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COSMETIC TOILETRY & FRAGRANCE ASSOCIATION OF SOUTH AFRICA

ISO WG Interim Meeting Held in Paris (15-17 May 2017) | Report by Judy Nobin

ISO/TC 217/WG3- Analytical Methods| 15.05.2017

Welcome and introduction by Convenor Pr. Pierre-Antoine Bonnet. Convenor thanked the WG secretariat (Aurelie Lollie) for her commitment and support and wished her the best in her new role. He proceeded to advise that the meeting would focus on commentary inputs on **ISO/DTR 1881 Cosmetics –Guidelines on the stability testing of cosmetic products**, with the next day focussing on the remaining agenda points.

He advised that WD2 commentary in Sydney was included in the draft which was sent out for balloting. Ballot comments received on new document DTR 18811 were collated into N246. 123 comments were to be reviewed and discussed including USA and RSA comments (6pgs) which had not been collated. An informal webex meeting had been held to address commentary received. The overall ballot indicated approval of the document with 1 disapproval from Japan with commentary.

A number of the editorial comments were accepted, as the documented did appear to be fragmented from initiation of the draft. Convenor advised that all editorial comments from points 65 onwards would be reviewed by the Stability WG for inclusion and focussed on the technical and major concerns due to time constraints. CE asked for the responsible person to be changed as it could be confused for the responsible person in accordance to the definition laid out by the European Commission.

RSA could only address the major technical concerns which were:

- (5.3.1) was addressed in a previous comment and revised to present six months as an option rather than the benchmark.
- (5.3.2) the proposed inclusions of the intermediate condition and 45*C +/- 2*C and 75% RH was rejected as a previous similar request for inclusion of an intermediatory condition was rejected. The convenor advised that the document was not aimed at including a comprehensive list and that in such cases of variation, national standards or relevant documents would be the point of reference.
- (5.3.4) 24 hours at 4*C with the suggested change to 24 hours at 5*C was rejected as it referenced the Brazilian standard and was correct.
- (5.3.4) Requested inclusion of 24 hours at 45*C and 24 hours at 5*C condition. This was rejected as it was again detailed that the document was not aimed at being a comprehensive list of conditions/examples and local standards/documents could be referenced for specific details/conditions.

WG were advised that the report needed to go for publication due the lengthy time already expended. The recommendation was made to incorporate changes and circulate to the Sub-team/WG for approval. Japan to provide draft comments for consideration and inclusion. It was noted that a lot of changes had been made and experts were asked limit comments only to the corrections made and discussed at the meeting. Convenor asked the WG to bear in mind that the final draft should not be perfect but good enough to publish. Changes to be captured by the end of May for circulation in June and WG expert response by end June.

ISO/TC 217/WG3- Analytical Methods | 16.05.2017
ISO/AWI TR 22716 Cosmetics- Analytical methods-Development of a Global approach for validation of quantitative analytical methods

Stewart Hewlings the project lead advised that ISO and CEN 392 were looking at commonality, expectation and criteria when engaging on this document. The document had been circulated a few weeks ago where the validation and the approach would need to be reviewed and ensured. Japan did not think that the title conveyed the correct meaning as it was not meant provide a global (harmonised) approach but rather the most true, consistent, predictive and reproducible approach. The project Leader concurred and advised that this would be given some thought prior to revision.

WG reviewed the scope and recommended a revision with the scope being extended to not only include traces but the broader application. The scope was also extremely long and should be edited to be concise (two- three paragraphs), aspects from the foreword and be focussed. The scope content should be separated into a scope and introduction.

It was further discussed that the EC regulations focussed on trueness and reproducibility (accuracy) and that these aspects should be included into the document. It was also advised that the scope should define how the global approach would lead to a globalised standard based on reproducibility.

A need for practical implementation with examples and statistical data were cited in order to show the practicality. The WG were taken through a presentation containing the principles surrounding the documentation. CEN representative was present and advised of the validating company. CEN specifically used 8 laboratories for performing ring studies and validation. The convenor advised that in some cases however there was no need as three laboratories would be used and validation based on reproducibility and accuracy. Although 8 laboratories are good in practice, it is more important to have comparable and accurate results. Level of validation requirements will need to be reviewed. It was recommended that the white paper submitted by CE be reviewed and amended for internal ISO application by end June, while Stewart Hewlings would continue with revision of WD for the global approach for WG commentary by end June.

The Chairman advisory group would discuss if the document should be a TR or not. The title change will require a vote, as it is already registered

ISO/TC 217/WG3- Analytical Methods | 16.05.2017
ISO 12787:2011- Cosmetics –Analytical methods-Validation criteria for analytical results using chromatographic techniques

Convenor advised that this standard had to be revised with 24 votes received for confirmation. Comments received thus far are generic, will require clarification and be taken into consideration.

Additionally TR for DEA had been approved and completed. It had been sent for publication and was still underway.

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ISO/TC 217/WG3- Analytical Methods | 16.05.2017
ISO/AWI TR 21392 Cosmetics- Analytical methods-Measurement of traces of heavy metals in finished products using ICP/MS technique

Project Leaders Laurence Garnier (Loreal) and Nicole Pruhs provided feedback on the project with inputs from expert Julian (Loreal). The ring trials had been launched in laboratories in Japan, China and India –countries are currently using these technologies. 0.01-3 ppm content measurements in triplicate will be done. Jay Ansel and Spanish expert advised that no one in USA and Spain are currently using this technology. Japan advised that they had found a laboratory and would be able to perform the test (samples need to be sent thru' to Japan for testing). Use of CMR material is problematic and does not have enough quantity for testing and analytical identification. The limiting step is preparation of the sample for analysis. The method would require adaptation.

Laurence will draft and send a list of existing equipment on the market that could be used. The convenor advised that it would be good exercise to have a combination of equipment types to run these ring studies without modification of conditions required but based on equipment type.

The project leaders proceeded to highlight aspects of the draft document advising that Rhodium and Lutetium were suggested for use as they were well suited for use as internal standards with others suggested. It was also important to ensure that there were no interferences. Guidance is provided together with tabulation of examples with reference solutions within the document.

Stewart Hewlings highlighted the need to include the use of traditional single cells and single reaction unit with multi vials. The draft will be revised to distinguish and include modern apparatus, including all types of microwaves used. There might be a need to introduce MSMS in the case of false positives. It was also suggested that clarity be provided on the different types of equipment with pros and cons. It should also include basic existing equipment with a recommendation and include a minimum requirement for reducing interference.

Jay Ansel advised that tattoo colourants were illegal in USA (Pg 9, Table 1) and that this should be considered for document relevance and harmonisation.

It was noted that some of the samples had to be spiked in order to conduct the study. It was also suggested that there should be a clear idea of accuracy and measure in terms of regulations. International regulations and their target levels should be investigated and considered for inclusion eg. India, China, Canada.

Recommendations made at session together with validation and supplier details to be incorporated. Commentary to be made by 15th August for discussion at next WG in October.

Laurence advised that Mercury had been removed from this study. A ring study is being co-ordinated to analyse Mercury via: AAS (Atomic Absorption using cold vapour technology after pressure digestion) and DMA (Direct Mercury Analysis) where no sample preparation is required. DMA Milestone is the equipment being used for direct Mercury analysis.

CEN representative was present and advised that CEN was currently working on 2 standards: Hydroquinone and Corticosteroids which was undergoing editorial comments for publication as a TR and Sun protection agent (UV) which is also undergoing editorial commentary for publication into a standard. Mercury is an upcoming project at CEN level, coming out of the meeting with EC in Brussels. EC had no mandate or interest from members to support such a study and project. The project would be A CEN initiative and would be put out in the form of a CEN standard.

Convenor thanked WG members and Aurelie Lollie and advised that the next meeting was to be held in Columbia, inclusive of WG and TC plenary meeting. Minutes and report to follow.

ISO/TC 217/WG7- Sunscreen | 16 May 2017

(Only afternoon session attended- could not attend session on the 17th due to WG 1 meeting attendance, HLR attended)

The convenor welcomed all with a brief round of introductions. The Project Leader Kurtis Cole advised that no more changes related to the technical aspects were to be considered due to the limited time. A number of editorial comments have been accepted and included. Intent to focus on the major concerns from the commentary submissions:

- (4.1.2, P5- Criteria for panellist acceptance) – Gathered data from 12 laboratories across 7 countries. Data was compiled on ITA and MED with the exception being in Singapore as the skin was too dark. Singapore was the outlier in terms of results/data received and plotted. Alain (TC 217 chairperson) recommended interrogating the results and the laboratory results. The recruitment of subjects should be re-evaluated to include the Caucasian population. Alain to go back to the 2 identified laboratories and to find the relevant subjects. Mean band used with one subject from the 3 bands; 28-45, 45-54 and > 54.
- (4.1.4 US two month restriction for subject or tests site, P7) Consider using another site, ethical or technical concerns. Nothing technically wrong with site use according to the Helskini agreement. ISO cannot enforce treatment. Non-normative note with no justification for 2 months. If changed then this would impact ISO 244442. USA comment was rejected.
- (5.1.3, MEDu doses by ITA, Pg 9) - Can burn subjects hence the inclusion to prevent this, which is a good practice. The comment was rejected.
- (5.1.4, Measuring small beam uniformity, Pg 11)- Quadrant tests for uniformity. High level of uniformity - 96% good beam 85% single port and 92% for multi ports. Fuji film and circular vessel to be included into ring tests with quadrant sensor to be provided at no cost. The ring test will be done separately for the film and quadrant sensor.
- (7.2, UK validation of new SPF standards, is SPF 50 needed?, Pg19) –The intent is to use the highest standard as the control. US queried the universality of the formulation and their inability tests if banned materials are used.

Two variants standards for SPF 30: one for US compliance and the other for other countries applicability. Cost, time, ethics and various considerations to be taken into account. The practicality needs to be Considered - possibly using the SPF 50 monthly for internal validation and not testing was suggested. It was noted that it could also interfere with results.

- (8.4.2.1, BR validation of < ITA for variance?. Pg 21) – This is common practice in EU from mean data generated. Brazil has a higher value which could be a constraint based on visual assessment. Variation accepted.
- (8.4.4.1, Br US allow use of naked finger, P22? Application dose 2.0 or 2.1 mg/cm 2. Pg 22) – Finger cotton or finger hence 2 different dosages. With finger cotton application the cotton can be weighed before and after to check the application dose. For fingercot an additional 10 % is included. There is variation with different results.
- (8.5.4.1, AU maximum MEDu progression of 115x?) – Different energy levels, dose rage 50j/m2 – 400j/m2 intensity for erythema. Unprotected MED mean, unprotected MED exposure, out of range MEDu – reject subject. Aus recommend 1.1 and 1, 25 MED for unprotected MED. Higher for unprotected and test products should be the same. Higher than 25 – 1, 15 and lower than 25 – 1, 25. Acceptance of MEDu midpoint values- single or polynomial fit. ITA and MED unprotected dose- second order fit.
- (8.5.4.2 DE expected SPF value or range – allow SPF to change during test?)- draft statement for inclusion- as Korea does not accept this within the methodology with the comment being accepted.
- (8.6.3.2, UK use of fluorescent bulbs not permitted, Pg 27/28)- must not be the sole light source. Comment accepted.
- (8.6.3.5, Pg 38) Annex F (US) definition of MED to fill site) - >50 % of site (majority) is sufficient for inclusion. The comment was rejected.
- (8.6.3.6) DE- definition for MED erythema when skin is pigmented, Pg 28) - only erythema is eligible as MED response. The comment was accepted.
- (Annex F, disagreements on examples and readings)- no agreements on readings. Caroline has had an offline group to work together to get better results. 2 ring tests done- do not agree with results. Should hold a workshop for all countries with comments, telecom and reach agreement next month for. Draft document development by end June for commentary by July/August

Recommendations:

- A separate ring test to be done on uniformity using the film and also the quadrant device.
- The technique for the film process has to be developed.
- Ring test to validate the SPF 30 and 50
- 2 sample standards from BASF
- 1 standard from PCPC. To consider petitioning FDA for proposal of alternative 2 sunscreens (2 new sunscreens not yet accepted and unsure if and when it will be accepted by FDA)

BASF presented the 2 standards that had been developed where the stability, challenge, analytical data and allergenicity testing had been done and the sample were ready for testing.

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ISO/TC 217/WG1- Microbiology |17 May 2017

The convenor welcomed everyone to the meeting, with WG introductions. Agenda was accepted with the inclusion of a discussion point of ISO 11930. Jay Ansell and the convenor were elected for the drafting committee. The committee went through the extensive commentary list which largely contained editorial comments.

USA raised a major concern: they did not think that the document should be adopted as a standard but rather as a TR/guideline. Should this document became a standard then it could prove problematic as local enforcement could use the recommended methods, which were not methods that were used by all countries and laboratories. The convenor advised that the WG had taken the decision to categorise this as a standard and was concerned about the change. The WG felt that there was insufficient details on size, recovery, materials and method used coupled with a gap on the ratio of sample and carrier material. A vote was taken with all countries indicating that there should be sufficient details included into the report then it should become a TR. **SA VOTED FOR THE DOCUMENT BEING PUBLISHED AS A TR IF RELEVANT ADDITIONAL CONTENT COULD NOT BE EFFECTIVELY INCLUDED**.

It was recommended that more details be included on the stomaching and filtration techniques. The Project Leader (Christine) asked for the WG to submit valid proposals and not just commentary calling for revision. She suggested that the WG go through the document section by section and provide commentary and proposals. It was suggested that Steve assist Christine in formulating content for the draft. Mrs Tabari and Jay Ansell would make necessary changes on the document for circulation to the WG by end June. Comments submitted on the revised draft would be discussed in Columbia.

ISO 11930: 2012: Japan presented 2 graphs citing experiments that had been conducted reflecting:

- Standard indicated that the solution prepared could be used up to two hours after preparation- however the results of the tests indicated otherwise
- Influence of peptone solution –with negative impact and would suggest use of Sodium Chloride solution.

It was suggested that Japan review details of their study in terms of bacterial strain, inoculation method and provide details and comments to group for review. USA and Japan proposed revision of standard with commentary inclusions. These would then be taken into consideration for the standard review.

AOB: Pedro advised that at the ICCR meeting in Brazil in July –ISO standards (methods) related to Microbiology would be endorsed and that the list would be available between 12-18 July. Next year ICCR would concentrate on reviewing and endorsing ISO challenge test related documents.

No work items were identified as new work items and the next meeting would be held in Columbia between the 23 and 27th October.

CLOSURE OF ISO WG MEETING
MAY 2017
