



## **Updated Annex of International Standards in Cosmetics Report**

At the July 2016 ICCR-10 meeting in Bethesda, Maryland, United States, the ICCR Steering Committee (SC) accepted the report of the Joint Regulators - Industry Working Group: "International Standards in Cosmetics" which was then published on the ICCR website.

The recommendation from that meeting was that in three years, the Chair of ICCR-13 would make certain that Table 1, included in the report's annex, would be updated. Further, and that it was expected the table would be updated every 3 years thereafter.

At the July 2018 ICCR-12 meeting in Tokyo, Japan, the ICCR SC agreed to reopen the Joint Working Group on International Standards to update the table of relevant ISO standards.

The Joint Working Group presented the updated Table 1 for the July 2019 ICCR-13 meeting in Montreal, Canada with a recommendation that Table 1 be reviewed annually.

At the July 2019 ICCR-13 meeting in Montreal, Canada, the ICCR SC decided that the ICCR Chair of each respective ICCR cycle will monitor publication of new ISO standards and technical reports on a yearly basis. The SC also agreed that the terminology in the legend will be revised to accurately describe the activity status in each jurisdiction.

The Brazilian Health Regulatory Agency coordinated the annual review of Table 1 in its role as ICCR-17 Chair. For the latest update refer to Table 1, at the end of this document.

**Table 1: State-of-play of ISO Technical Committee 217 - cosmetics standards, technical specifications and technical reports in ICCR Jurisdictions – July 2023**

International Standards													
	Standard number	Standard Title	Theme / WG	Revised	Next planned revision*	BRAZIL	CANADA	CHINESE TAIPEI	EUROPEAN UNION	ISRAEL	JAPAN	REPUBLIC OF KOREA	UNITED STATES OF AMERICA
1.	ISO 10130:2009	Cosmetics - Analytical methods - Nitrosamines: Detection and determination of N-nitroso diethanolamine (NDELA) in cosmetics by HPLC, post-column photolysis and derivatization	Analytical methods	2021	2026	Endorsed	Endorsed <sup>1</sup>	Under Review	Reviewed	Under Review	Reviewed	Adopted (KS M ISO 10130)	Under Review <sup>1</sup>
2.	ISO 12787:2011	Cosmetics - Analytical methods - Validation criteria for analytical results using chromatographic techniques	Analytical methods	2022	2027	Endorsed	Endorsed <sup>1</sup>	Under Review	Reviewed	Under Review	Reviewed	Adopted (KS M ISO 12787)	Under Review <sup>1</sup>
3.	ISO 15819:2014	Cosmetics - Analytical methods - Nitrosamines: Detection and determination of N-nitroso diethanolamine (NDELA) in cosmetics by HPLC-MS-MS	Analytical methods	2020	2025	Endorsed	Endorsed <sup>1</sup>	Referenced	Reviewed	Under Review	Reviewed	Under Review	Under Review <sup>1</sup>
4.	ISO 21392:2021	Cosmetics — Analytical methods — Measurement of traces of heavy metals in cosmetic finished products using ICP/MS technique	Analytical methods	2021	2026	Endorsed	Under Review	Under Review	Adopted EN ISO 21392:2021 (Vienna agreement)	Under Review	Under Review	Endorsed <sup>1</sup>	Under Review <sup>1</sup>

\* ISO strives to review standards every 5 years.

International Standards													
	Standard number	Standard Title	Theme / WG	Revised	Next planned revision*	BRAZIL	CANADA	CHINESE TAIPEI	EUROPEAN UNION	ISRAEL	JAPAN	REPUBLIC OF KOREA	UNITED STATES OF AMERICA
5.	ISO 22716:2007	Cosmetics - Good Manufacturing Practices (GMP) - Guidelines on Good Manufacturing Practices	GMP	2022	2027	Reviewed <sup>1</sup>	Referenced <sup>2,3</sup>	Adopted <sup>1</sup>	Referenced EN ISO 22716:2007 (Vienna agreement) <sup>1</sup>	Adopted <sup>1</sup> (22716 י"ת) And Referenced	Endorsed <sup>1,3</sup>	Adopted (KS M ISO 22716)	Referenced <a href="https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-cosmetic-good-manufacturing-practices">https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-cosmetic-good-manufacturing-practices</a> ; <a href="https://www.fda.gov/media/78441/download">https://www.fda.gov/media/78441/download</a>
6.	ISO 11930:2019/ Amd 1: 2022	Cosmetics - Microbiology - Evaluation of the antimicrobial protection of a cosmetic product	Microbiology	2022	2027	Endorsed	Endorsed <sup>1</sup>	Referenced	Adopted EN ISO 11930:2019 (Vienna agreement) <sup>2</sup>	Under Review	Under Review	Adopted (KS M ISO 11930)	Under Review <sup>1</sup>
7.	ISO 16212:2017	Cosmetics - Microbiology - Enumeration of yeast and mould	Microbiology	2022	2027	Endorsed	Endorsed <sup>1</sup>	Under Review	Adopted EN ISO 16212:2017 (Vienna agreement) <sup>2</sup>	Under Review	Under Review	Adopted (KS M ISO 16212)	Under Review <sup>1</sup>
8.	ISO 17516:2014	Cosmetics - Microbiology - Microbiological limits	Microbiology	2020	2025	Reviewed <sup>2</sup>	Referenced <sup>2,3</sup>	Reviewed <sup>2</sup>	Referenced (SCCS Notes of Guidance) Adopted EN ISO 17516:2014 (Vienna agreement)	Referenced <sup>2</sup>	Endorsed <sup>1</sup>	Reviewed <sup>1</sup>	Under Review <sup>1</sup>
9.	ISO 18415:2017	Cosmetics - Microbiology - Detection of specified and non-specified microorganisms	Microbiology	2022	2027	Endorsed	Endorsed <sup>1</sup>	Under Review	Adopted EN ISO 18415:2017 (Vienna agreement)	Under Review	Under Review	Adopted (KS M ISO 18415)	Under Review <sup>1</sup>

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International Standards													
	Standard number	Standard Title	Theme / WG	Revised	Next planned revision*	BRAZIL	CANADA	CHINESE TAIPEI	EUROPEAN UNION	ISRAEL	JAPAN	REPUBLIC OF KOREA	UNITED STATES OF AMERICA
10.	ISO 18416:2015	Cosmetics - Microbiology - Detection of <i>Candida albicans</i>	Microbiology	2021	2026	Endorsed	Endorsed <sup>1</sup>	Referenced	Adopted EN ISO 18416:2015 (Vienna agreement) <sup>2</sup>	Under Review	Under Review	Adopted (KS M ISO 18416)	Under Review <sup>1</sup>
11.	ISO 21148:2017	Cosmetics - Microbiology - General instructions for microbiological examination	Microbiology	2022	2027	Adopted (ABNT NBR ISO 21148:2008) <sup>3</sup>	Endorsed <sup>1</sup>	Under Review	Adopted EN ISO 21148:2017 (Vienna agreement) <sup>2</sup>	Under Review	Under Review	Adopted (KS M ISO 21148)	Under Review <sup>1</sup>
12.	ISO 21149:2017	Cosmetics - Microbiology - Enumeration and detection of aerobic mesophilic bacteria	Microbiology	2022	2027	Adopted (ABNT NBR ISO 21149:2008) <sup>3</sup>	Endorsed <sup>1</sup>	Referenced	Adopted EN ISO 21149:2017 (Vienna agreement) <sup>2</sup>	Under Review	Under Review	Adopted (KS M ISO 21149)	Under Review <sup>1</sup>
13.	ISO 21150:2015	Cosmetics - Microbiology - Detection of <i>Escherichia coli</i>	Microbiology	2021	2026	Adopted (ABNT NBR ISO 21150:2020)	Endorsed <sup>1</sup>	Referenced	Adopted EN ISO 21150:2015 (Vienna agreement) <sup>2</sup>	Under Review	Under Review	Adopted (KS M ISO 21150)	Under Review <sup>1</sup>
14.	ISO 22717:2015	Cosmetics - Microbiology - Detection of <i>Pseudomonas aeruginosa</i>	Microbiology	2021	2026	Adopted (ABNT NBR ISO 22717:2020)	Endorsed <sup>1</sup>	Referenced	Adopted EN ISO 22717:2015 (Vienna agreement) <sup>2</sup>	Under Review	Under Review	Adopted (KS M ISO 22717)	Under Review <sup>1</sup>
15.	ISO 22718:2015	Cosmetics - Microbiology - Detection of <i>Staphylococcus aureus</i>	Microbiology	2021	2026	Adopted (ABNT NBR ISO 22718:2020)	Endorsed <sup>1</sup>	Referenced	Adopted EN ISO 22718:2015 (Vienna agreement) <sup>2</sup>	Under Review	Under Review	Adopted (KS M ISO 22718)	Under Review <sup>1</sup>
16.	ISO 29621:2017	Cosmetics - Microbiology - Guidelines for the risk assessment and identification of microbiologically low-risk products	Microbiology	2022	2027	Endorsed	Endorsed <sup>1</sup>	Endorsed	Adopted EN ISO 29621:2017 (Vienna agreement) <sup>2</sup>	Under Review	Under Review	Under Review	Under Review <sup>1</sup>
17.	ISO 21322:2020	Cosmetics — Microbiology — Testing of impregnated or coated wipes and masks	Microbiology	2020	2025	Endorsed	Under Review	Under Review	Adopted EN ISO 21322:2020 (Vienna agreement)	Under Review	Under Review	Under Review	Under Review <sup>1</sup>

\* ISO strives to review standards every 5 years.

International Standards													
	Standard number	Standard Title	Theme / WG	Revised	Next planned revision*	BRAZIL	CANADA	CHINESE TAIPEI	EUROPEAN UNION	ISRAEL	JAPAN	REPUBLIC OF KOREA	UNITED STATES OF AMERICA
18.	ISO 22715:2006	Cosmetics - Packaging and labelling	Pack and label	2022	2027	Reviewed	Endorsed <sup>6</sup>	Reviewed <sup>3</sup>	Reviewed	Under Review	Reviewed	Adopted (KS M ISO 22715)	Reviewed <sup>4</sup>
19.	ISO 24443:2021	Determination of sunscreen UVA photoprotection in vitro	Sun protection	2021	2026	Endorsed	Endorsed <sup>1</sup>	Endorsed	Referenced (indirectly via EU Recommendation 2006) Adopted EN ISO 24443:2021 (Vienna agreement) <sup>3</sup>	Referenced <sup>3</sup>	Reviewed	Adopted (KS M ISO 24443)	Reviewed <sup>2</sup>
20.	ISO 24444:2019	Cosmetics - Sun protection test methods - In vivo determination of the sun protection factor (SPF)	Sun protection	2019	2024	Endorsed	Referenced <sup>5,6</sup>	Referenced <sup>4</sup>	Referenced (Indirectly via EU Recommendation 2006) Adopted EN ISO 24444:2020 (Vienna agreement) <sup>3</sup>	Referenced <sup>3</sup>	Endorsed <sup>1,3</sup>	Endorsed <sup>4</sup>	Reviewed <sup>2</sup>
21.	ISO 16217:2020	Cosmetics — Sun protection test methods — Water immersion procedure for determining water resistance	Sun protection	2020	2025	Reviewed	Under Review	Under Review	Adopted EN ISO 16217:2021 (Vienna agreement) <sup>3</sup>	Reviewed	Reviewed	Endorsed <sup>4</sup>	Reviewed <sup>2</sup>
22.	ISO 18861:2020	Cosmetics - Sun protection test methods - Percentage of water resistance	Sun protection	2020	2025	Reviewed	Under Review	Under Review	Adopted EN ISO 18861:2021 (Vienna agreement)	Reviewed	Endorsed <sup>1,3</sup>	Reviewed <sup>5</sup>	Reviewed <sup>2</sup>

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International Standards													
	Standard number	Standard Title	Theme / WG	Revised	Next planned revision*	BRAZIL	CANADA	CHINESE TAIPEI	EUROPEAN UNION	ISRAEL	JAPAN	REPUBLIC OF KOREA	UNITED STATES OF AMERICA
23.	ISO 24442:2011	Cosmetics - Sun protection test methods - In vivo determination of sunscreen UVA protection	Sun protection	2022	2027	Endorsed	Referenced <sup>6,7</sup>	Referenced	Referenced (Indirectly via EU Recommendation 2006) Adopted EN ISO 24442:2011 (Vienna agreement) <sup>3</sup>	Referenced <sup>3</sup>	Endorsed <sup>1,3</sup>	Adopted (KS M ISO 24442)	Reviewed <sup>2</sup>
24.	ISO 16128-1:2016	Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients and products - Part 1: Definitions for ingredients	Terminology	2022	2027	Under Review	Endorsed <sup>8</sup>	Endorsed	Endorsed	Referenced <sup>4</sup>	Endorsed <sup>2,3</sup>	Reviewed <sup>2</sup>	Reviewed <sup>3</sup>
25.	ISO 16128-2:2017	Cosmetics -- Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients -- Part 2: Criteria for ingredients and products	Terminology	2022	2027	Under Review	Endorsed <sup>10</sup>	Endorsed	Endorsed	Referenced <sup>4</sup>	Endorsed <sup>2,3</sup>	Reviewed <sup>2</sup>	Reviewed <sup>3</sup>
26.	ISO 23674:2022	Cosmetics — Analytical methods — Direct determination of traces of mercury in cosmetics by thermal decomposition and atomic absorption spectrometry (mercury analyser)	Analytical methods	2022	2027	Endorsed	Under Review	Under Review	Adopted EN ISO 23674:2022 (Vienna agreement) <sup>3</sup>	Under Review	Under Review	Under Review	Reviewed
27.	ISO23821:2022	Cosmetics — Analytical methods — Determination of traces of mercury in cosmetics by atomic absorption spectrometry (AAS) cold vapour technology after pressure digestion	Analytical methods	2022	2027	Endorsed	Under Review	Under Review	Adopted EN ISO 23821:2022 (Vienna agreement) <sup>3</sup>	Under Review	Under Review	Under Review	Reviewed

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Technical Specifications													
	Technical specification number	Technical Specification Title	Theme / WG	Revised	Next planned revision**	BRAZIL	CANADA	CHINESE TAIPEI	EUROPEAN UNION	ISRAEL	JAPAN	REPUBLIC OF KOREA	UNITED STATES OF AMERICA
1	ISO/TS 22176:2020	Cosmetics — Analytical methods — Development of a global approach for validation of quantitative analytical methods	Analytical methods	2023	2026	Endorsed	Under Review	Under Review	Reviewed	Under Review	Under Review	Under Review	Reviewed

Technical Reports													
	Technical report number	Technical Report Title	Theme / WG	Revised	Next planned revision	BRAZIL	CANADA	CHINESE TAIPEI	EUROPEAN UNION	ISRAEL	JAPAN	REPUBLIC OF KOREA	UNITED STATES OF AMERICA
1	ISO/TR 14735:2013	Cosmetics - Analytical methods - Nitrosamines: Technical guidance document for minimizing and determining N-nitrosamines in cosmetics	Analytical methods	2013	Not applicable	Endorsed	Endorsed <sup>9</sup>	Under Review	Reviewed <sup>4</sup>	Under Review	Reviewed	Under Review	Under Review <sup>1</sup>
2	ISO/TR 17276:2014	Cosmetics - Analytical approach for screening and quantification methods for heavy metals in cosmetics	Analytical methods	2014	Not applicable	Endorsed	Endorsed <sup>9</sup>	Under Review	Reviewed <sup>4</sup>	Under Review	Reviewed	Under Review	Under Review <sup>1</sup>
3	ISO/TR 18818:2017	Cosmetics -- Analytical method -- Detection and quantitative determination of Diethanolamine (DEA) by GC/MS	Analytical methods	2017	Not applicable	Endorsed	Reviewed	Under Review	Reviewed	Under Review	Reviewed	Under Review	Under Review <sup>1</sup>
4	ISO/TR 18811:2018	Cosmetics -- Guidelines on the stability testing of cosmetic products	Analytical methods	2018	Not applicable	Endorsed	Reviewed	Under Review	Reviewed	Under Review	Reviewed	Under Review <sup>6</sup>	Reviewed <sup>5</sup>

\*\* ISO strives to review technical specifications standards every 3 years.

Technical Reports													
	Technical report number	Technical Report Title	Theme / WG	Revised	Next planned revision	BRAZIL	CANADA	CHINESE TAIPEI	EUROPEAN UNION	ISRAEL	JAPAN	REPUBLIC OF KOREA	UNITED STATES OF AMERICA
5	ISO/TR 24475:2010	Cosmetics - Good Manufacturing Practices - General training document	GMP	2010	Not applicable	Reviewed	Endorsed <sup>9</sup>	Endorsed	Under Review <sub>5</sub>	Under Review	Endorsed <sup>1,3</sup>	Endorsed <sup>3</sup>	Under Review <sup>1</sup>
6	ISO/TR 26369:2009	Cosmetics - Sun protection test methods - Review and evaluation of methods to assess the photoprotection of sun protection products	Sun protection	2009	Not applicable	Endorsed	Endorsed <sup>9</sup>	Under Review	Under Review <sub>5</sub>	Under Review	Reviewed	Reviewed <sup>5</sup>	Reviewed <sup>2</sup>
7	ISO/TR 19838:2016	Microbiology -- Cosmetics - Guidelines for the application of ISO standards on Cosmetic Microbiology	Microbiology	2016	Not applicable	Endorsed	Reviewed	Under Review	Under Review <sub>5</sub>	Under Review	Reviewed	Under Review	Under Review <sup>1</sup>
8	ISO/TR 22582:2019	Cosmetics -- Methods of extract evaporation and calculation of organic indexes -- Supplemental information to use with ISO 16128-2	Terminology	2019	Not applicable	Under Review	Reviewed	Endorsed	Reviewed	Under Review	Under Review	Under Review	Reviewed <sup>3</sup>
9	ISO/TR 23199:2019	Cosmetics -- Calculation of organic indexes of hydrolates -- Supplemental information for ISO 16128-2	Terminology	2019	Not applicable	Under Review	Reviewed	Endorsed	Reviewed	Under Review	Under Review	Under Review	Reviewed <sup>3</sup>
10	ISO/TR 23750:2021	Cosmetics — Answers to frequently asked questions on ingredients and product characterization according to ISO 16128-1 and ISO 16128-2	Terminology	2021	Not applicable	Under Review	Under Review	Endorsed	Reviewed	Under Review	Endorsed <sup>2,3</sup>	Under Review	Reviewed <sup>3</sup>



Answer	Elucidation
<b>Adopted</b>	ISO standard has been translated and adopted or is intended to be adopted, without major changes, as a national/regional standard. Please refer the number of the national /regional standard.
<b>Aligned</b>	ISO standard has been translated and adopted, but with modification, to account for national specificities and needs. Please refer the number of the national /regional standard.
<b>Referenced</b>	ISO standard is explicitly taken as a reference in the Regulation or in other official publications.
<b>Endorsed</b>	If none of the above, it is applied or used by stakeholders, such as industry, without national adoption for products/processes/services in your country.
<b>Under Review</b>	ISO standard is known and being reviewed, but no decision is made.
<b>Reviewed</b>	ISO standard was reviewed, but is not taken into account.

<b>BRAZIL</b>	<ol style="list-style-type: none"> <li>- The Brazilian normative RDC 48/2013 is based on ISO 22716:2007, but has additional requirements.</li> <li>- The Brazilian normative RDC 752/2022 defines microbiological limit for cosmetics. It's similar to ISO 17516:2014, but few requirements are different.</li> <li>- The ISO standard has been adopted in 2008, without major changes, but the ABNT NBR ISO was not updated.</li> </ol>
<b>CANADA</b>	<ol style="list-style-type: none"> <li>- CAC encourages consideration of ISO methods, where appropriate; will direct members to the availability of this method, as required</li> <li>- HC website directs stakeholders to ISO standard (<a href="http://hc-sc.gc.ca/cps-spc/cosmet-person/regulations-reglements/gmp_cosmet-bpf-eng.php">http://hc-sc.gc.ca/cps-spc/cosmet-person/regulations-reglements/gmp_cosmet-bpf-eng.php</a>)</li> <li>- CAC encourages consideration of ISO standards, where appropriate; will direct members to the availability of this standard and highlight incorporation by reference in HC guidance, as required</li> <li>- CAC will direct members to the availability of this guidance, as required</li> <li>- Referred to in HC Guidance Document – Sunscreen Monograph (<a href="http://www.hc-sc.gc.ca/dhp-mps/consultation/natur/sunscreen-ecransolaire-eng.php">http://www.hc-sc.gc.ca/dhp-mps/consultation/natur/sunscreen-ecransolaire-eng.php</a>)</li> <li>- CAC encourages consideration of ISO methods, where appropriate; will direct members to the availability of this method and highlight incorporation by reference in HC guidance, as required</li> <li>- 2009 version referred to in HC Guidance Document – Sunscreen Monograph (<a href="http://www.hc-sc.gc.ca/dhp-mps/consultation/natur/sunscreen-ecransolaire-eng.php">http://www.hc-sc.gc.ca/dhp-mps/consultation/natur/sunscreen-ecransolaire-eng.php</a>)</li> <li>- CAC will direct members to the availability of this guidance, as required</li> <li>- CAC encourages consideration of ISO technical reports, where appropriate; will direct members to the availability of this report, as required</li> <li>- HC website provides information about natural and organic claims for cosmetics (<a href="https://www.canada.ca/en/health-canada/services/cosmetics/cosmetic-advertising-labelling-ingredients.html">https://www.canada.ca/en/health-canada/services/cosmetics/cosmetic-advertising-labelling-ingredients.html</a>)</li> </ol>
<b>CHINESE TAIPEI</b>	<ol style="list-style-type: none"> <li>The Regulations are formulated in reference to the ISO 22716: Cosmetics-Good manufacturing practice (GMP)-Guidelines on good manufacturing practices.</li> <li>The Microorganisms limits in cosmetic products (Wei-Shou-Shi-Zi No. 1101606101) is based on part of ISO 17516:2014.</li> <li>The labelling requirements are stated in Article 7 of the Cosmetic Hygiene and Safety Act.</li> <li>Taiwan FDA guideline refers to 2010 version.</li> </ol>
<b>EUROPE</b>	<ol style="list-style-type: none"> <li>- Citation in OJEU: 2011-04-21 developed in the framework of the M/375 Mandate</li> <li>- Developed in the framework of the M/426 Mandate</li> <li>- To be discussed</li> <li>- Transposes at national level (e.g. France)</li> <li>- EN ISO TR (Vienna agreement)</li> </ol>

<b>ISRAEL</b>	<ol style="list-style-type: none"> <li>1 - 2012 the standard was officially recognized in Israel, in 2021 the standard became mandatory according to the Pharmacists' Ordinance.</li> <li>2 - In the Pharmacists' Ordinance and the Pharmacists' Regulations there is a reference to the microbiological limits in the standard.</li> <li>3 - Pharmacist regulations</li> <li>4 - There is a guide regarding natural, organic and herbal claims that, among other things, refers to this standard.</li> </ol>
<b>JAPAN</b>	<ol style="list-style-type: none"> <li>1 - Endorsed as JCIA's self-regulatory standard</li> <li>2 - Endorsed as JCIA's industry guideline</li> <li>3 - Translated into Japanese and published from Japanese Industrial Standards Committee</li> </ol>
<b>REPUBLIC OF KOREA</b>	<ol style="list-style-type: none"> <li>1 - MFDS provides the related regulations.</li> <li>2 - MFDS regulates the natural and organic cosmetic relevant standards in the Act and provides cosmetic labelling and advertisement management guidelines.</li> <li>3 - MFDS provides the regulations and guidelines of the standards for safety management after manufacturing and quality control of good cosmetics to align with ISO standards but not the same.</li> <li>4 - Sun blocks are categorized as functional cosmetics in Korea. MFDS provides the regulations for qualification test for functional cosmetics and adopted additional ISO testing methods.</li> <li>5 - Sun blocks are categorized as functional cosmetics in Korea. MFDS provides the regulations for qualification test for functional cosmetics.</li> <li>6 - MFDS provides the related guidelines.</li> </ol>
<b>USA</b>	<ol style="list-style-type: none"> <li>1 - FDA is internally discussing this standard</li> <li>2 - If ICCR wants to consider this, we will need to involve FDA's CDER</li> <li>3 - FDA does not regulate use of the term "organic." US Dept. of Agriculture does. "Natural" is not an FDA regulated term.</li> <li>4 - Not Considered. - FDA regulations for cosmetics cover "Labelling", not "Packaging" (21 CFR 701). Conflicts with ICCR ToR not to require changes to Member statutes or regulations.</li> <li>5 - Not considered. - FDA cGMP regulations for drugs cover "stability testing" (21 CFR 211.166); there are no comparable regulatory mandates for cosmetics.</li> </ol>