mercury or more.
- 8) Document commercials for skin-lightening products in your country, e.g. take photos, record radio jingles, advertisements in newspapers, etc. What kind of message do they convey, and who are the target groups?

Please use the format of the matrix in the appendix 2 for logging the information on legal requirements and marketing on skin-lightening products.

Send the information about legal requirements Andreas Prevodnik no later than June 15th.

Commercials (point 8) should ideally be documented continuously throughout the 4 year project period, and we can decide later on how often you report this information back to the working group, and how this information can be posted on the ZMWG web page.

Appendix 1: Matrix for logging the skin-lightening cream samples

- Log the brand name.
- Log the date of expiration. If not on the package, put a minus sign in the matrix.
- Log the country of origin of the product. If unknown, put a minus sign in the matrix.
- Indicate if there is any indication that the product contains mercury. Log "ingred list" if it is from the ingredient list, log "instr" if it is from other instructions on the package, e.g. that the product should not be in touch with gold, silver or rubber, or log "oral acc." if it is from oral account.
- Log the name of the shop and the address. If the product was bought by a street hawker, log "hawker".
- Log if you have taken a photo of the product with an X.
- Log if you have taken a photo of the ingredient list with an X.

Brand name	Date of expiration	Country of origin	Indication of mercury content	Shop name and address	Photo of the product taken	Photo of the ingredient list taken

Please send the completed log and photos in an e mail with the topic "Log and photos, skin-lightening cream project" to: andreas.prevodnik@ssnc.se

Appendix 2: Matrix for logging laws and regulation governing use, manufacture and export of skin-lightening cosmetics

- Log the number or name of the law/regulation governing use, manufacture, import and export of skin-lightening cosmetics in your country.
- Log the main requirements of the law/regulation in question.
- Log the number or name of the law/regulation governing listing of ingredients of cosmetics and personal hygiene products in your country.
- Log the main requirements of the law/regulation in question.
- Log "yes" or "no" with respect to a law banning mercury in concentrations of 1ppm or more in cosmetics and personal hygiene products.

Law/regulation number or name of law governing use, manufacture, import and export of skin-lightening cosmetics	Main requirements stipulated in the law /regulation	Law/regulation for the ingredient list for cosmetics and personal hygiene products	Main requirements stipulated in the law/ regulation	A law already banning mercury in concentrations of 1ppm or more in cosmetics

Please send the completed log with the topic "Log and photos, skin-lightening cream project" to: andreas.prevodnik@ssnc.se

Annex C-2: 2018 sampling instructions



Instructions for sampling of skin-lightening creams (2018)

Building upon our earlier sampling protocol, this second round of sampling of skin-lightening creams will primarily focus on further targeting skin-lightening creams suspected of containing high mercury levels from our NGO campaign partners, and in particular from the following countries:

- Bangladesh
- Mauritius
- the Philippines
- Caribbean islands, mainly Dominican Republic and Trinidad Tobago

We wish to have an additional 20 samples per identified country. This means:

- 20 additional samples from Bangladesh
- 20 additional samples from Mauritius
- 20 additional samples from Philippines
- If possible (as relevant after discussion with BRI), 20 additional samples from Dominican Republic, and 20 from Trinidad Tobago

For all other than the above countries

In case of indication or suspicion of mercury content in skin-lightening creams from other than the above countries, additional creams can be bought and send to regional testing hubs. Indication or suspicion could be:

- brand name previously associated with high mercury levels (see attached appendix 2)
- listing in product alerts/detention lists (see attached appendix 3)
- country of origin previously associated with high mercury content i.e. Caribbean islands (appendix 1), Pakistan, China, etc..
- indications from ingredient lists (see below)

The samples are to be sent to our regional testing hubs for Africa at CASE, in Côte d'Ivoire, for Asia, at Ban Toxics in the Philippines, and for the Americas, at the Biodiversity Research Institute (BRI) in the USA, for screening of mercury content, based upon XRF or Lumex readings. Creams with concentrations equaling or exceeding 1 part per million (PPM) will be sent to an accredited lab for confirmatory analyses.

Please carefully read and follow the below instructions for selecting, handling, packaging and shipping the products.

Criteria for selecting the brands:

- 9) Look for and buy the (generally inexpensive) creams in **informal market settings**.
- 10) Check the **country of origin** on the box, and/or the **brand name** and/or look for specific products previously listed in product alerts/detention lists as not in compliance with national laws as relevant (see Annex 2)

- a) In the Caribbean, buy popular skin-lightening cream brands from this geographical region (see Appendix 1), or look for specific Caribbean products previously listed in product alerts/detention lists as not in compliance with national laws.
 - b) In Mauritius and Bangladesh, look for brands from Pakistan.
 - c) In other countries, check for brands in which high mercury levels were detected in the first sampling round (appendix 2). Or creams from the detention list in Appendix 3
- 11) Select creams that are not too close to their expiration dates, providing that the date is printed on the package. Old products exposed to heat may potentially have lost mercury.

Criteria for selecting the brands: ingredient lists

- 12) Check if there is an **ingredient list** on the package. If so, look for the following kinds of ingredients that are the most common mercury compounds used for skin lightening:

- **Mercury (I) chloride** (also called **calomel**, or mercuric chloride (I)) (with the chemical formula Hg_2Cl_2)
- **Mercury (II) chloride** (also called mercuric chloride (II)) (with the chemical formula $HgCl_2$)
- **Mercury (I) iodide** (also called **red mercury**, or mercuric iodide (I)) (with the chemical formula Hg_2I_2)
- **Mercury (II) iodide** (also called **red mercury**, or mercury diiodide, or mercuric iodide (II)) (with the chemical formula HgI_2)
- **Mercury (I) oxide** (also called mercuric oxide (I)) or hydragyri oxydum rubrum (with the chemical formula Hg_2O)
- **Mercury (II) oxide** (also called mercuric oxide (II)) or hydragyri oxydum rubrum (with the chemical formula HgO)
- **Mercuric amidochloride** (also called ammoniated mercury) (with the chemical formula $HgNH_2Cl$)

The following organic mercury compounds are used as preservatives in cosmetics, and probably not for bleaching, but are listed here, in case you anyway would find them in the ingredient lists:

- **Thiomersal** (also known under the brand name **Merthiolate**, or Ethyl(2-mercaptobenzoato-(2-)-O,S) mercurate(1-) sodium, or Mercury((o-carboxyphenyl)thio)ethyl sodium salt)
- **Phenylmercury acetate** (also called Phenylmercurio acetate)
- **Mercury (II) acetate** (also called mercuric acetate, or mercuriacetate) (with the chemical formula $Hg(O_2CCH_3)_2$)

Any other compound with the name "mercury" in it and not listed here but in the ingredient lists should of course also catch your attention.

Furthermore, directions to avoid contact with silver, gold, aluminum, jewelry, and rubber, may also indicate the presence of mercury.

Please keep in mind that producers that sell products containing mercury do not always list mercury as an ingredient. In a study from South Africa in 2012, it was found that nearly half of the skin-lightening products examined contained mercury but had no indication of that on the package.⁹ Furthermore, studies have shown that active bleaching ingredients are often combined in a product. E.g., according to another South African study, combinations of

⁹ Dlova, N.C., Hendricks, N.D., Martincgh, B.S., 2012. Skin-lightening creams used in Durban, South Africa. International Journal of Dermatology 51, 51-53.

ultrapotent steroids, hydroquinone and mercury are common.^P Since hydroquinone is still permitted as a skin-lightening agent in many countries, it cannot be ruled out that products with hydroquinone listed as an ingredient on the product packages also contain unlisted mercury, as the latter is banned in cosmetics in concentrations exceeding 1ppm in a number of countries.

Handling and storing of the purchased products, instructions to sampling organizations and to the regional testing hubs

- 1) Do not store the purchased products in hot conditions, as this may enhance breakdown of some mercury compounds, with subsequent loss of the mercury. Try to find the coolest secure place outside the house or office, or if not possible find a secure place inside but do not store the product near food, e.g. in the fridge.
- 2) Do not remove the package materials around the products. Do not open the tube/box. They need to be delivered intact to the regional testing hubs.
- 3) Log the name of the product, the producer, if there is any indication of possible mercury content (e.g. from the ingredient list), the place where you bought the product (i.e. note the name of the store and address), and take photos of the product and its ingredient list (if it has a list). Please use the format of the matrix in the appendix 4 for logging the information.

Legal requirements and marketing of skin-lightening products

- 4) Also review if there is a legal requirement in your country and log them in appendix 5:
 - a. to regulate the use, manufacture, import and export of such cosmetics.
 - b. to have ingredient lists on cosmetics and personal hygiene products, and how the requirement is formulated.
 - c. If your country already has banned skin-lightening products with 1ppm mercury or more.

Please send the products to your regional hub, as below:

For Asia:

Ban Toxics

To be updated

For Africa

CASE

To be updated

If you have general questions on the study and sampling, as well as information about legal requirements, please e mail:

Andreas Prevodnik, Swedish Society for Nature Conservation

e-mail : andreas.prevodnik@ssnc.se

Telephone: +46 8 702 65 33

If you have specific questions about delivering the samples, please contact:

^P Maneli, M.H., Wiesner, L-, Tinguely, C., Davids, L.M., Spengane, Z., Smith, P., van Wyk, J.C., Jardine, A., Khumalo, N.P., 2016. Combinations of potent topical steroids, mercury and hydroquinone are common in internationally manufactured skin-lightening products: a spectroscopic study. *Clinical and Experimental Dermatology* 41, 196-201.

Michael Bender, ZMWG

Email: mercurypolicy@aol.com

Telephone: +1 802 223-9000

Appendix 1: Caribbean countries

Anguilla	Grenada	Saint Barthelemy
Antigua and Barbuda	Guadeloupe	Saint Kitts & Nevis
Aruba	Haiti	Saint Lucia
Bahamas	Jamaica	Saint Martin
Barbados	Martinique	Saint Vincent
British Virgin Islands	Montserrat	Trinidad & Tobago
Cayman Islands	Netherlands Antilles (Aruba, Bonaire, Curacao)	Turks & Caicos Islands
Cuba	Puerto Rico (Unincorporated territory of USA)	US Virgin Islands
Dominica		
Dominican Republic		

Appendix 2: Brands in which high mercury levels were detected in the first sampling round

Crema Blanqueadora Whitening Cream Lisso by Laboratorios LISSO, S.R.L., from the Dominican Republic;

Chandni Whitening Cream by SJ Enterprises from Pakistan;

New Face

Glutathione Grapeseed extract whitening/anti-aging night by Geml from Hong Kong;

Jiaoli miraculous day cream from China,

Jiaoli miraculous night cream from China; and

Non-Oily Deluxe Silken Bleaching Cream from Jamaica.

Appendix 3: FDA Import Detention for Skin Creams 5/25/16

Sources: https://www.accessdata.fda.gov/cms_ia/importalert_137.html, and main link that brought me here: https://www.accessdata.fda.gov/cms_ia/industry_53.html

Import Alert 53-18

(Note: This import alert represents the Agency's current guidance to FDA field personnel regarding the manufacturer(s) and/or products(s) at issue. It does not create or confer any rights for or on any person, and does not operate to bind FDA or the public).

Import Alert # 53-18

Published Date: 05/25/2016

Type: DWPE

Import Alert Name:

"Detention Without Physical Examination of Skin Whitening Creams Containing Mercury"

Reason for Alert:

The toxicity of mercury compounds has been extensively documented. In accordance with 21 CFR 700.13 (FR, Vol. 38 No. 3, January 5, 1973, pgs. 853-854), effective July 5, 1973, except for those cosmetics meeting the conditions of 21 CFR 700.13(d)(2)(i) or (d)(2)(ii), any cosmetic product containing mercury as an ingredient is deemed adulterated and subject to regulatory action.

Analysis performed by CFSAN's Color Technology Branch found a skin cream, Manning Beauty Cream, to contain approximately 8% mercury by weight. In addition, the product is labeled to contain calomel, a form of mercury known as mercurous chloride. Additional creams from other firms have also been labeled as containing mercury compounds.

Guidance:

Districts may detain, without physical sampling and analysis, shipments of products from firms and products identified in the Red List.

For questions or issues concerning science, Science policy, sample collection, analysis, preparation, or analytical methodology, contact the Division of Field Science at 301 796-6600.

All requests for removal from detention without physical examination should be address to DIOP 301-796-0356.

Product Description:

Skin Whitening Creams

Charge:

"The article is subject to refusal of admission pursuant Section 801(a)(3) in that it appears to contain mercury, a poisonous and deleterious substance, which may render it injurious to users under the conditions of use prescribed in its' labeling or under such conditions of use as are customary or usual [Adulteration, Section 601(a)]."

OASIS charge code - POISONOUS

**List of firms and their products subject to Detention without Physical Examination (DWPE)
under this Import Alert (a.k.a. Red List)**

DOMINICAN REPUBLIC

Laboratorios Contifarma, C. por A.
Date Published : 09/18/2009

Santo Domingo , D.N. , Dominican Republic, DOMINICAN REPUBLIC
53 L - - - Skin Care Prep
Date Published: 09/18/2009

Desc:Santa Cream (
Problems: MERCURY;
53 Y - - - Cosmetics and Cosmetic Products,n.e.c.
Date Published: 09/18/2009

Desc:Santa Cream (
Problems: MERCURY;
66 V - - - Patent Medicines, Etc
Date Published: 09/18/2009

Desc:Santa Cream
Problems: MERCURY;

Laboratorios Key C Por A
Date Published : 09/18/2009

Calle Central No. 3 , Zona Industrial de Herrera , Santo Domingo, DOMINICAN REPUBLIC
53 L - - - Skin Care Prep
Date Published: 09/18/2009

Desc:Miss Key Whitening Cream
Problems: MERCURY;
53 Y - - - Cosmetics and Cosmetic Products,n.e.c.
Date Published: 09/18/2009

Desc:Miss Key Whitening Cream
Problems: MERCURY;
66 V - - - Patent Medicines, Etc
Date Published: 09/18/2009

Desc:Miss Key Whitening Cream; Crema Bianqueadora Miss Key; 7/21/03
Problems: MERCURY;

Leivon Cosmetics, Inc. Division Laboratorios Contifarma
Date Published : 09/18/2009

Unknown , Santo Domingo, DOMINICAN REPUBLIC

November 2018

53 L - - - Skin Care Prep
Date Published: 09/18/2009

Desc:Dermaline Cream; 7/21/03
Problems: MERCURY;
53 Y - - - Cosmetics and Cosmetic Products,n.e.c.
Date Published: 09/18/2009

Desc:Dermaline Cream; 7/21/03
Problems: MERCURY;
66 V - - - Patent Medicines, Etc
Date Published: 09/18/2009

Desc:Dermaline Cream; 7/21/03
Problems: MERCURY;

LEBANON

Ets Diana De Beaute
Date Published : 11/08/2011

P.o. Box 11-7599 , Riad El Solh , Beirut, LEBANON
53 L - - 99 Other Skin Care Preparations, N.E.C.
Date Published: 11/08/2011

Desc:Crema Diana/Eliminates Freckles

MEXICO

Aguaruto Cosmetics/Gloria Maricela Castro
Date Published : 11/01/2011

Josefa Ortiz de Dominguez 126 Oriente , Colonia Tierra Blanca , Culiacan, MEXICO
53 L - - - Skin Care Prep
Date Published: 11/01/2011

Desc:Crema Aquamary
Notes:Mexico
53 Y - - - Cosmetics and Cosmetic Products,n.e.c.
Date Published: 11/01/2011

Desc:Crema Aquamary
Notes:Mexico
66 V - - - Patent Medicines, Etc
Date Published: 11/01/2011

Desc:Crema Aquamary
Notes:Mexico

November 2018

Laboratories Vido Natural S.A de C.V.

Date Published : 09/18/2009

Unknown , Tampico, Tamaulipas MEXICO

53 L - - - Skin Care Prep

Date Published: 08/06/2010

Desc:Manning Beauty Cream/Manning Cream de Belleza

Notes:DWPE date - 7/22/1996

Problems: MERCURY;

Viansilk

Date Published : 05/25/2016

Maria 153, Residencias , Mexicali, Baja, California , Baja, MEXICO

53 J - - 99 Other Personal Cleanliness Products (not Antiperspirant), N.E.C.

Date Published: 05/25/2016

Desc:Viansilk Skin Cream (Viansilk Crema Piel de Seda)

Problems: MERCURY;

53 L - - 01 Cleansing (Cold Creams, Cleansing Lotions, Liquids, Pads) (Skin Care Preparations)

Date Published: 05/25/2016

Desc:Viansilk Skin Cream (Viansilk Crema Piel de Seda)

Problems: MERCURY;

53 L - - 06 Moisturizing (Skin Care Preparations)

Date Published: 05/25/2016

Desc:Viansilk Skin Cream (Viansilk Crema Piel de Seda)

Problems: MERCURY;

53 L - - 10 Wrinkle Smoothing (Skin Care Preparations)

Date Published: 05/25/2016

Desc:Viansilk Skin Cream (Viansilk Crema Piel de Seda)

Problems: MERCURY;

53 L - - 99 Other Skin Care Preparations, N.E.C.

Date Published: 05/25/2016

Desc:Viansilk Skin Cream (Viansilk Crema Piel de Seda)

Problems: MERCURY;

53 Y - - 99 Other Cosmetic and Cosmetic Products, N.E.C.

Date Published: 05/25/2016

Desc:Viansilk Skin Cream (Viansilk Crema Piel de Seda)

Problems: MERCURY;

53 - - - - Cosmetics

Date Published: 05/25/2016

Desc:Viansilk Skin Cream (Viansilk Crema Piel de Seda)

Problems: MERCURY;

63 V - - 99 Depigmentor N.E.C.

Date Published: 05/25/2016

Desc: Viansilk Skin Cream (Viansilk Crema Piel de Seda)

Problems: MERCURY;

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Appendix 4: Matrix for logging the skin-lightening cream samples

- Log the brand name.
- Log the date of expiration. If not on the package, put a minus sign in the matrix.
- Log the country of origin of the product. If unknown, put a minus sign in the matrix.
- Indicate if there is any indication that the product contains mercury. Log "ingred list" if it is from the ingredient list, log "instr" if it is from other instructions on the package, e.g. that the product should not be in touch with gold, silver or rubber, or log "oral acc." if it is from oral account.
- Log the name of the shop and the address. If the product was bought by a street hawker, log "hawker".
- Log if you have taken a photo of the product with an X.
- Log if you have taken a photo of the ingredient list with an X.

Brand name	Date of expiration	Country of origin	Indication of mercury content	Shop name and address	Photo of the product taken	Photo of the ingredient list taken

Please send the completed log and photos in an e mail with the topic "Log and photos, skin-lightening cream project" to: andreas.prevodnik@ssnc.se

Appendix 5: Matrix for logging laws and regulations

- Log the number or name of the law/regulation governing use, manufacture, import and export of skin-lightening cosmetics in your country.
- Log the main requirements of the law/regulation in question.
- Log the number or name of the law/regulation governing listing of ingredients of cosmetics and personal hygiene products in your country.
- Log the main requirements of the law/regulation in question.
- Log "yes" or "no" with respect to a law banning mercury in concentrations of 1ppm or more in cosmetics and personal hygiene products.

November 2018

Law/regulation number or name of law governing use, manufacture, import and export of skin-lightening cosmetics	Main requirements stipulated in the law/regulation	Law/regulation for the ingredient list for cosmetics and personal hygiene products	Main requirements stipulated in the law/regulation	A law already banning mercury in concentrations of 1ppm or more in cosmetics

Please send the completed log with the topic "Log and photos, skin-lightening cream project" to:
andreas.prevodnik@ssnc.se

Annex D: Sampling protocol for the Innov-X Delta Professional DS 2000 XRF

The materials for the analysis of samples include the sample sheets (thin transparent plastics, either mylar or polypropylene), a ruler used to measure the depth and diameter of the creams, plastic spoons used as spreader of the creams on the sheet, gloves, and Innov-X Delta Professional DS 2000: Handheld XRF Analyzer which is set in consumer product mode.

The thin-film method was used in the sample preparation of skin whitening creams, as it is a standard operating procedure for XRF screening of mercury in skin creams.²⁵ With this method the gap between the sample and the sensor of the XRF analyzer, which might affect the X-ray penetration, is avoided. In this method, an amount of cream is spread onto the sample sheet using the spoon, so that the cream becomes a circle of at least 3 cm in diameter and the depth of the cream should be at least 0.3 mm. The skin-lightening creams subjected to this method are either (1) observed to be at a lower level of its container, approximately at least 0.5mm from the opening of the container, (2) contained in a plastic tube, or (3) contained in a cream jar with opening diameter less than 4 cm.

The measurement of mercury in skin-lightening cream was done using the “consumer product” mode of the instrument. Each sample was tested three times, for 30 seconds, and the average of the three readings calculated.

Annex E: Sampling protocol for the Niton XL3t-970 GOLDD+ Analyzer SDD XRF

1. **Type of instrument:** Niton XL3t-970 GOLDD+ Analyzer SDD XRF
2. **Preparation of analysis**
 - a. The sample preparation was done with sample cup with a film of polypropylene (TF 240 255).
 - b. The sample cups were filled in half, to about 2 cm depth. The diameter of the cup was 3 cm, but window of analysis 8 mm.
 - c. The creams depending on their consistency were steered with a plastic spoon or shaken.
 - d. While placed in the cup, the cup was tapped gently to ensure the cream is evenly distributed.
3. **Analysis**
 - a. The mode used is cosmetics, semi solid (which uses a combination of the algorithm of the soil and plastic mode)
 - b. Time of analysis was 60 seconds and each sample was read once.



Annex F: Published surveys of skin-lightening products

Surveys of skin-lightening products, reference, location, number and share [%] of products with a mercury concentration of ≥ 1 ppm, and the range of detected mercury concentrations [ppm].

Reference	Location	Hg ≥ 1 ppm /total sample	Mercury content [ppm]
Maneli <i>et al.</i> (2016) ²⁶	South Africa	12/29 (41.4%)	30-2,300
SDPI (2016) ¹⁷	Pakistan	12/20 (60.0%)	2.04-26 500
Murphy <i>et al.</i> (2015) ²⁷	Cambodia	13/60 (21.7%)	2,022-6,305
EcoWaste Coalition (2015) ²⁸	Philippines	316/355 (89.0%)	Not available
Hamann <i>et al.</i> (2014) ²²	USA, China, Taiwan, Thailand, Japan, Sri Lanka	33/549 (6.0% contained ≥ 1000 ppm)	$\geq 1,000$ -45 622
Travasso (2014) ²⁹	India	14/32 (43.8%)	0.1-1.97
Adawe and Oberg (2013) ³⁰	USA	11/27 (40.7%)	1.07-33,000
Alquadami <i>et al.</i> (2013) ³¹	Saudi Arabia	22/34 (64,7%)	1.29-2,745
CEJ (2013) ³²	Sri Lanka	16/25 (64%)	1.10-30,267.7
ESDO (2012) ²¹	Bangladesh	12/12 (100.0%)	3,361-4,643
Mortality and Morbidity Weekly Report (2012) ³³	USA	11/12 (91.6%)	2,000-5,700
Peregrino <i>et al.</i> (2011) ³⁴	Mexico	6/16 (16.7%)	878-35,824
Al-Saleh <i>et al.</i> (2011) ³⁵	Saudi-Arabia	2/23 (8.7%)	95.75 and 314.4
McKelvey <i>et al.</i> (2011) ³⁶	USA	8/17 (47.1%)	3.37-41,600
Al-Ashban <i>et al.</i> (2006) ³⁷	Saudi-Arabia	30/88 (34.1%)	2.46-23,222
EARTH (2012) ³⁸	Thailand	10/47(21.3%)	63.53-99,070
Al-Saleh and Al-Doush (1997) ³⁹	Saudi-Arabia	17/38 (45.0%)	1.18-5,650

Annex G: Regulation and legislation

Regulatory issues

Of the 22 countries where sampling took place, 15 already have legislation or other requirements meeting the Minamata convention provisions. Of the 7 countries where high mercury samples were found, 4 have legal or other requirements prohibiting creams with more than 1ppm mercury content.

Furthermore over 50% of the countries sampled, appear to have requirements for labeling of ingredients.

With regard to the countries where skin-lightening creams with excessive levels of mercury were purchased, the following observations are made:

- Bangladesh, Indonesia and the Philippines have measures aligned with the Minamata Convention provisions for cosmetics, but skin-lightening creams with more than 1ppm mercury are still found in their markets.
- Bangladesh has no legislation requiring ingredients to be listed, but it does have relevant guidelines.
- Indonesia and the Philippines have legislation requiring ingredients to be listed, yet mercury was not mentioned among the ingredients for the skin creams that were tested and found to contain excessive mercury.
- The Dominican Republic has no specific regulation for mercury in cosmetics, but it does require ingredients to be listed. However, mercury or mercury compounds were not listed among the ingredients on the high mercury cream tested.
- Mauritius, where high-mercury samples were also found, has no legislation dealing with the contents of cosmetics.
- No legislation or regulations dealing with the contents of cosmetics were identified in Trinidad and Tobago, where high-mercury creams were also purchased.
- Thailand appears to have relevant legislation prohibiting the manufacture, import and sale of cosmetics that are not safe to use, respecting the Minamata requirements. Labeling of ingredients is also required for cosmetics. Nevertheless, high mercury products were found in the marketplace.

Our research demonstrates that hazardous substance restrictions in many countries are incomplete and/or inadequately enforced, thereby raising the risk of health effects, primarily to women, from toxic levels of mercury as well as other hazardous substances in cosmetics.

Even though the Minamata Convention provisions for cosmetics have already been integrated into the national legislation of Bangladesh, Indonesia, the Philippines and Thailand, the follow-up and enforcement appear to be insufficient, as skin-lightening creams containing more than 1ppm mercury are still on the market in these countries.

Enforcement efforts must improve, for example, by enabling the customs services to do more compliance checks of imported goods, and the producers and suppliers of skin-lightening creams with excessive mercury should be identified and brought into compliance. This requires training of staff involved in the enforcement work, and access to good screening equipment such as an XRF.

Despite the requirements of many countries to list active ingredients, mercury was not listed as an ingredient in any of the creams sampled.

As a result, for cosmetics there should be mandatory ingredient lists that are periodically controlled or certified. Publicly available detention lists for products that don't meet national standards may further discourage suppliers and producers of mercury containing skin-lightening cosmetics.

It should be noted, however, that in some countries where skin-lightening creams with mercury content above 1ppm are banned, no creams in our samples were found to exceed these requirements. It would be useful to examine whether enforcement practices or other measures in effect in these countries may be responsible for this high level of compliance.

For example, in Kenya there is strict surveillance by the Kenya Bureau of Standards (KBS). Currently, the government has instituted a multi-agency team to crack down on counterfeit, illegal and substandard goods at ports of entry, which has helped to reduce imports of illegal goods such as cosmetic products containing mercury, and other banned chemicals.

However, the KBS continues to deal with various challenges which appear to permit some illegal products to still enter the country. These include:

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

Laws/regulations governing use, manufacture, import and export of skin-lightening cosmetics, in the participating countries (2017 and 2018).

Country	Law/regulation no. or name of law, governing use, manufacture, import, and export of skin-lightening cosmetics	Main requirements stipulated in the law/regulation	A law conforming with the 1ppm limit for mercury in cosmetics, according to the Minamata Convention.
Bangladesh	Nb.: BDS 1924: 2017/Annex A-s Name: "Standard Guideline for Cosmetic Products in Bangladesh"	<p><u>Import requirements</u></p> <p>a) Certify for clearance of imported products for placing the product in the market should be based on the requirements of import policy of Bangladesh.</p> <p>b) Technical document and Certificate Mark licensing procedures should be followed.</p> <p>e) Product labeling is required to ensure informed choice by consumers and to allow effective control by the regulatory authorities. Cosmetic products in the market should conform to designated labeling requirements.</p> <p><u>Export requirements</u></p> <p>Requirements for the export of cosmetic products will be based on the requirements of individual countries, if any. If the products meant for the export market are also sold locally and hence comply with the relevant regulatory requirements, free sale certificates may be issued by the authentic authorities upon request.</p>	Yes
Barbados	No relevant regulations found	NA	NA
Belgium/EU*	The Cosmetic Products Regulation 1223/2009 and EU Mercury Regulation 2017/852	Mercury-based products and hydroquinone are banned. Import , export and manufacturing	Yes

Cote d'Ivoire	Decree #2015-288 from 29 th April 2015 related to cosmetics and personal care products regulation	<p style="text-align: center;">-Manufacture requirements</p> <p>Prohibition of manufacture of lightening cosmetics or any personal care products with :</p> <ul style="list-style-type: none"> • Hydroquinone limit > 2% • Mercury and its derivatives • Corticoids and corticosteroids • Retinol derivatives and Vitamin A <p style="text-align: center;">Advertisement and commercialization requirements</p> <p>Prohibition of advertising and commercializing of skin lightening cosmetics or any personal care products with :</p> <ul style="list-style-type: none"> • Hydroquinone limit > 2% • Mercury and its derivatives • Corticoids and corticosteroids • Retinol derivatives and Vitamin A <p style="text-align: center;">Other requirements</p> <ul style="list-style-type: none"> • Prohibition of artisanal mix of cosmetics; • Creation of a compliance and authorization committee for cosmetics and personal care hygiene commercialization; • Provisions for cosmetics and personal care products safe labelling <p>Provisions for controls and sanctions (administrative and penal)</p>	YES Art 7 §2 prohibits manufacture of cosmetics or others personal care products with mercury or mercury components as ingredient.
Dominican Republic	General Law of Health 42-01, Article 109	<p>Calls for control of cosmetics, personal and household hygiene products, with respect to toxic substances that constitute a risk to health. However, no specification of which chemicals.</p> <p>"Sanitary control of the process, import and export, evaluation and registration, control of the promotion and advertising of food, alcoholic and non-alcoholic beverages, beers, medicines, cosmetics, personal and household hygiene products; pesticides, toxic substances that constitute a risk to health and all the materials involved in their preparation.</p> <p>There seems to be no control or any law that talks about the composition of the products with a limit of ppm of specific chemicals in the products. The MINSAP Ministry of Public Health is obliged to ensure that the products do not exceed the allowed values, but those were not found.</p>	No

for more info http://proconsumidor.gob.do/			
Gabon	No relevant law found	NA	No
Ghana	Public Health Act, 851. 2012, and associated guidelines for imports of cosmetics and household chemicals	Mercury-based products and hydroquinone are banned.	Yes
Grenada	Food and Drug Act of 1986	Not relevant provisions to cosmetics yet, to be followed	No
India	The drugs and cosmetic rules, 1945	Import of cosmetics containing mercury compounds prohibited.	Yes
Indonesia**	None in the country. ASEAN Cosmetics Directive	Prohibition of manufacture of cosmetics containing mercury compounds. Annex II, reference number 221 to the ASEAN Cosmetics Directive	Yes
Kenya	Banned cosmetics by Kenya Bureau of Standards. Food Drugs and Chemical Substances Act	All skin care preparations like creams, lotions, gels, soaps, etc., containing hydroquinone, steroids and hormonal preparations should be registered by the Pharmacy and Poisons Board of the Ministry of Health for medical use. Their use in cosmetics was prohibited through gazette notices 4310 of 14th August 1998 and 7169 of November 2000. Any person who sells, prepares, preserves, packages, conveys, stores or displays for sale any cosmetic under insanitary conditions shall be guilty of an offence. Any person who sells any cosmetic that has in or upon it any substance that may cause injury to the health of the user when the cosmetic is used (i) according to the directions on the label of, or accompanying, such cosmetic, or (ii) for such purposes and by such methods of use as are customary or usual therefor; or shall be guilty of an offence.	Yes (but via gazette)
Mauritius	No Existing regulation	N/A	No
Nepal	Consumer Protection	It is expedient to make provisions for protecting consumers from irregularities	No

	Right Act 1998	concerning the quality, quantity and prices of consumer goods or services, ensuring that no one lowers or removes the attributes or usefulness of consumer goods or services. However, this is not sufficient legislation with respect to cosmetics, but new is under development for cosmetics.	
Nigeria	NAFDAC ACT CAP F33 LFN 2004 Cosmetics Products (Prohibition of bleaching agents) Regulation 2005	<p>Prohibition of Unsafe Cosmetics</p> <p>(1) No person shall import, manufacture, distribute, display for sale or offer for sale any cosmetics, which are adulterated or which contains any substance which when used according to the direction on the label accompanying the cosmetic product is likely to cause injury to the health of the user.</p> <p>(2) No person shall import, manufacture, distribute, sell, display for sale or offer for sale any cosmetic product which contains any of the skin bleaching agents listed in the Schedule A to these Regulations.</p> <p>Interpretation</p> <p>For the purpose of these Regulations, unless the context otherwise requires: -</p> <p>“Adulterated cosmetic” means any of the following, that is, if -</p> <p>(a) it contains more than a trace of mercury or any mercury salt which under normal condition of manufacturing practice is unavoidable; or</p> <p>(b) contains more than a trace of mercury or any mercury salt calculated as the metal or preservative; or</p> <p>(c) contains beyond 2% hydroquinone; or</p> <p>(d) bears or contains any poisonous or deleterious substances as to render it injurious to a user under the conditions prescribed in its labeling or under such conditions of use as are customary or usual for the cosmetic product; or</p> <p>(e) has been prepared, packed or held under unsanitary conditions thereby rendering it likely to be injurious to health; or</p> <p>(f) the container in which it is packed is composed in whole or part of poisonous or delirious substance which may render the contents injurious to health; or</p> <p>(g) contains more than the permissible limit of an ingredient; or</p>	Yes

		<p>(h) revalidates any information originally indicated on its label or container by the manufacturer.</p> <p>“cosmetics” includes any substance or mixture of substances intended to be rubbed, poured, sprinkled or sprayed, introduced into or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the complexion, skin, hair or teeth and includes deodorants and detergent powder.</p>	
Philippines	<p>Republic Act No. 7394, “The Consumer Act of the Philippines.</p> <p>Republic Act No. 9711, “Food and Drug Administration (FDA) Act of 2009</p>	<p><u>Article 15 - Imported Products</u> Any consumer product offered for importation into the customs of the Philippine territory shall be refused admission if such product:</p> <ol style="list-style-type: none"> 1. fails to comply with an applicable consumer product quality and safety standard or rule; 2. is or has been determined to be injurious, unsafe and dangerous; 3. is substandard; or 4. has a material defect <p>Any consumer product, the sale or use of which has been banned or withdrawn in the country of manufacture, shall not be imported into the country</p> <p>Pursuant to Republic Act No. 9711, “the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, or retail of any health product is prohibited without the License to Operate (LTO) from the Food and Drug Administration (FDA) required under this Act.”</p> <p>Chapter VI, Section 11</p> <ol style="list-style-type: none"> (a) The manufacture, sale, offering for sale or transfer of any food, drug, device or cosmetic that is adulterated or misbranded is prohibited (b) The adulteration or misbranding of any food, drug, device, or cosmetic <p>Chapter X - Cosmetics</p> <p>Section 23. Cosmetics shall be deemed to be adulterated (a) if it contains any poisonous or deleterious substances which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under the conditions of use as are usual</p> <p>Section 24. Cosmetics shall be deemed to be misbranded (c) if any word, statement or other information required by the FDA is not placed on the label</p>	<p>Yes</p> <p>Administrative Order No. 2005-0015, “Adoption of the ASEAN Harmonized Cosmetic Regulatory Scheme and ASEAN Common Technical Documents” and Administrative Order No. 2005-0025, “Implementation of the ASEAN Scheme and ASEAN Common Technical Document”</p>

Republic Act No. 3720,
"Food, Drug and Cosmetic
Act" an act to ensure the
safety and purity of foods,
drugs, and cosmetics
being made available to
the public

with conspicuousness and in such terms likely to be read or understood by ordinary individual

Chapter XII: Imports and Exports

A. The Commissioner of Customs shall obtain samples, taken at random from every shipment of food, drugs, devices, and cosmetics which are being imported or offered for import into the Philippines, and deliver these to the food and drug administration for examination to ensure that these are manufactured under safety regulations of the country.

A cosmetic intended for export shall not be deemed to be misbranded under this Act if it conforms with the specifications of the foreign purchaser, is not conflict with laws of the country to which it is intended for export, and is labelled on the outside of the shipping package to show that it is intended for export.

A. Documents required in the registration of locally manufactured cosmetic products:

1. Administrative documents- notarized letter application for cosmetic product registration and valid license to operate

2. Technical documents- composition, product description, information sheet containing product description/use, method of decoding batch reference, pack size available, and name and address of the product owner, manufacturer, or assembler, company's notarized declaration of absence of prohibited substances, compliance with the content limit of restricted substances, unattached specimen of the labeling layout per pack size, per variant and specimen of the finished commercial product.

B. For the imported cosmetic products, in addition to the administrative and technical documents mentioned above, any one of the following should be submitted:

- certificate of free sale and license to operate/ manufacture
- certificate of origin or certificate issued by the Board of Health or competent authority stating that the manufacturing plant meets the national requirements in terms of hygiene, safety and quality

C. For the listing of cosmetics specialties, persons or cosmetic establishments responsible for placing cosmetics in the market shall file for notification using the FDA Notification Template and must submit notarized FDA notification form, valid license to operate reflecting the manufacturer/source of the applicant, specimen of the finished

- commercial product and corresponding fees and charges for notification
- D. The cosmetic products for exports shall submit the same administrative and technical requirements of the locally manufactured cosmetics products

ASEAN Cosmetic Directive (ACD), adopted and implemented through the issuance of A.O. 2005-0015 and 2005-0025, states in Article 1.3

“The company or person responsible for placing the cosmetic products in the market shall notify the regulatory authority responsible for cosmetics of each Member State where the product will be marketed, of the place of the manufacture, or of initial importation before the product is placed in the market”

Requirements for all cosmetics establishments:

A. Products for Notification

1. Documentary Requirements: Revised assessment slips, Notarized Cosmetic Product Notification Form and Declaration
2. Attachments: Copy of Valid License to Operate

Technical Requirements: Test for heavy metals done on the finished product (Ref.: BC 17 s. 2005 Subject: Update of Accepted Whitening Agents for Cosmetics), Unattached and readable specimen of all labeling materials per pack size, Specimen of the finished commercial product or digital pictures of these samples showing the container and actual content of the product/s

Administrative Order No.
2005-0025,
"Implementation of the
ASEAN Harmonized
Cosmetic Regulatory
Scheme and ASEAN
Common Technical
Document" Bureau
Circular No. 2006-001,
"Updated Guidelines for

	the Submission of Application for Notification, Registration and Export of Cosmetic Products"		
South Africa	Foodstuffs, cosmetics and disinfectants Act, 1972 (Act nb. 54)	No person may sell, manufacture or import for sale, any cosmetic that may cause damage to human health when used under normal or reasonably foreseeable conditions of use.	Yes
Sri Lanka	the Cosmetics, Devices and Drugs Act, No. 27 of 1980	"No person shall import, distribute, offer for sale or sell any cosmetic that - has in or upon it any substance that may cause injury to the health of the user when the cosmetic is used"	Yes
Tanzania	THE TANZANIA FOOD, DRUGS AND COSMETICS ACT, 2003	Section 87.-(1) Whenever the Authority considers it necessary or desirable in the public interest that any ingredient should be declared to be prohibited, the Minister may, on advice of the Director General by notice in the Gazette declare such ingredient to be a prohibited ingredient and may in like manner amend or revoke such notice. (2) Except as otherwise provided in the regulations, a cosmetic shall not contain any prohibited ingredients. Section 88. No person shall himself or by any other person on his behalf - (a) sell, supply or distribute cosmetics that contain poisonous or harmful substances that might injure users under normal conditions; (b) manufacture or hold cosmetics under in sanitary conditions, using non-permitted colours, or including any filthy, putrid or decomposed substance; (c) sell, or stock or exhibit or offer for sale or distribute any cosmetic which has been imported or manufactured in contravention of any of the provisions of this Act.	Yes
Thailand	Cosmetics act, B.E. 2558 (2015)	Section 25. Upon the publication under Section 6 (9), the importation for the sale of cosmetics must be inspected by the competent official at the inspection of cosmetics. Section 27. No person shall produce for sale; import for sale; contract manufacturing or sales of cosmetics: (1) That are not safe to use;	Yes

		(2) fake cosmetics; (3) The wrong standard cosmetics; (4) cosmetics prohibited by the Minister under Section 6 (1); (5) cosmetics that have been revoked under the provisions of Section 36 or Section 37	
	Notification of the Ministry of Public Health B.E. 2559 (2016): Determines the characteristics of cosmetics that are prohibited to produce, import or sell. ⁹	Article 1 of the notification specifies that certain cosmetic products are prohibited to produce, import or sell.	
	Notification of the Ministry of Public Health B.E. 2559 (2016): Name of cosmetics that are prohibited to be manufactured, imported or sold.	List of 34 cosmetics products that are prohibited to produce, import or sell.	
	Notification of the Ministry of Public Health B.E. 2559 (2016): ingredients.	List of 1387 substances that prohibited for use as ingredients	
Trinidad/Tobago	No relevant law found	Cosmetics are not required by local laws to list all their ingredients	No
Uganda	From the MIA report	A number of mercury containing creams have hitherto been available on the Ugandan market. Whereas these cosmetics products have since been banned, they still find their way onto the market through the country's porous borders. https://www.unbs.go.ug/index.php/alerts/86-banned-product	Yes

⁹ Under "Cosmetics act, B.E. 2558 (2015)".

Constitution of Uganda	Provides for the sound management of chemicals. Article 39 of the constitution states that every person has a right to a clean and healthy environment.
The National Environment Act Cap 153 Laws of Uganda:	Framework legislation for environmental management in Uganda. The Act defines a chemical as a substance in any form whether by itself or in a mixture or preparation whether manufactured or derived from nature and for the purposes of Act to include industrial chemicals, pesticides, fertilizers and drugs. The guidelines and measures called for in this Act, to manage chemicals, are to include <i>inter alia</i> : registration, labelling, packaging, advertising, control of importation and exportation, distribution, storage, transportation, monitoring of effects, disposal, restriction and banning of toxic and hazardous chemicals and materials.
Uganda National Bureau of Standards Act Cap 237:	The Act sets up the Uganda National Bureau of Standards (UNBS) whose objectives are to formulate and promote the use of National standards and to develop quality control and quality assurance systems that will enhance consumer protection, public health and safety, industrial and commercial development and international trade, among others.
External Trade Act, Cap 88:	This Act makes provision for the regulation of external trade and other matters incidental thereto and connected therewith. This Act is relevant as it can be used effectively to prevent entry of dangerous chemicals and consumer products from entering Uganda.
Public Health Act Cap 281:.	Consumer products that contain hazardous chemicals and therefore cause disease may also fall under this Act. It regulates the use of chemicals for public health and sets up the Health Inspectorate to ensure compliance
The East African Community Customs Management Act, 2005:	This is an Act of the East African Community which makes provisions for the management and administration of customs and other related matters. Section 18 and Schedule A among other things prohibits chemical products which are injurious to health; all soaps and cosmetic products containing mercury; agricultural chemicals such as DDT and industrial chemicals such as Methlbromide
United States	21 U.S.C. ch. 9 § 301 et The 1938 Federal Food, Drug, and Cosmetic Act (FFDCA) granted the Food and
	Yes

seq.

Drug Administration (FDA) the authority to regulate the safety of food, drugs, and cosmetic products and their ingredients. FDA's statutory provisions provide the agency with primary responsibilities for regulating cosmetics, which include ensuring that cosmetics are not adulterated or misbranded. In addition to the FFDCa, cosmetics are regulated under the Fair Packaging and Labeling Act (FPLA) and related regulations. The cosmetics provisions were amended by the Color Additive Amendments Act of 1960 and the Poison Prevention Packaging Act, but remain basically the same as the provisions in the 1938 FFDCa. Under the law, FDA has the authority to take certain enforcement actions—such as seizures, injunctions, and criminal penalties—against adulterated or misbranded cosmetics. Additionally, FDA may conduct inspections of cosmetic manufacturers and prohibit imports of cosmetics that violate the FFDCa, including cosmetics containing mercury levels over 1 ppm.. FDA has issued rules restricting the use of some ingredients in cosmetic products, such as those that it has determined are poisonous or deleterious, which would cause the cosmetic to be adulterated. The agency also has issued rules restricting the use of ingredients that the agency has determined are poisonous or deleterious.

*The EU represented by Belgium in the study.

**All ASEAN countries (<https://asean.org/asean/asean-member-states/>) follow the ASEAN Cosmetics Directive (<http://aseancosmetics.org/uploads/UserFiles/File/TECHNICAL%20DOCUMENTS/Technical%20Documents.pdf>)

Laws/regulations governing ingredient lists for cosmetics and personal hygiene products for the countries in the study, 2017 and 2018.

Country	Law/regulation nb. or name of law, governing ingredient lists for cosmetics and personal hygiene products	Main requirements stipulated in the law/regulation
Bangladesh	<p>Under the BDS 1924:2017, Annex G, it is described that, in the absence of effective regulations or standards, cosmetics and toilet goods may constitute a potential health hazard to the consumer. Due to its growing demand the sectional committee decided to prepare a broad-based classification of the raw materials into:</p> <p>a) Generally recognized as safe (GRAS) b) Generally not recognized as safe (GNRAS).</p> <p>Dyes, pigments and colors, are listed as GRAS (BDS 1340 part-1). For raw materials other than dyes, pigments and colors, GNARS list could be produced (BDS1340 Part-2). Such a list is expected to adequately safeguard the interest of the consumer, while leaving enough room for development of new raw materials.</p>	Since this is not a regulation or law, in the absence of regulation, this is a guideline under BSTI act (BDS 1924: 2017)
Barbados	No relevant regulations found	-
Cote d'Ivoire	Under the Decree #2015-288 from 29 th April 2015 related to cosmetics and personal care products regulation, the list of ingredients subject to public health concern is addressed.	<p>Art 7: Prohibition of manufacture of lightning cosmetics or any personal care products with:</p> <ul style="list-style-type: none"> • Hydroquinone limit > 2% • Mercury and its derivatives • Corticoids and corticosteroids <p>Retinol derivatives and Vitamin A</p>
Dominican Republic	Food and Drug Act	Article 8: Insert and labels required for cosmetics.

		<p>Already in regulation 117-18, FOR THE AUTOMATIC RENEWAL OF SANITARY RECORDS OF FOOD, MEDICINES, SANITARY, COSMETIC AND HYGIENE PRODUCTS, in its article 8 there is a little more about the subject:</p> <p>ARTICLE 8. In the case of cosmetic and hygiene products, the specific requirements are the following: 1) Insert labels, and any other type of packaging material as authorized. This requirement does not require a physical sample and applies only to the first time imports; the renewal is automatic. PARAGRAPH: If the product is of imported origin, in addition to the requirements established in article 8, the applicant must provide: 1) Certificate of Free Sale of the product. 2) Certificate of Good Manufacturing Practices, or certification of the quality system used, corresponding to the classification of the requested product, as applicable. 3) In case of maquila, it must comply with manufacturing certification.</p> <p>However, it is not clear to us if this means an ingredient list.</p>
EU*	The Cosmetic Products Regulation 1223/2009	<p>§46: Transparency is needed regarding the ingredients used in cosmetic products. Such transparency should be achieved by indication of the ingredients in a cosmetic product on its packaging. Where for practical reasons it is impossible to indicate the ingredients on the packaging, such information should be enclosed, so that the consumer has access to this information.</p> <p>§47: A glossary of common ingredient names should be compiled by the Commission to ensure uniform labelling and facilitate identification of cosmetics ingredients. This glossary should not be intended to constitute a limitative list of substances used in cosmetic products.</p>
Gabon	No relevant law found	NA
Ghana	Public Health Act, 851. 2012, and associated requirements for labelling of products.	<p>The information on the label should include, but not be limited to the following:</p> <ol style="list-style-type: none"> Name of the product, and generic INN/INCI. A list of the active ingredients using INN/INCI or IUPAC system, where applicable, showing the amount of each present in a dosage unit. The net content of the container. The batch number. Date of manufacture and best before/expiry date. Directions for use, and any warnings or precautions that may be necessary. Any special storage conditions or handling precautions that may be necessary.

		<p>h) Indications, frequency, route and conditions of use when applicable.</p> <p>i) The name of any excipients known to be of safety concern.</p> <p>j) Name, postal address and premises address of the manufacturer and distributor.</p> <p>k) Country of origin.</p>
Grenada	Food and Drug Act of 1986	Not covering relevant provisions, to be followed
India	IS 4707 (Part 2) : 2009 Classification of Cosmetics Raw Material and Adjuncts	Mercury and its compound not recognized as safe for use in cosmetics
Indonesia**	ASEAN Cosmetics Directive, Article 6	Appropriate labelling in compliance with the cosmetics labelling requirements in Annex II of the directive.
Kenya	None	None
Mauritius	No relevant law found	-
Nepal	None	None
Nigeria	NAFDAC ACT CAP F33 LFN 2004 Cosmetics Products (Labelling) Regulations 2005	<p>Prohibition.</p> <p>No person shall manufacture, import, export, distribute, advertise, display for sale or sell a cosmetic, unless a label has been affixed thereto with the information required by these Regulations appearing on both the inner and outer container (as applicable).</p> <p>2. Cosmetics not to be described or labelled.</p> <p>A cosmetic shall not be described or presented on any label -</p> <p>(a) in a manner which is false, misleading, deceptive or is likely to create an erroneous impression regarding its character, quality, quantity and origin;</p> <p>(b) by words, pictorial or other means which refer to any other product or suggests either directly or indirectly, that the cosmetics is connected with such other product.</p> <p>3. Product identity.</p> <p>(1) The outer and inner labels of a cosmetic shall be required to bear the name of the cosmetic product which shall indicate the accurate nature of the cosmetic.</p> <p>(2) Where a class name has been established for the cosmetic, it shall be used in conjunction with the brand name of the cosmetic product.</p> <p>(3) Where no class name exists for a cosmetic product, an appropriate descriptive name shall be affixed thereto.</p> <p>(4) Where a coined or fanciful name is used for the cosmetic product, the name shall not be misleading and shall be accompanied by an appropriate descriptive term.</p> <p>4. List of ingredients.</p> <p>(1) A complete list of ingredients used in preparing the cosmetic product shall be</p>

declared on the outer label and inner label where appropriate in decreasing order of predominance, except that fragrance, colour or flavour may be listed in any order after the other ingredients as fragrance, colour or flavour and an ingredient that is a fragrance, colour and flavour shall be designated by each of the functions it performs, unless such ingredient is identified by name.

(2) Where there is no outer packaging, the list of ingredients shall appear on the inner label.

(3) Ingredients in concentrations of less than 1% may be listed in any order after those concentrations of 1% or more.

(4) For decorative cosmetics, marketed in several colour shades, all colouring agents may be listed, preceded by the words "may contain".

(5) Where the ingredients of a cosmetic product have more than one component the name of the components shall be included in the list of ingredients.

(6) The declaration of ingredients shall appear with such prominence and conspicuousness as to render it likely to be read and understood by ordinary individuals under normal conditions of purchase.

(7) Where a cosmetic product is also an over-the-counter drug product, the declaration of ingredients shall declare the active drug ingredients as set forth in the Drug Labeling Regulations.

(8) Where the ingredients of a cosmetic product are known to cause hypersensitivity, such shall be declared on the label.

(9) Where multi-packs are involved the following shall apply - where the ingredient labeling is on the outer packaging, the ingredients for each product may be separately listed or combined into one list;

(a) where labeling on the outer packaging is impossible for practical reasons or impracticable for reasons of size or shape, the list shall be given on a leaflet, label, tag, tape or card enclosed with the product and the consumer shall be referred to the text either by abbreviated information or by a special symbol;

(b) if the products within the multi-pack have containers which are individually labeled or printed with an ingredient list, there is no need for a separate leaflet, label, tape, tag or card; and

(c) in the case of transparent packaging, where the ingredient labeling of the products is clearly visible, separate labeling is not required.

(10) For the purposes of labeling, the following shall not be regarded as cosmetic ingredient and need not be shown on the label:

		<p>(a) impurities of the raw materials;</p> <p>(b) subsidiary technical materials used in the preparation of the cosmetic product but not present in the final product; and</p> <p>(c) materials used in strictly necessary quantities as solvents or as carriers for perfumes and aromatic compositions.</p> <p>(11) Where the information specified in regulation 4 is impracticable for reasons of size or shape, the information shall be given on a label, tag, tape or card attached to the product and the consumer shall be referred to it, either by abbreviated information or a special symbol on the outer packing.</p>
Philippines	Administrative Order No. 2005-0025, "Implementation of the ASEAN Harmonized Cosmetic Regulatory Scheme and ASEAN Common Technical Document"	<p>The following particulars shall appear on the outer packaging of cosmetic products or, where there is no outer packaging, on the immediate packaging of cosmetic products:</p> <ul style="list-style-type: none"> • The name of the cosmetic products and its function • Instructions on the use of cosmetic products • Full ingredient listing; the ingredients shall be specified by using the nomenclature from the latest edition of standard references • Country manufacture • The name and address of the company or person responsible for placing the product on the local market • The contents given by weight or volume, in either metric on both in metric and imperial system • The manufacturing date or expiry date of the product in clear terms • Special precautions to be observed in use • Registration number from the country of origin (Manufacture) or the country of registration <p>The use of leaflets, pamphlets, etc. is allowed if the size, shape or nature of the container or package does not permit the particulars mentioned above be displayed.</p>
South Africa	Foodstuffs, cosmetics and disinfectants Act, 1972 (Act nb. 54)	<p>The labelling should include:</p> <p>a) Name of the cosmetic</p> <p>b) The name of the manufacturer, packer, importer, distributor, or person on whose behalf the cosmetic is packed. Provided where it is physically not possible to provide this information on the primary container, such information must appear on the secondary container.</p> <p>c) The country of origin for imported cosmetics-</p> <p>d) The normal content at the time of packaging given by weight or volume.</p>

		e) The date of minimum durability (where necessary)
Sri Lanka	-	-
Tanzania	-	-
Thailand	Notification of Cosmetic Committee B.E. 2554 (2011)	Cosmetic Label"; mentioned the label of cosmetic must at least identify required message - "The names of all substances used as ingredients in the manufacture of cosmetics. They must be FDA compliant and must be sorted in order of quantity"
Trinidad/Tobago	No relevant law found	-
Uganda	-	-
United States	1 C.F.R. §§ 700.13(d)(1), 701.2, 701.3.	Levels of mercury over 1ppm make these products eligible to be classified under the federal U.S. Food, Drug and Cosmetic Act as "misbranded" and therefore illegal.

*The EU represented by Belgium in the study.

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Annex H: Mercury readings by BRI, 2017

List of skin creams analyzed on the Milestone DMA 80 with detectable levels of THg, 2017 (arranged by country and increasing THg).

Country of purchased	Country of manufacture	Manufacturer	Brand name	THg [ppm]*
Bangladesh	Not available	Not available	New Face Whitening Cream	Too high
Bangladesh	I.R.P	Kaw Cosmetics	Noor Herbal Beauty Cream	Too high
Bangladesh	Gazipur, Bangladesh	Lata Herbal Co.	Lata Herbal Skin Bright Cream	Too high
Bangladesh	Not available	Not Available	Chandni Whitening Cream	Too high
Belgium	Cote D'Ivoire	SIVOP parfumes et cosmetiques	Sivoderm	0.0004
Belgium	Cote D'Ivoire	Dream Cosmetics	Perfect white	0.0005
Belgium	France/Cote D'Ivoire	El Paradis cosmetic	Nature Secrete lightening serum	0.0074
Belgium	Lebanon	Diana de Beaute, S.A.L.	Diana beauty cream	0.0150
Cote d'Ivoire			White & beautiful cream	0.0002
Cote d'Ivoire			Skin repair lotion clarifying formula	0.0004
Cote d'Ivoire			Ami Body white	0.0005
Cote d'Ivoire			CT + clear therapy	0.0008
Cote d'Ivoire			Rapid white 21 jours	0.0012
Cote d'Ivoire			Rapi d'clair	0.0016
Cote d'Ivoire			Caro white, lightening beauty cream	0.0031
Cote d'Ivoire			Nature white	0.0035
Cote d'Ivoire			Neoli light collagen	0.0035
Dominican Republic	Dominican Republic	Laboratorios Key, SRL	Crema Blanqueadora Whitening Cream Miss Key	0.0042
Dominican Republic	Dominican Republic	Productos Portela, S.A.	Michelle Marie Sun Screen Day Use Whitening Cream	0.0343
Dominican Republic	Dominican Republic	Laboratorios LISSO, S.R.L.	Crema Blanqueadora Whitening Cream Lisso	too high
Gabon	Cote d'Ivoire	N.P. Gandour	Maxi light, lightening cream	0.0006
Gabon	CEMAC	G. Clacos Sarl, groupe Cladel Cosmetics Sarl	42 heures juste whitening cream	0.0037
Gabon		Dodo cosmetics	Dodo, white up	0.0012
Gabon	CEMAC	Serena Cosmetic	Magic White potion magique Bio	0.0014
Ghana	Togo	Dodo Cosmetics	Maricha whitening lotion	0.0190
India	India	BIO VEDA Action Research co.	Biotique; whitening cream	0.0016
India	India	Pushkar Industries pvt.ltd	Derma Klay-derma light	0.0033

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Kenya	Togo	Dodo Cosmetics	Maricha, whitening body cream	0.0008
Mauritius	Indonesia	PT Orson	Royal Orchard Fruity Soap, Grape	0.0004
Mauritius	India	Wadhwa Beauty Care	Zaira Gold Neem Fair Triple Filter SPF 15	0.0036
Mauritius	India	British Herbal Cosmetics	Christy Vanishing Cream	0.0057
Mauritius	India	Nature's Organics	Nature's Essence Gold Bleach Fairness Bleach Cream (Component 1 of 2 in Gold Bleach product)	0.0060
Mauritius	South Africa	SFL	Light & Bright Restoring Vanishing Cream	0.0071
Mauritius	India	?	Pond's Dream Fairness Cream	0.0072
Mauritius	India	Hindustan Unilever Ltd	Fair & Lovely Anti Marks Face Wash	0.0099
Mauritius		Kreative Cosmetics (Pvt) Ltd	Due Whitening + Anti Acne Soap Enriched with Avocado	0.0109
Mauritius	India	Emami Limited	Boro Plus Antiseptic Cream	0.0112
Mauritius		Lulanjina	Gold Aloe Acne-dispelling Plaster	0.0166
Mauritius	Thailand	BK Cosmetic	Allot Cake Powder and Foundation In-One, Pink 3	0.0200
Mauritius	Thiland	Smilephan Company Limited	POP Popular Facial Cream	0.0208
Mauritius	India	Nature's Organics	Nature's Essence Gold Bleach Fairness Bleach Activator (Component 2 of 2 in Gold Bleach product)	0.0649
Mauritius	Pakistan	SJ Enterprises	Chandni Whitening Cream	too high
Nigeria	Cote D'Ivoire	SIVOP	Sivo Clair lightening cream	0.0007
Nigeria	Cote D'Ivoire	N.P. Gandour	Carotone brightening body lotion	0.0009
Nigeria	Cote D'Ivoire	N.P. Gandour	Bio Claire lightening body lotion	0.0010
Nigeria	Philippines	Splash corporation	Extract whitening lotion	0.0014
Nigeria	Cote D'Ivoire	SIVOP	Cocoderm lightening cream	0.0025
Nigeria	Togo	dodo cosmetics	Clinic Clear whitening body lotion	0.0027
Nigeria	Cote D'Ivoire	for Rodis	Skin Light Cream	0.0030
Philippines	Indonesia	PT Yasulor Indonesia	Garnier light complete multi action whitening cream	0.0003
Philippines	Philippines	for intelligent	Belo essentials Day cover whitening cream	0.0004
Philippines	Indonesia	Unilever	Pond's day cream, spotless rosy white	0.0010
Philippines	Thailand	Procter & Gamble	Olay natural white, fairness cream	0.0014
Philippines	Philippines	Splash corporation	Skin white classic whitening face cream	0.0014
Philippines	Philippines	Amira pharma inc.	Amira skin whitening cream	0.0022
Philippines	Thailand	Beiersdorf; for export only	Nivea sun protect & white face cream, spf 50	0.0127
Philippines	N/A	for Sara Med	The real magic cream whitening	0.0174

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Philippines	Philippines		Professional Skin Care formula, bleaching cream 4 in 1	0.0223
Philippines	Hong King	Gemli	Glutathione Grapeseed extract whitening and anti-aging-night cream	0.2523
Philippines	China, Taiwan	?	Anspaili reckelpaster	0.3295
Philippines	Hong King	Gemli	Glutathione Grapeseed extract whitening and anti-aging-day cream	too high
Philippines	China	?	Jiaoli miraculous day and night cream	too high
South Africa	India	Shalina labs pvt. ltd.	diprosone creme betamethasone dipropionate usp-0.05%	0.0004
South Africa	India	Shalina labs pvt. ltd.	Epiderm Cream (antibacterial etc)	0.0023
South Africa	India	Shalina labs pvt. ltd.	Betasol, anti-inflammatory cream	0.0029
South Africa	Dem. Republic of Congo	Femco sprl	TOP creme, lightening	0.0030
Sri Lanka	Sri Lanka	Shello Cosmetics Co. (Pvt) Ltd.	Shello Whitening Moisturizing Face Cream	0.0001
Sri Lanka	?	?	Chavikanthi (Sandunlepaya)	0.0002
Sri Lanka	India	?	Fair and Handsome Deep Action Peptide	0.0003
Sri Lanka	Sri Lanka	Native Herbals (PVT) LTD	Chavikanthi (Kankunalepn) ??	0.0004
Sri Lanka	India	CavinKare Pvt. Ltd.	Fairever Natural Fairness	0.0005
Sri Lanka	Sri Lanka	Nature's Beauty Creations Ltd	Nature Secreates Lotus Skin Whitening Cream	0.0013
Sri Lanka	Sri Lanka	Sanjeevaka Ayurvedic Products (Pvt) Ltd.	Chandanalepa Soft Cool and Soothing	0.0019
Sri Lanka	Sri Lanka	Janet Lanka Pvt. Ltd.	Janet Ayurveda Fair and Natural Fairness Cream	0.0021
Sri Lanka	India	The Himalaya Drug Company	Himalaya Herbals Natural Glow Fairness Cream	0.0078
Sri Lanka	?	?	No. 40 Saffron Cream, 21 Quality Sri Lankan Spice & Herbs, Saffron, Spice & Herbal Garden	0.0096
Sri Lanka	?	?	Golden Pearl Beauty Cream	0.2684
Tanzania	Cote D'Ivoire	NPG	Doctor Clear, lightening face cream	0.0007
Tanzania	Dem. Republic of Congo	Femco	Princess Claire, whitening cream	0.0015
Tanzania	?	Dodo cosmetics	Dodo multi vitamin whitening cream	Not available
Tanzania	Dem. Republic of Congo	C&C International Ltd. UK	Miki Clair plus	Not available
Trinidad and Tobago	?	?	Emami Fair and Handsome	0.0018
Trinidad and	?	?	Emami Naturally Fair Pearls	0.0177

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Tobago				
Trinidad and Tobago	Jamaica	?	Non-Oily Deluxe Silken Bleaching Cream	too high
USA (OH)	USA	Daggett & Ramsdell	Skin lightening Serum	0.0002
USA (OH)	USA	Daggett & Ramsdell	Hand & Body lightening creme	0.0030
USA (CA)	England	Crusader ultra for Elliot Irving Ltd, UK	Ultra Skin tone soap	0.0001
USA (CA)	China	Chesapeake, VA	Sassy +Chic	0.0028
USA (CA)	UK	Elliot Irving	Ultra skin Lightening cream	0.0030
USA (CT)	EU	?	Precious Beauty skin lightening gel	0.0001
USA (CT)	Cote d'Ivoire	Dream cosmetics	Perfect white	0.0004
USA (CT)	EU	Rico skin care ltd. UK	Rico complexion cream	0.0044
USA (CT)	France	Labo Derma	Fair & White gel cream	0.0054
USA (CT)	Italy	Beneks pharmaceuticals ltd, Lagos Nigeria	Hot movate gel; Beneks'	0.0128
USA (DC)	EU France, Paris	Topiclear Labs	Topiclear lemon cream-skin lightening	0.0007

*15 of the creams had total mercury (THg) concentrations <0.0005 ppm, the limit approaching the blank.

Annex I: Mercury readings by BT, 2018

List of creams analyzed on the Innov-X Delta Professional DS 2000 XRF, 2018 (arranged by country and increasing THg).

Country of purchase	Country of manufacture	Manufacturer	Brand name	THg [ppm]*
India	India		Lotus Herbals Safe Sun Whitening	N.d.
India	India		Spinz BB Brightening and Beauty Fairness Cream	N.d.
India	Thailand		Olay White Radiance Advanced Whitening	N.d.
India	India		Lakme Absolute Perfect Radiance Skin Lightening Night Creme	N.d.
India	India		Prepair 5060 Regenerating Skin Cream	N.d.
India	India		Citra Pearl Fair Face Cream	N.d.
India	India		Himalaya Natural Glow Fairness Cream	N.d.
India	India		Clean Clear: Clear Fairness Cream	N.d.
Indonesia	Indonesia		Pond's White Beauty Instabright Tone Up Milk Cream	N.d.
Indonesia	Indonesia		Citra Pearly White UV: Facial Moisturizer	N.d.
Indonesia	Indonesia		MECO Lightening Cream	N.d.
Indonesia	Indonesia		Fair Cheek Beauty Cream	N.d.
Indonesia	Philippines		RDL Whitening Treatment Day Cream 8 Days Treatment	N.d.
Indonesia	Thailand		Olay Natural White Pinkish Fairness with UV protection	N.d.
Indonesia	Indonesia		Garnier Skin Naturals Light Complete White Speed	N.d.
Indonesia	Malaysia		Temulawak Cream (day cream)	N.d.
Indonesia	?		Collagen Plus Vit E Day Cream	N.d.
Indonesia	Philippines		RDL Whitening Treatment Night Cream 8 Days Treatment	3,319±37
Indonesia	Malaysia		Temulawak Cream (night cream)	3,892±71
Indonesia	?		Collagen Plus Vit E Night Cream	7,276±80
Indonesia	?		Natural 99 Vitamin E plus	1,000±19
Philippines	?		Sheep Placenta Cream	N.d.
Philippines	Thailand		Renow-D Facial Cream Formula-One	N.d.
Philippines	Taiwan		Golden Horse Face Cream	N.d.
Philippines	Taiwan		Top Shirley medicated cream	N.d.
Philippines	Philippines		Professional Skin Care Formula Bleaching Cream 4 in 1	N.d.
Philippines	Philippines		Crystal Infinity Beauty Products Pekas Cream for Melasma/Highly Pigmented Skin	N.d.
Philippines	?		Feminine White Cream	N.d.

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Philippines	Philippines	White Glow Beauty Radiance White Glow all in one Premium Magic Cream	N.d.
Philippines	Philippines	The Real Amira Magic Cream Skin Whitening Cream	N.d.
Philippines	Thailand	Bouche Ling Zhi Beauty Pearl cream	N.d.
Philippines	Hong Kong	Sanli Pearl Sheep Placenta Whitening Cream	N.d.
Philippines	Thailand	Yoko Whitening Q10 Cream	N.d.
Philippines	Thailand	Yoko Whitening Cream (Papaya Extract)	N.d.
Philippines	Not indicated	Ansina	N.d.
Philippines	?	Erna SPF	N.d.
Philippines	Hong Kong	Gemli Glutathione Grapeseed Extract (Night cream)	N.d.
Philippines	China	Jiaoli Day Cream	3,156±56
Philippines	China	Jiaoli Night Cream	269±11
Philippines	Hong Kong	Gemli Glutathione Grapeseed Extract (Day cream)	652±18
Philippines	Pakistan	Goree Beauty Cream	22,133±0.1

Annex J: Mercury readings by CASE and EEB, 2018

List of creams analyzed on the Niton XL3t-970 GOLDD+ Analyzer SDD XRF, 2018 (arranged by country and increasing THg).

Country of purchase	Country of manufacture	Manufacturer	Brand name	THg [ppm]*
Bangladesh	China	Hearben Gelidai Jiabao Cosmetics	Jiaulihuic Hunsu Jioli Miraculous Day and Night Cream	732±9
Bangladesh	China, imported via Malaysia	Guangzhou Tengzhang International Trade Co. Ltd	Temulawak New Beauty White Cream (Day and Night Cream)	1273±13
Bangladesh	Pakistan	Hamza Company	Hoor! Whitening Cream	1672±18
Bangladesh	Taiwan	Spring International Cosmetic Group Company	Egg White and Cherry 7 days specific eliminating freckle whitening cream	4371±31
Bangladesh	Pakistan	Poonia Brothers	Faiza Beauty Cream	4636±43
Bangladesh	Taiwan	Hua Thu Li	Green Tea Whitening Anti-freckle cream	4870±32
Bangladesh	Taiwan	Bird's Nest Cosmetology	Huayenong - Bird's Nest Cosmetology	6515±42
Bangladesh	Pakistan	Kreative Cosmetics Private LTD	Due Beauty Cream	8185±112
Bangladesh	Pakistan	H Pharmacy	Goree Beauty Cream with Lycopene	9356±62
Bangladesh	Pakistan	Golden Pearl Cosmetics	Golden Pearl Beauty Cream	10567±107*
Bangladesh	Pakistan	Golden Pearl Cosmetics	Golden Pearl Beauty Cream, measured on cellophane	10776±110*
Bangladesh	India	Ratnasagar Herbals Pvt. Ltd	Joy 24 Caret Gold Glow Bleache	N.d.
Bangladesh	India	Cosmetica Corporation	Blue Heaven Bleach Cream	N.d.
Bangladesh	India	Hindustan Unilever Ltd.	Ponds White beauty BB+ Fairness Cream	N.d.
Bangladesh	Sri Lanka	Nature's Beauty Creations Ltd.	Nature's Secret natural Beauty Based BB Cream	N.d.
Bangladesh	Indonesia	PT Yasulor Indonesia (for Garnier)	New Garnier skin naturals Sakura White Pinkish Radiance and Smooth Pores	N.d.
Bangladesh	Thailand	M.S. Beautyline Co. Ltd.	YC Dark Spot Fade Out Cream with Pure lemon essence +mulberry extract	N.d.
Bangladesh	Thailand	M.S. Beautyline Co. Ltd.	YC Whitening and Anit-freckle gold caviar night cream	N.d.
Bangladesh	Thailand	M.S. Beautyline Co. Ltd.	YC Whitening and Anti-freckle gold caviar Night Cream	N.d.
Bangladesh	Sri Lanka	Nature's Beauty Creations Ltd.	Nature's Secret under eye cream enriched with gotukola extract	N.d.
Bangladesh	India	VLCC Personal Care Ltd.	VLCC Natural Science Ltd Snigdha Skin Whitening Night Cream	N.d.

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Kenya	Côte d'Ivoire	SIVOP	Cocoderm	N.d.
Kenya	Togo	Dodo Cosmetics	Clinic Clear	N.d.
Kenya	Côte d'Ivoire	SIVOP	Peau Claire	N.d.
Kenya	Côte d'Ivoire	Picos-Ci	Rapid White - 21 Jours	N.d.
Kenya	Côte d'Ivoire	N.P. Gandour -CI	Maxi Light	N.d.
Kenya	Côte d'Ivoire	N.P. Gandour -CI	Bio Claire	N.d.
Kenya	Democratic Republic of Congo	Ghandour Industrie Congo	Extra Claire	N.d.
Kenya	France	Labo. DERMA	Paris Fair & White	N.d.
Kenya	Democratic Republic of Congo	Femco Spri	Top Lemon Plus	N.d.
Nepal	Vietnam	Rohto-Mentholatum Co. Ltd.	Oxy Whitening Cream	N.d.
Nepal	India	L'Oreal India Pvt.Ltd.	L'Oreal	N.d.
Nepal	Nepal	Unilever Nepal	Fair and Lovely	N.d.
Nepal	India	Hygenic Research Institute Pvt. Ltd.	Florozone	N.d.
Nepal	India	Emami Limited	Emami- Fair and Handsome	N.d.
Nepal	India	Lotus Herbal Pvt. Ltd.	Lotus Herbal - Whiteglow	N.d.
Nepal	India	Hindustan Unilever Ltd.	Fair and Lovely Men	N.d.
Nepal	India	Hindustan Unilever Ltd.	Pond's White Beauty	N.d.
Nepal	India	L'Oreal India Pvt.Ltd.	Garnier Skin Natural	N.d.
Nepal	Thailand	Olay	Olay	N.d.
Nigeria	Côte d'Ivoire	N.P. Gandour	Maxi Light	N.d.
Nigeria	Italy	Ever Evelyn Cosmetics UK	Rapid White	N.d.
Nigeria	-	Maymex Int'l Co. Ltd.	White Care	N.d.
Nigeria	Côte d'Ivoire	RODIS	Skin Light	N.d.
Nigeria	-	SIVOP	Caro-Light	N.d.
Nigeria	-	UNIPARCO	Pure White Cosmetics- Gold Glowing	N.d.
Nigeria	Nigeria	Beauty Fair Laboratories Ltd.	Beauty Fair- Citron Extra Riche	N.d.
Nigeria	Italy	H Cosmetiques CI	La Dakaroise	N.d.
Nigeria	-	Maymex Int'l Co. Ltd.	White Care Gold Body Milk	N.d.
Nigeria	Italy	Stan Elvis Pharmaceuticals Ltd.	Silky White	N.d.

Annex K: Mercury as an active ingredient in skin-lightening creams and health concerns

Mercury has the ability to inactivate a key enzyme responsible for melanin production, hence its skin-lightening effect.⁴⁰ Listed below are some inorganic mercury compounds that have been used in skin-lightening products.⁴¹

Mercury compound, name	Mercury compound, chemical formula
Mercury(I) chloride, also called calomel, or mercurous chloride	Hg ₂ Cl ₂
Mercury(II) chloride, also called mercuric chloride	HgCl ₂
Mercury(II) iodide, also called red mercury, or mercury diiodide, or mercuric iodide	HgI ₂
Mercury(I) oxide, also called mercurous oxide	Hg ₂ O
Mercury(II) amidochloride, also called mercuric amidochloride, or ammoniated mercury	HgNH ₂ Cl

Application of mercury salts to the skin may in the short term cause sensitization,^r in up to 13% of users.⁴² Acute contact dermatitis,^s with symptoms like mild swelling, blistering, scaling and irritation may follow.¹³ Long-term use frequently leads to a brown, gray or blue-black discoloration of the skin.⁴³

Lethal doses of inorganic mercury can be absorbed through the skin, and up to 10% of inorganic mercury ingested may be absorbed via the digestive system.^{44, 45, 46} Accidental ingestion of skin-lightening products applied around the mouth, hand-to-mouth transfer of inorganic mercury compounds from the hands, or through food prepared by the user of skin-lightening products, cannot be excluded. In the latter case, the whole family of the user of skin-lightening products may at risk.^{47, 48} Children might touch cloths or towels that are contaminated with a mercury containing cosmetic, or they might simply touch a person's face or kiss their cheek.^t

Another, though largely unexplored, potential exposure route for mercury from skin-lightening products is inhalation of elemental mercury^u formed when mercury salts are chemically reduced.^v For example, UV-light has shown to catalyze reduction of mercury in mercuric chloride to elemental mercury.^{49, 50} It is not known whether this could happen in the skin when the skin-lightening product is exposed to sunlight, or on clothing or other surfaces contaminated by inorganic mercury. High temperatures also enhance the reduction of inorganic to elemental mercury, and Copan *et al.* have suggested that this may perhaps even take place at room temperature.^{20, 51}

Particularly alarming is the evidence that use of inorganic mercury in skin-lighteners during pregnancy may place the unborn fetus at risk for neurological, kidney and dermatological

^r Exposure to an agent that results in the development of hypersensitivity against the agent.

^s Inflammation in the skin due to agent causing hypersensitivity.

^t Food and Drug Administration (FDA), *Mercury Products Linked to Skin Products* (July 16, 2016) (<https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm294849.htm>).

^u Elemental mercury is electrically non-charged and has a low vapor pressure, so it readily transforms between liquid and gaseous phases.

^v Chemical reduction implies the gaining of electrons by one of the atoms involved in the reaction.

disorders, cataracts^w and anemia.^{x, 52, 53} It is not unlikely that a breastfeeding child could ingest inorganic mercury applied to the skin of the breasts while breastfeeding. It should also be noted that mercury can be transferred to the child via breastmilk. Mahé *et al.* reported that 69% of the pregnant women in their study used skin-lighteners while pregnant.⁵⁴ In a Somali community in the USA, all interviewed women applied skin-lightening creams to the body twice a day during pregnancy and when breastfeeding.³⁰ In a study from Senegal, 81% of the interviewed women continued applying skin bleaching products throughout pregnancy, while 87% did so during lactation.⁵⁵ The corresponding figures in Saudi Arabia were 10.3% throughout pregnancy and 20.8% during lactation.⁵⁶ In Sweden, 2.6% of pregnant women primarily of non-European origin were found to use skin-lightening products.⁵⁷

After absorption into the body, inorganic mercury is potentially distributed to all tissues.³ The liver and kidneys readily accumulate inorganic mercury.^{3, 58} Kidney damage is a sign of systemic mercury poisoning, with symptoms that range from mild to severe, including eventual death from acute kidney failure.^{59, 60} Hypersalivation, a metallic taste in the mouth, sores and swelling of the gums, abdominal pain, and nausea are disorders that may also be signs of systemic inorganic mercury poisoning, or acute poisoning from accidental ingestion.^{13,59} Because of poor solubility in fat, only a small percentage of inorganic mercury crosses the blood-brain barrier^y into the central nervous system (CNS),^z but prolonged exposure combined with slow elimination of mercury by the body will eventually result in accumulation in the CNS, and neurotoxicity.^{aa,3,61} A number of neuro-psychological manifestations, such as tremors, depression, anxiety and paranoid delusions may develop over time, and are sometimes irreversible, even if the mercury exposure terminates.^{13,58}

Symptoms of mercury poisoning are slow and insidious, and may be mistaken to have other causes, not least since patients may be reluctant to admit their use of skin-lightening products, because of the stigma surrounding this complexion-altering behavior. And the stigma is also the reason why existing estimates of the prevalence of skin-lightening in various parts of the world have most likely been underestimated.^{55, 62}

Onset and severity of health effects are associated with different exposure factors, such as the mercury concentration in the product, product compounds with varying solubility, skin characteristics, time length of exposures and other factors, all affecting mercury distribution in the body. Thus, mercury poisoning symptoms do not follow a standard pattern, posing an additional challenge for appropriate diagnosis. The renal system may be critically affected following inorganic mercury exposure. Several cases have been reported of decreased renal function after prolonged use (between 2 months and 18 years) of products containing ammoniated mercury. Nephrotic syndrome has also been reported in users averaging 13 months of use, with a certain degree of remission after use is discontinued.⁵⁸

Among others, the following cases were reported in California between 2010 and 2014.²⁰

- A 20month-old child diagnosed with mercury poisoning presented a 52 µg/g mercury urine level, presenting symptoms such as refusal to walk, irritability, difficulty sleeping, and poor appetite. Contamination occurred through the mother, who used a skin-lightening cream found to contain 38,000ppm of mercury.
- A teenager presented levels of 208 µg/g creatinine from a 24-h urine test. The patient presented symptoms such as weakness in legs; twitching of lower extremities, tongue

^w Clouding of the lens in the eye which leads to a decrease in vision.

^x Decrease in the total amount of red blood cells, i.e. a decrease in the oxygen carrying pigment hemoglobin in the blood.

^y A biological structure separating the central nervous system from the bloodstream. It is highly selective to the compounds that can pass from the blood into the central nervous system.

^z Brain and spinal cord.

^{aa} Toxic effects manifested as disturbances in the normal functions of the nervous system.

and lips; unsteady gait; delirium; agitation; sleep disturbances; profuse sweating; persistent tachycardia; and hypertension. Nine family members who were non-users also had elevated mercury levels. The cream used was found to contain 96,000-210,000 ppm mercury.

- A 39-year-old woman presented 482 µg/g creatinine; her 4-year-old child had 107 µg/g creatinine. The cosmetic cream was analyzed and found to contain 20,000 ppm-57,000 ppm mercury.^{bb}

Skin-lightening is not only a women's issue, although often regarded as such in the past, but is also a practice that is increasing among men.^{16, 17}

There are skin-lightening creams that are mercury free. However, they may contain other harmful chemicals, notably hydroquinone and steroids for which a range of side effects have been reported for hydroquinone and steroids in skin-bleaching creams.^{62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75} Hydroquinone is banned in the EU, as it is a suspected carcinogen.⁷⁶ In the USA, hydroquinone is allowed in concentrations up to 2% as an active ingredient in cosmetics, and up to 4% in prescription skin-lightening products.⁷⁷ Some of the skin-lightening creams in this study contained hydroquinone according to the ingredient lists on their packaging.

Mercury also has serious effects in the environment. Mercury is a unique metal in the sense that it can be both liquid and gaseous at room temperature, which makes it prone to long-range atmospheric transport and thus a pollutant of global distribution.^{13,14,15} Furthermore, it can be transformed by bacteria into organic forms that accumulate in the fatty tissue of living organisms and biomagnify^{cc} in food webs^{dd} in the ecosystems.¹⁵ Although cosmetics are not considered a key source of mercury to the environment, their production and use contribute to the overall environmental burden. For example, mercury from these products may eventually end up in wastewater when users of these creams wash their skin, or in municipal waste when creams are discarded.

^{bb} See <https://www.paho.org/hq/dmdocuments/2017/2017tn.mercury.products.pdf>

^{cc} Biomagnify implies that each organism in a food web acquires the accumulated burden of a chemical from its food source (plants or prey organisms), so that the concentration of the chemical increases in the food web from plants, grazers, lower-level predators, to top predators.

^{dd} A food web is a flowchart of who eats what in an ecological community. Humans, as top predators, are usually at the top of their food web.

Annex L: QACS laboratory methodology

The determination of mercury was assessed with atomic absorption spectrometry.

The apparatus was a Perkin Elmer Model Analyst 800 Atomic Absorption Spectrophotometer; equipped with a 4-inch burner head, mercury electrodeless discharge lamp (EDL). FIAS 100 Flow Injection Analysis System for Hydride generation with a quartz cell.

Parameter settings Hg

- I. Wavelength 253.7 nm
- II. Lamp current 185.0 mA
- III. Slit 0.7 nm High Slit
2. FIAS
 - I. FIAS flow (Argon) 100 ml / min.
 - II. Carrier solution 3 % (v/v) HCL
 - III. Reducing agent 0.2 % NaBH₄ in 0.05% NaOH
 - IV. Sample loop 500 µl
 - V. Read time 20s

For the sample preparation

Accurately weigh, to the nearest mg, 0.35 – 0.50 g of sample into a high-pressure resistance PTFE-TFM microwave digestion vessel. Avoid contact with the side of the vessel. Add 8 ml trace grade nitric acid, 1ml of trace grade hydrogen peroxide by using a graduated pipette. If samples contain talcum or pigment add 1ml of trace grade hydrochloric acid.

Close the vessel lid. Leave for about 15 minutes to ensure complete reaction. Digest in microwave digestion system at the specified program (Organic B).

After the digestion procedure has completed, allow the vessel to cool to room temperature before opening and the sample is transferred into a 50 ml volumetric flask and dilute with distilled water. If necessary, additional dilutions can be performed after this step, to bring the concentration of Mercury within the calibration range. 10 ml of the sample solution is transferred into a 20 ml volumetric flask, 0.2 ml of HCl 37% for trace metal and one to two drops of a 5% solution of KMnO₄ are added and the sample is diluted to volume with water.

Standard preparation

Prepare a working stock solution by dissolving 1 ml of the Mercury standard solution 1000g/L ± 0.002 into a 100 ml volumetric flask. 0.1, 0.2, 1.0 and 2.0 ml of the working stock are transferred into 20 ml volumetric flasks. Then 10 ml water are added, followed by 0.2 ml HCl 37% for trace metal and one to two drops of a 5% solution of KMnO₄, the standards are diluted to volume with water.

Blank preparation

Into a 20 ml volumetric flask is placed 15 ml water, 0.5 ml of HCl 37% and one to two drops of 5 % KMnO₄ added and the blank is diluted to volume with water.

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