ISO/TC 217 Meeting held in Cartagena, Colombia
23-27 October 2017

ISO/TC 217/WG 7, Sun Protection Methods Meeting held in Cartagena, Colombia, 23/24-10-2017 | Recommendations and Report

1. Official ISO Recommendations

ISO/TC 217/WG 7– Recommendation 01, Cartagena 2017
ISO/TC 217/WG 7 recommends the project leader Curtis COLE will address the comments received on WD 3 and prepare a revised version of WD 4, ISO 24444:2010 "Cosmetics - Sun protection test methods - In vivo determination of the sun protection factor (SPF)".

ISO/TC 217/WG 7 – Recommendation 02, Cartagena 2017
ISO/TC 217/WG 7 recommends to use the approaches presented by both Ad hoc group 1 and Cosmetics Europe – that is, to check the bias of candidate alternative methods and their correlation with the in vivo method (subject to satisfactory explanation of the 0:5 x reproducibility SD factor proposed by Ad Hoc Group 1 and check the values of CV% using the mean SPF values of the Cosmetics Europe proposal).

ISO/TC 217/WG 7 – Recommendation 03, Cartagena 2017
ISO/TC 217/WG 7 recommends that Ad Hoc Group 3 design and execute a study to identify possible lead methods from among the 4 candidates. This study will use at least 3 laboratories per method and the 12 products defined for SPF testing (for which in vivo results will be available).

ISO/TC 217/WG 7– Recommendation 04, Cartagena 2017
ISO/TC 217/WG 7 recommends that Marc PISSAVINI (France) distribute the product to be used. If additional samples are required it also recommends that ISO/TC 217/WG7 define and distribute samples to be used, as per recommendation "ISO/TC 217/WG 7 – Recommendation 03, Cartagena 2017".

ISO/TC 217/WG 7– Recommendation 05, Cartagena 2017
ISO/TC 217/WG 7 recommends the revision of ISO 24443:2012 "Determination of sunscreen UVA photoprotection in vitro". The recommended time-frame will be 36 months and the project leader will be Caroline TRICAUD (France). The revision will commence at the Committee Draft stage. .

ISO/TC 217/WG 7– Recommendation 06, Cartagena 2017
ISO/TC 217/WG 7 recommends the revision of ISO 24442:2012 "Determination of sunscreen UVA photoprotection in vivo". The recommended time-frame will be 36 months and the project leader will be Masato HATAO (Japan). The revision will commence at the Working Draft stage. .

ISO/TC 217/WG 7– Recommendation 07, Cartagena 2017
ISO/TC 217/WG 7 recommends that further meetings are organised before the next Plenary to resolve pending issues raised in this current meeting.

2. Report (J. Nobin)

1→6. The following agenda formalities were dealt with: **1. Opening of the meeting, 2. Roll call of experts, 3. Adoption of the agenda and 4. Approval of the last meeting report ISO/TC 217/WG 7 doc. N277, 5. Appointment of drafting committee and 6. Report of the Convenor, Pr. Philippe Masson.**

7. ISO/NP 24444 Cosmetics – Sun protection test methods – In vivo determination of the sun protection factor (SPF): Comments submitted were discussed and finalized for Curtis Cole's revision into WD 4 for WG review, future amendments and final planned publication by 2019.
It was noted that all ring study samples were to be blinded for testing. There were delays with the P2 sample, which would be relabeled and tested at year end/beginning January with data being available for the next ISO interim meeting in May. A brief discussion was held on the use of sunscreen boosters (synergistic materials) '

which are not classified as sunscreens and their allowance for use in the sunscreen standard.13 Laboratories will participate in the ring study and conduct testing on all five standards; with the further participation of 2 USA laboratories who will test 3 standards (developed to align with USA approved UV filter list) with SPFs between of 30 and 50, labelled > 20 accordingly.

8. Discussions about the SPF in vitro

8.1 Ad hoc group 1 "Minimum criteria for in vitro SPF data to qualify ISO international standard"

Cosmetics Europe presented in vivo data from a study conducted on 36 products across 18 laboratories. The results provide actual data of currently marketed products; which the WG accepted as acceptance criteria. It was noted that the

systematic differences between methods (in vivo and in-vitro) should be negligible. After rigorous discussions it was finally agreed that the Cosmetics Europe would check the bias of candidate alternative methods and their correlation with the in vivo method and values.

8.2 Ad hoc group 3 "Possible link between the in vitro SPF reported methods"

Project Leader confirmed that the 4 laboratories showed good repeatability results (ie. same laboratory and analyst) and advised that the next step was to assess reproducibility (same method, different laboratories, accuracy profile). It was agreed that 3 out of the 4 laboratories would be selected to conduct further tests on 12 products (used as part of sample set in CE study) which were to be supplied by Marc Pissavani for in vitro SPF testing. The CE results would be available and would form part of the acceptance criteria for correlation of results.

9. PWI Measurement of the Sunscreen Efficacy by Diffuse Reflectance Spectroscopy

Eduardo Ruvuolo advised that this test method provided an alternative procedure to characterize the *in vivo* SPF, UVA and Critical Wavelength (CW) protection of sunscreen products without damaging *in vivo* UV exposures. The aim of this proposed protocol is to provide a *hybrid* (in vitro and in vivo) testing procedure to characterize UV protection provided by sun care preparations. Furthermore **HDRS** is an efficient and economical method and can process from eight to ten products in an hour. A single test sample could produce results for SPF, UVA and CW values, using the dorsal forearm.

Diffuse-reflectance spectroscopy was conducted using the Bentham (instrument/equipment), the hybrid and non-irradiated method which correlated to ISO 24444 and ISO 24443 and was inclusive of product photo stability testing. At present there are a minimum of 5 laboratories currently using the equipment: 2 users in Germany, 1 in Brazil and others elsewhere. It was noted that there could be variance when tests/studies are conducted across different laboratories –which should be addressed. An IP patent has also been filed and is pending approval on new equipment utilizing this method. ISO can include alternative methods without any IP infringement on the equipment design. The DRS method has already been published but there is a need to meet the new criteria requirements and should the project be accepted then there would be a 3 years period allowed to deliver on a final published document. Further studies will be conducted in alignment with the samples, acceptance criteria and requirements already determined and in accordance to ad hoc WG 3; for further development and future initiation of NWIP.

10. ISO/AWI 16217 Cosmetics – Sun protection test methods – Water resistance: At current 5 laboratories have submitted results on the water resistance ring study 5; with a need to validate P2. ISO 24444 was used with 40 minutes water resistance with variability noted. It was proposed that a range of 60-85% be used with a comparison between study 4 and 5 and the use of P2 due to water resistance.

11. ISO/AWI 18861 Cosmetics – Sun protection test methods – Determination of percentage of water resistance:

Ring study 2: Data has been collated from 5 laboratories and currently awaiting a further 5 sets of data. WE 10 and WE 11 formulations were proposed as references for the water resistance test for post immersion SPF and percentage of pre- immersion with P2 acceptance ranges. John Straton was tasked to modify, edit and circulate the previous document and add proposal limits for discussion by end of January.

12. ISO 24443:2012 Determination of sunscreen UVA photoprotection in vitro: Minor technical errors were identified for revision with approximately six Australian and USA comments received. The scope would remain unchanged and the vote was aligned to the correction of this standard; with Caroline Tricaud as the Project Lead.

13. Items for future work: ISO 24442: 2012 was recommended for revision with Japan (Masato Hatao) as Project Lead.

14 →17. The remaining agenda items were dealt with prior to meeting closure: **14 Approval of recommendations, 15 Any other business, 16 Requirements concerning a subsequent meeting and 17 Closure of the meeting (20:00).**