



Updated Annex of Report International Standards in Cosmetics

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 the Chair of ICCR-13 would make certain that the Table 1, included in the report's annex, be updated 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 European Commission coordinated the annual review of Table 1 in its role of ICCR-14 Chair. The following table consists of updated or new standards, technical specifications and technical reports during the period August 2019 – September 2020. The terminology in the legend has also been revised and agreed upon by regulators and industry.

Past updates of Table 1 may be found at: <https://iccr-cosmetics.org/>.

Table 1: State-of-play of ISO Technical Committee 217 - cosmetics standards, technical specifications and technical reports in ICCR Jurisdictions – September 2020 (ISO strives to review standards every 5 years)

International Standards										
	Standard number	Standard Title	Theme / WG	Published	Next planned revision	BRAZIL	CANADA	EUROPEAN UNION	JAPAN	UNITED STATES OF AMERICA
1.	ISO 10130:2009	Cosmetics - Analytical methods - Nitrosamines: Detection and determination of N-nitrosodiethanolamine (NDELA) in cosmetics by HPLC, post-column photolysis and derivatization	Analytical methods	2009 2015	2021	Endorsed	Endorsed ¹	Reviewed	Reviewed	Under Review ¹
2.	ISO 12787:2011	Cosmetics - Analytical methods - Validation criteria for analytical results using chromatographic techniques	Analytical methods	2011 2017	2023	Endorsed	Endorsed ¹	Reviewed	Reviewed	Under Review ¹
3.	ISO 15819:2014	Cosmetics - Analytical methods - Nitrosamines: Detection and determination of N-nitrosodiethanolamine (NDELA) in cosmetics by HPLC-MS-MS	Analytical methods	2014 2020	2025	Endorsed	Endorsed ¹	Reviewed	Reviewed	Under Review ¹
4.	ISO 22716:2007	Cosmetics - Good Manufacturing Practices (GMP) - Guidelines on Good Manufacturing Practices	GMP	2007 2011 2017	2023	Reviewed ¹	Referenced ^{2,3}	Referenced EN ISO 22716:2007 (Vienna agreement) ¹	Endorsed ^{1,3}	Referenced https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-cosmetic-good-manufacturing-practices ; https://www.fda.gov/media/78441/download

International Standards										
	Standard number	Standard Title	Theme / WG	Published	Next planned revision	BRAZIL	CANADA	EUROPEAN UNION	JAPAN	UNITED STATES OF AMERICA
5.	ISO 11930:2019	Cosmetics - Microbiology - Evaluation of the antimicrobial protection of a cosmetic product	Microbiology	2012 2019	2025	Endorsed	Endorsed ¹	Adopted EN ISO 11930:2012; (Vienna agreement) ²	Under Review	Under Review ¹
6.	ISO 16212:2017	Cosmetics - Microbiology - Enumeration of yeast and mould	Microbiology	2008 2015 2017	2023	Endorsed	Endorsed ¹	Adopted EN ISO 16212:2008; (Vienna agreement) ²	Under Review	Under Review ¹
7.	ISO 17516:2014	Cosmetics - Microbiology - Microbiological limits	Microbiology	2014 2020	2025	Reviewed ²	Referenced ^{2,3}	Referenced (SCCS Notes of Guidance) Adopted EN ISO 17516:2014 (Vienna agreement)	Endorsed ¹	Under Review ¹
8.	ISO 18415:2017	Cosmetics - Microbiology - Detection of specified and non-specified microorganisms	Microbiology	2007 2015 2017	2023	Endorsed	Endorsed ¹	Adopted EN ISO 18415:2007 (Vienna agreement)	Under Review	Under Review ¹
9.	ISO 18416:2015	Cosmetics - Microbiology - Detection of <i>Candida albicans</i>	Microbiology	2007 2015	2021	Endorsed	Endorsed ¹	Adopted EN ISO 18416:2016; ² (Vienna agreement) ²	Under Review	Under Review ¹
10.	ISO 21148:2017	Cosmetics - Microbiology - General instructions for microbiological examination	Microbiology	2006 2015 2017	2023	Adopted (ABNT NBR ISO 21148:2008) ³	Endorsed ¹	Adopted EN ISO 21148:2017; (Vienna agreement) ²	Under Review	Under Review ¹
11.	ISO 21149:2017	Cosmetics - Microbiology - Enumeration and detection of aerobic mesophilic bacteria	Microbiology	2006 2015 2017	2023	Adopted (ABNT NBR ISO 21149:2008) ³	Endorsed ¹	Adopted EN ISO 21149:2017; (Vienna agreement) ²	Under Review	Under Review ¹
12.	ISO 21150:2015	Cosmetics - Microbiology - Detection of <i>Escherichia coli</i>	Microbiology	2006 2015	2021	Adopted (ABNT T NBR ISO 21150:2020)	Endorsed ¹	Adopted EN ISO 21150:2015; (Vienna agreement) ²	Under Review	Under Review ¹
13.	ISO 22717:2015	Cosmetics - Microbiology - Detection of <i>Pseudomonas aeruginosa</i>	Microbiology	2006 2015	2021	Adopted (ABNT NBR ISO 22717:2020)	Endorsed ¹	Adopted EN ISO 22717:2015; ² (Vienna agreement) ²	Under Review	Under Review ¹

International Standards										
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14	ISO 22718:2015	Cosmetics - Microbiology - Detection of <i>Staphylococcus aureus</i>	Microbiology	2006 2015	2021	Adopted (ABNT NBR ISO 22718:2020)	Endorsed ¹	Adopted EN ISO 22718:2015 (Vienna agreement) ²	Under Review	Under Review ¹
15	ISO 29621:2017	Cosmetics - Microbiology - Guidelines for the risk assessment and identification of microbiologically low-risk products	Microbiology	2010 2017	2023	Endorsed	Endorsed ¹	Reviewed	Under Review	Under Review ¹
16	ISO 21322:2020	Cosmetics — Microbiology — Testing of impregnated or coated wipes and masks	Microbiology	2020	2025	Endorsed	Under Review	Under Review	Under Review	Under Review ¹
17	ISO 22715:2006	Cosmetics - Packaging and labelling	Pack and label	2006 2012 2016	2022	Reviewed	Endorsed ⁶	Reviewed	Reviewed	Reviewed ⁴
18	ISO 24443:2012	Determination of sunscreen UVA photoprotection in vitro	Sun protection	2012	Under revision	Endorsed	Endorsed ¹	Referenced (indirectly via EU Recommendation 2006) Adopted EN ISO 24443:2012 (Vienna agreement) ³	Reviewed	Under Review ²
19	ISO 24444:2019	Cosmetics - Sun protection test methods - In vivo determination of the sun protection factor (SPF)	Sun protection	2010 2019	2024	Endorsed	Referenced ^{7,8}	Referenced (indirectly via EU Recommendation 2006) Adopted EN ISO 24444:2020 (Vienna agreement) ³	Endorsed ^{1,4}	Under Review ²
20	ISO 16217:2020	Cosmetics — Sun protection test methods — Water immersion procedure for determining water resistance	Sun protection	2020	2025	Reviewed	Under Review	Under Review	Under Review	Under Review ²

International Standards										
	Standard number	Standard Title	Theme / WG	Published	Next planned revision	BRAZIL	CANADA	EUROPEAN UNION	JAPAN	UNITED STATES OF AMERICA
21	ISO 18861:2020	Cosmetics - Sun protection test methods - Percentage of water resistance	Sun protection	2020	2025	Reviewed	Under Review	Under Review	Under Review	Under Review ²
22	ISO 24442:2011	Cosmetics - Sun protection test methods - In vivo determination of sunscreen UVA protection	Sun protection	2011	Under Revision	Endorsed	Referenced ^{8,9}	Referenced (indirectly via EU Recommendation 2006) Adopted EN ISO 24442:2011 (Vienna agreement) ³	Endorsed ^{1,3}	Under Review ²
23	ISO 16128-1:2016	Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients and products - Part 1: Definitions for ingredients	Terminology	2016	2022	Under Review	Endorsed ¹⁰	Endorsed	Endorsed ^{2,3}	Under Review ³
24	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	2017	2023	Under Review	Endorsed ¹²	Endorsed	Endorsed ^{2,3}	Under Review ³

Technical Specifications										
	Technical specification number	Technical Specification Title	Theme / WG	Published	Next planned revision	BRAZIL	CANADA	EUROPEAN UNION	JAPAN	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	2020	Not applicable	Endorsed	Under Review	Under Review	Under Review	Under Review ¹

Technical Reports										
	Technical report number	Technical Report Title	Theme / WG	Published	Next planned revision	BRAZIL	CANADA	EUROPEAN UNION	JAPAN	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 ¹¹	Reviewed ⁵	Reviewed	Under Review ¹
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 ¹¹	Reviewed ⁵	Reviewed	Under Review ¹
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	Reviewed	Reviewed	Under Review ¹
4	ISO/TR 18811:2018	Cosmetics -- Guidelines on the stability testing of cosmetic products	Analytical methods	2018	Not applicable	Endorsed	Reviewed	Reviewed	Reviewed	Reviewed ⁵
5	ISO/TR 24475:2010	Cosmetics - Good Manufacturing Practices - General training document	GMP	2010	Not applicable	Reviewed	Endorsed ¹¹	Under Review ⁶	Endorsed ^{1,3}	Under Review ¹
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 ¹¹	Under Review ⁶	Reviewed	Under Review ²

Technical Reports										
	Technical report number	Technical Report Title	Theme / WG	Published	Next planned revision	BRAZIL	CANADA	EUROPEAN UNION	JAPAN	UNITED STATES OF AMERICA
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 ⁶	Reviewed	Under Review ¹
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	Reviewed	Under Review	Under Review ³
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	Reviewed	Under Review	Under Review ³

Answer	Elucidation
Adopted	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.
Aligned	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.
Referenced	ISO standard is explicitly taken as a reference in the Regulation or in other official publications.
Endorsed	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.
Under Review	ISO standard is known and being reviewed, but no decision is made.
Reviewed	ISO standard was reviewed, but is not taken into account.

BRAZIL	<p>1 - The Brazilian normative RDC 48/2013 is based on ISO 22716:2007, but has additional requirements.</p> <p>2 - The Brazilian normative Res 481/1999 defines microbiological limit for cosmetics. It's similar to ISO 17516:2014, but few requirements are different.</p> <p>3 - The ISO standard has been adopted in 2008, without major changes, but the ABNT NBR ISO was not updated.</p>
CANADA	1 - CAC encourages consideration of ISO methods, where appropriate; will direct members to the availability of this method, as required

	<p>2 - HC website directs stakeholders to ISO standard (http://hc-sc.gc.ca/cps-spc/cosmet-person/regulations-reglements/gmp_cosmet-bpf-eng.php)</p> <p>3 - 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</p> <p>4 - HC waiting for recommendation from ICCR WG</p> <p>5 - CAC encourages consideration of ISO standards, where appropriate; will direct members to the availability of these limits, as required</p> <p>6 - CAC will direct members to the availability of this guidance, as required</p> <p>7 - Referred to in HC Guidance Document – Sunscreen Monograph (http://www.hc-sc.gc.ca/dhp-mps/consultation/natur/sunscreen-ecransolaire-eng.php)</p> <p>8 - 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</p> <p>9 - 2009 version referred to in HC Guidance Document – Sunscreen Monograph (http://www.hc-sc.gc.ca/dhp-mps/consultation/natur/sunscreen-ecransolaire-eng.php)</p> <p>10 - CAC will direct members to the availability of this guidance, as required</p> <p>11 - CAC encourages consideration of ISO technical reports, where appropriate; will direct members to the availability of this report, as required</p> <p>12 - HC website provides information about natural and organic claims for cosmetics (https://www.canada.ca/en/health-canada/services/cosmetics/cosmetic-advertising-labelling-ingredients.html)</p>
EUROPE	<p>1 - Citation in OJEU: 2011-04-21 developed in the framework of the M/375 Mandate</p> <p>2 - Developed in the framework of the M/426 Mandate</p> <p>3 - To be discussed</p> <p>4 - Developed in the framework of the M/389 Mandate</p> <p>5 - Transposes at national level (e.g. France)</p> <p>6 - EN ISO TR (Vienna agreement)</p>
USA	<p>1 - FDA is internally discussing this standard</p> <p>2 - If ICCR wants to consider this, we will need to involve FDA's CDER</p> <p>3 - FDA does not regulate use of the term "organic." US Dept. of Agriculture does. "Natural" is not an FDA regulated term.</p> <p>4 - Not Considered. - FDA regulations for cosmetics cover "Labeling", not "Packaging" (21 CFR 701). Conflicts with ICCR ToR not to require changes to Member statutes or regulations.</p> <p>5 - Not considered. – FDA cGMP regulations for drugs cover "stability testing" (21 CFR 211.166); there are no comparable regulatory mandates for cosmetics.</p>
JAPAN	<p>1 - Endorsed as JCIAs self-regulatory standard</p> <p>2 - Endorsed as JCIAs industry guideline</p> <p>3 - Translated into Japanese and published from Japanese Industrial Standards Committee</p> <p>4 - Previous version ISO 24444:2010 has been translated into Japanese and published from Japanese Industrial Standards Committee</p>