Latest Regulation changes in Asia

Alain Khaiat, Ph. D.
President Seers Consulting
Lifetime Achievement Award in-cosmetics, Paris 2010
ASEAN TEN NATIONS, ONE COMMUNITY AND ONE STANDARD
<table>
<thead>
<tr>
<th>Country</th>
<th>Population</th>
<th>GDP/capita (World Bank) in $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brunei</td>
<td>0.4</td>
<td>71,800</td>
</tr>
<tr>
<td>Cambodia</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>Indonesia</td>
<td>252</td>
<td>9,600</td>
</tr>
<tr>
<td>Laos</td>
<td>6.7</td>
<td></td>
</tr>
<tr>
<td>Malaysia</td>
<td>30</td>
<td></td>
</tr>
<tr>
<td>Myanmar</td>
<td>51</td>
<td></td>
</tr>
<tr>
<td>Philippines</td>
<td>100</td>
<td>6,500</td>
</tr>
<tr>
<td>Singapore</td>
<td>5.5</td>
<td>78,750 (4th)</td>
</tr>
<tr>
<td>Thailand</td>
<td>66.7</td>
<td>14,400</td>
</tr>
<tr>
<td>Vietnam</td>
<td>92.5</td>
<td></td>
</tr>
</tbody>
</table>

**Total population: 620 MM**
ASEAN

- The ASEAN Cosmetic Directive (ACD) is in force in all 10 ASEAN member countries;
- The ACD is modeled after the EU Directive (6th amendment);
- Definition is same as EU, only one category of products;
- Ingredients are regulated by the annexes:
  - Annex II: banned ingredients;
  - Annex III: restricted ingredients;
  - Annex IV: positive list of colors;
  - Annex VI: positive list of preservatives;
  - Annex VII: positive list of UV filters;
Latest news

- Thailand has transposed the ACD into local regulations;
ASEAN Cosmetic Directive

The first amendment of the ACD will be discussed during the week of November 23 in Bangkok;
<table>
<thead>
<tr>
<th>Issue</th>
<th>Regulation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increase of non-tax revenue</td>
<td>Draft regulation</td>
<td>• Import license letter @ 100,000 Rp/product</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Notification fee for non-ASEAN product @ 1,500,000 Rp (instead of 500,000)</td>
</tr>
<tr>
<td>Pre-shipment inspection</td>
<td>MOT regulation 83/2012</td>
<td></td>
</tr>
<tr>
<td>Import tariff increase</td>
<td>MOF regulation 132/2015</td>
<td>Increase from 5% to 10-15%</td>
</tr>
<tr>
<td>Priority import license</td>
<td>Draft revision of BPOM</td>
<td>Priority is determined based on track record</td>
</tr>
<tr>
<td></td>
<td>regulation 27/2013</td>
<td></td>
</tr>
<tr>
<td>Issue</td>
<td>Regulation</td>
<td>Description</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>-----------------------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Heavy metal testing required in COA for imported products</td>
<td>Revision of BPOM regulation 27/2013</td>
<td>Each batch imported must be accompanied by a COA including heavy metal results</td>
</tr>
<tr>
<td>Halal certification</td>
<td>Law 33/2014 Presidential decree 83/2015</td>
<td>Products must be labeled “Halal” if they are certified or “non Halal” if they are not</td>
</tr>
<tr>
<td>Income tax on imported products</td>
<td>MOF 107/2015</td>
<td>Import tax of ~2.5% on imported cosmetics</td>
</tr>
<tr>
<td>Import license</td>
<td>MOT 54/M-DAG/PER/10/2009</td>
<td>Importers must acquire an import license before the goods enter the custom area. Failure result in loss of the importer permit and re-exportation of goods</td>
</tr>
</tbody>
</table>
Country specifics

- Indonesia:
  - Notification with quantitative formula;
  - Notification number must be printed on the packaging;
  - Mandatory expiry date;
  - Name of licensor if product made under license;
  - Name of primary manufacturer if product final pack is made by a different company;
  - Certificate of Free Sale;
  - Letter of representation legalized;
Country specifics

- Thailand:
  - Notification number to be printed;
  - Product picture and artwork need to be uploaded for some products;
Country specifics

- Vietnam:
  - Certificate of Free Sale;
  - Letter of representation legalized;
China

Population 1.35 billion
22 Provinces
5 Autonomous Regions
4 Direct controlled municipalities (Beijing, Chongqing, Shanghai, and Tianjin)
China

Population: 1.2 billion

© Seers Consulting
China today

- China regulation defines two categories:
  - “Normal cosmetics”;
  - “Special cosmetics”;

9 categories of special cosmetic based on the claim and formula:
1. Sunscreen
2. Spot corrector/Anti-pigmentation/ Whitening (claim related with anti-pigmentation, spot, melanin, etc)
3. Slimming,
4. Breast care
5. Hair growth
6. Hair colors
7. Perms
8. Deodorant
9. Depilatories
Additionally the requirements are very different for imported products vs. locally made products:

- Locally made “normal cosmetics”: notification file to be submitted to Provincial bureau, manufacturing can start before license approval. No submission of samples required;
- Imported products as well as locally made “special cosmetics”: a full dossier has to be submitted for registration to CFDA for review by the technical review expert committee. Samples have to be submitted as well: CFDA will have them tested for “hygienic-chemical” properties (i.e. Pb, As, Hg, methanol), toxicology (on animals) and sometimes efficacy (Sunscreen);
Local Testing are mandatory for product registration:
- Hygienic chemical tests – i.e. Mercury, Lead, Methanol, pH, etc.
- Microbiological tests – i.e. bacterial count, fecal coliforms, etc.
- Toxicological tests – i.e. eye irritation, skin irritation on rabbits, etc.

Selective Testing based on claims and formula:
- Human patch test;
- SPF/PA test: NEW foreign testing reports are now accepted;
- Human use test for safety;
- Impurity test i.e. asbestos in talc;
- Ingredients tests for “sunscreen, anti-spot, anti-acne” claim products;
Registration lead time is about 2 weeks for locally made “normal cosmetics” up to 12 + months for imported “special cosmetics”;
China

- CFDA has issued the list of ingredients that can be used in cosmetics: 8,783 ingredients are on the list vs. over 20,000 in INCI!
- If your product formula uses only ingredients from the list, you can submit it for registration;
- If you want to use an ingredient which is not on the list, you first have to register the ingredient;
- In the last 5 years only 3 ingredients have been approved!
- China positive list is a major blockage to innovation and consumers travel to other countries to buy the latest product they want!
China: new

- New Cosmetic Supervision and Administration Regulation (CSAR):
  - Draft published November 8, 2014 for comments;
  - revision published July 15, 2015 for further comments;
China: new

Key principles of CSAR:
- Responsibility of Manufacturer;
- Locally made and imported products are treated the same way;
- Product classification is based on risk assessment and claims;
- Oral care products will be classified as “cosmetics”;
- Reduction of the number of categories in “special cosmetics”;
China: new

- New ingredients: approach based on risk management. Notification with answer given in 90 days;
- Mandatory GMP compliance, Safety assessment, Substantiation and validation of claims, adverse effect monitoring and defective product recall;
- Consolidation of all licenses into one manufacturing license;
- New advertising law as of September 1, 2015;
China: new

- The new CSAR will be more aligned with International practices, focusing on consumer protection and will promote competitiveness as well as innovation;
India
Population 1.1 billion

28 states and 7 union territories divided into districts
Animal testing regulation

- Rule 145-C states “no person shall use any animal for cosmetic testing”;
- Draft rule 135-B reinforces: “no cosmetic tested on animal shall be imported”;

© Seers Consulting
GSR 137 related to metrology of packaged goods requires cosmetics to bear on the top of the main display panel a:
- Red or brown dot for non-vegetarian products;
- Green dot for vegetarian products;

The rule was published on 17 June 2014, with a date of application of 1st July 2014!
There is no definition of “vegetarian cosmetics”, there is no grace period;
Korea

- Cosmetics: no registration required, but need FSC, notarized formula and BSE certificate to import products. Lists of banned ingredients, positive lists for preservatives, colors, UV filters;
- Functional Cosmetics: Whitening, Sunscreen, anti-wrinkles. Positive list of active ingredients. Registration takes about 6 months;
- Quasi-Drug: acne, mouthwash, hair dyes, etc. registration takes about 10 months;
Korea New

- **Animal Testing Ban on Finished Cosmetics products** (Jan 2015) only when available in vitro tests are validated;
- New Cosmetic recall process;
- Stringent penalties put in place:
  - Absence of distribution manager: 3 months sales ban;
  - Violation of recall process: 6 months sales and manufacturing ban;
  - Advertising during an advertising ban: 3 months sales ban;
Korea New

- Anti bacterial claim not allowed unless for a cleansing products with in vivo supporting data;
- Organic claim not allowed unless it meets the Korea organic standard and 95% of the ingredients (except water and salt) are organic;
Cosmetic Regulation in Taiwan

Competent Authority: Taiwan FDA (TFDA)
Taiwan

- 2 categories: cosmetics or medicated cosmetics. Negative list, positive list for sunscreens, preservatives, colors, hair dyes, antibacterial, antiperspirant;
- Cosmetics: notification;
- Medicated cosmetics: e.g. acne, whitening, sunscreen: registration (~ 4/6 months);
Taiwan

- Alignment of the allowed colors with the EU Annex IV;
- Alignment of nanomaterial risk assessment with EU;
- Bill to ban animal testing has been introduced and pressure is high to pass soon;
THANK YOU