FUTURE COSMETICS CC

From Concept to Product

Overseas Report no: 2017/05/19
by
Heibrie Le Roux

SABS STANDARDS DEVELOPMENT
ISO/ TC217 Working Group 7 Sun Meetings

Paris- France
16 May to 17 May 2017

The working group 7 meetings of ISO/TC 217 was held on 16 to 17 May 2017 at AFNOR in Paris (France).

South African delegates: Heibrie Le Roux (Future Cosmetics)
(Attended all both meeting dates)
Judy Nobin (CTFA)
(attended on afternoon 16 May 2017)
1 SABS representative (present but did not meet)

Quantity of Delegates attending: 3
Quantity of meetings scheduled: 7 meetings,
(all meetings attended except for Terminology by CTFA & Future Cosmetics)

1. SESSIONS ATTENDED

Committee Meeting and Working Group	Date
Cosmetics Member Association Bodies Meeting	NA
Plenary Meeting Opening Chairman Advisory Group Conference	NA
1. WG 3 *Analytical Methods (all day)* 2. *WG 4 Terminology (afternoon)*	2017-05-15
3. WG 3 *Analytical Methods (morning)* 4. *WG 4 Terminology (all day)* 5. WG 7 *Sun protection test methods (afternoon)*	2017-05-16
6. WG 7 *Sun protection test methods (all day)* 7. *WG 1 Microbiological standards and limits (all day)*	2017-05-17
Plenary Meeting Close	NA

Date of arrival: 15 December 2016;
Date of departure: 17 December 2016.

Member: Heibrie le Roux
Registration Number: 2001/055088/23
Physical Address: 287 Sinovich Drive, Grootfontein Country Estate, Garsfontein Road Ext., Pretoria East
Postal Address: PO Box 39675, Garsfontein East, South Africa, 0060
Tel: +27-12-8110621 Fax: +27-12-8110510 Mobile: +27-82-9613509
E-mail: heibrie@futurecosmetics.co.za

ISO/TC 217 WG 7, *Sun Protection Test methods for cosmetics*. The South African delegation consisted of Ms Heibrie Le Roux (Future Cosmetics) on both days and Judy Nobin (SABS) on afternoon of 2017/05/16

ISO/TC 217 WG 1 Microbiological standards and limits. The South African delegation consisted of Ms Judy Nobin (SABS) full day

ISO/TC 217 WG 3 *Analytical Methods.* The South African delegation consisted of Ms Judy Nobin (SABS) both days

ISO/TC 217 WG 4 Terminology. These sessions could not be attended as the schedule clashed with the other sessions; no expert was funded by SABS.

3 OBJECTIVES SET BY SABS TC 217 *COSMETICS*

Trip motivation not received, not sure of final objectives.

3 PROGRESS MADE

3.1 WG 1 - Microbiological – to be completed by SABS/CTFA
3.2 WG 3 - Analytical Methods – to be completed by SABS/CTFA
3.3 WG 4 - Terminology – to be completed by SABS/CTFA

3.4 WG 7 – Sun Protection Test Methods

3.4.1 Professor Phillip Masson (FRANCE), the convener of the working group opened the meeting and welcomed all the participants.
3.4.2 Roll call of experts was circulated.
3.4.3 Adoption and approval for agenda (N258) and previous minutes (N259)
3.4.4 A drafting committee was appointed.

3.5 Professor Phillip Masson reported back on all activities as from last plenary in Australia in December 2107-

- Several conference calls were scheduled in order for work to be completed and reports were sent through for discussion before interim meeting.
- The date and place of the next plenary meeting was confirmed as the week of 23 to 28 October 2017 in Cartagena (Colombia). This is also referenced in recommendation 08 in document N272 Recommendations of the ISO/TC 217/WG7 for Paris dated 2017/05/18.
- The expected outcome for each agenda point was discussed.
- The PWI Measurement of the Sunscreen Efficacy by Diffuse Reflectance Spectroscopy (Point 9 on the agenda) was voted on (as per recommendation

5 made in Sydney) and it was accepted. This project will now be moved to working draft.

- ISO24442:2011 was opened for revision and it was agreed during the Sydney meeting to revise and amend, but during the voting processe many countries voted against this. **The convenor addressed the importance of countries being represented during meetings and requested participants to inform their countries of votes and decisions taken during meetings as binding.**

- The following 2 standards need to be completed within 48 months and the convenor commented that these can only be finalised after the agreements on changes needed in the revision of ISO24444 In vivo determination of the sun protection factor (SPF)-
    - ISO/AWI 16217 Cosmetics – Sun protection test methods – Water resistance – water immersion procedure and,
    - ISO/AWI 18861 Cosmetics – Sun protection test methods – Determination of percentage of water resistance

3.6 Revision of ISO 24444:2010 "Cosmetics - Sun protection test methods - In vivo determination of the sun protection factor (SPF)"

Project leader discussed the technical topics (N270) that was raised during the comments submitted (N256) on working draft 2 (N257) that was circulated after the Sydney meeting.

Most comments was categorised under major and minor items. Due to time constraint only the major topics were addressed during the meeting.

4.1.2 Acceptance Criteria of Panel Selection:
The criteria for acceptance of a panellist was discussed and it was decided to split the test panel into the following categories –

* ⅓ of test subjects must have an ITA greater than 54 in a test panel. This is a very strict criteria and it was suggested to have at least 1 subject per test panel in the category.
* ⅓ of test subjects in the test panel must be between ITA 28 – 45

4.1.4 Two Months Restriction for Testing a Test Subject:
It was agreed that the sentence should read "you should not use a subject in less than 2 months but must not irradiate the same sub-site in 2 months.

5.1.3 Measurement and Control of Total Irradiance of Solar Simulator at each port:
It was agreed that this needs to be controlled and must be measured at each test sub-site and calibrated. The new device required must be capable to measure between 280 to 1800nm.

5.1.3 MEDu doses to be calculated by ITA:
In order to unify the dose to be administered to test subjects, it was agreed to use ITA assessment to predict the MEDu needed. Each lab will have to develop their own chart to qualify the MED relationship to ITA as per Annex E of ISO24444.

Member: Heibrie le Roux
Registration Number: 2001/055088/23
Physical Address: 287 Sinovich Drive, Grootfontein Country Estate, Garsfontein Road Ext., Pretoria East
Postal Address: PO Box 39675, Garsfontein East, South Africa, 0060
Tel: +27-12-8110621 Fax: +27-12-8110510 Mobile: +27-82-9613509
E-mail: heibrie@futurecosmetics.co.za

5.1.4 Calculation and Measurement of Beam Uniformity:
The uniformity of beam for solar simulators needs to be measured and if more than 15% variation in beam uniformity is calculated, the solar simulator (single/multi port) is rejected. South Africa agreed to partake of this ring study.

7.2 **New SPF30 and SPF50 standards**:
Three new standards were approved for SPF testing and it was agreed to initiate in second ring study. South Africa agreed to partake of this ring study.

8.4.2.1 Rejection Criteria of ITA>3 on test sub-sites:
Test subject to be rejected if ITA differs more than 3 between each test area and/or MEDu sites

8.4.4.1 Application with naked finger:
Criteria were set for the use of application via naked finger in cases where a finger cot will be influenced by test product.

8.5.4.1 Maximum MED progression:
It was agreed to leave as per existing standard.

8.6.3.2 It was agreed to reject fluorescent lamps for reading of MEDs.

8.6.3.5 Grading Scale for MEDs:
France to supply a presentation of new grading scale and evaluation.

8.6.3.6 Pigmentation responses rejected during evaluation, only erythematic responses allowed.

Action needed before October meeting –
1. Beam uniformity ring study
2. Ring study for verification of 3 new standards
3. Ring study for verification of new changes to ISO24444.

Member: Heibrie le Roux
Registration Number: 2001/055088/23
Physical Address: 287 Sinovich Drive, Grootfontein Country Estate, Garsfontein Road Ext., Pretoria East
Postal Address: PO Box 39675, Garsfontein East, South Africa, 0060
Tel: +27-12-8110621 Fax: +27-12-8110510 Mobile: +27-82-9613509
E-mail: heibrie@futurecosmetics.co.za

3.7. Discussions on In Vitro SPF Projects:

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

Project leader reported back on additional work done and more methods have been suggested by the different statistical experts. Experts also evaluates existing ISO standards for adoption.

ISO5725-6: this standard was written for 1 sample but this working group would be evaluating more than 1 sample.

Conclusion-
Three methods were suggested-

1. Mixed model (Uhlig) – most difficult method but address accuracy of in vivo. It was recommend to use this approach. Disadvantage- data is based on in vivo method which might not be accurate.
2. Funnel (original) – Still uncertain how to quantify the funnels, 2 options were proposed
3. Dr Held - Brought 2 new aspects to the table, 90% of data should be within the funnel. Included the 95% CI. Limits have to be set.

Recommendations were as follow-

1. Expectation from statisticians to be confirmed and agreed upon by ad hoc group.
2. Need to obtain consensus from all statiscians on which statistical approach, not more models.
3. Need to finalise on criteria to validate the in vitro data.

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

Feedback was supplied by project leader.
Working group to collect more data and assess according to final stats method once ready.

Member: Heibrie le Roux
Registration Number: 2001/055088/23
Physical Address: 287 Sinovich Drive, Grootfontein Country Estate, Garsfontein Road Ext., Pretoria East
Postal Address: PO Box 39675, Garsfontein East, South Africa, 0060
Tel: +27-12-8110621 Fax: +27-12-8110510 Mobile: +27-82-9613509
E-mail: heibrie@futurecosmetics.co.za

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

Project moves from prelim to working draft and name changes agreed.
All work up to date looks positive and an enormous mount of samples have been tested and it was reported to be repeatable.
Ad hoc group 1's stats model was used and device complied with all criteria's

Device is suggested to be used for the following test methods-

1. SPF evaluation
2. UVA evaluation
3. Water resistant evaluations
4. Sand Resistant evaluation.

Advantages-

1. Short measuring time (10 sec and less than10^{-6} joules/m^2 irradiation)
2. Similar as flash from photograph (much less invasive than solar simulators
3. Can measure up to SPF60
4. Substrates has no influence on results (PMMA sandblasted/ in vitro collagen skin)
5. Does not involve high level of training for technicians**.**

Disadvantages-

Limitations – some equipment are not as sensitive as others.
Dark skin absorption is a limitation but in future filter systems could be investigated
Photo unstable samples are uncertain, thus need more work**.**
Estimated amount for equipment is 60 000 Euro.
Can not measure below 320nm, no signal below 310nm, but suggested test method will include in-vitro spectrophotometer data modification.

Conclusion:

All work up to date proof that this method could be successful.
The next step and request is for testing labs to get involved and sign up for ring studies for intra lab verification.

South Africa agreed to investigate the purchase of new device for inclusion of existing ring studies scheduled for June/July.

Member: Heibrie le Roux
Registration Number: 2001/055088/23
Physical Address: 287 Sinovich Drive, Grootfontein Country Estate, Garsfontein Road Ext., Pretoria East
Postal Address: PO Box 39675, Garsfontein East, South Africa, 0060
Tel: +27-12-8110621 Fax: +27-12-8110510 Mobile: +27-82-9613509
E-mail: heibrie@futurecosmetics.co.za

3.9. ISO/AWI 16217 Cosmetics - Sun protection test methods - Water resistance - water immersion procedure
Ring study to be performed in conjunction with in vivo SPF.

3.10 ISO/AWI 18861 Cosmetics - Sun protection test methods - Determination of percentage of water resistance
Update from the Project leader and follow-up to be given
Project leader not available but await data form ring study as agreed in 3.9

3.11 ISO 24442 : 2011 Cosmetics - Sun protection test methods - In vivo determination of sunscreen UVA protection
Working group agreed during Sydney meeting to review standard but system vote was negative for revision. **The convenor addressed the importance of countries being represented during meetings and requested participants to inform their countries of votes and decisions taken during meetings as binding**

4. **Items for future work**
It was agreed that no new projects will be agreed on at this stage.

5. Recommendations were approved.

6. Next Plenary Meeting:
It was confirmed that the next meeting will be in **Colombia Catagena 23 October 2017 as per Recommendation 8.**

7. Meeting was closed at 17:30

Member: Heibrie le Roux
Registration Number: 2001/055088/23
Physical Address: 287 Sinovich Drive, Grootfontein Country Estate, Garsfontein Road Ext., Pretoria East
Postal Address: PO Box 39675, Garsfontein East, South Africa, 0060
Tel: +27-12-8110621 Fax: +27-12-8110510 Mobile: +27-82-9613509
E-mail: heibrie@futurecosmetics.co.za

4 BENEFITS OF SOUTH AFRICA PARTICIPATING IN ISO WORK.

It is recommended that South Africa must continue to participate in the development of documents under the auspices of ISO/TC217 to ensure that they reflect the South African perspective and in so doing remove barriers to trade.

South African National Standards in specific areas of cosmetics will be shared with ISO Committees.

The new DRS Hybrid test method and revision of existing ISO24444 and ISO24442 and ISO24443 will have a big impact on compliance on all local cosmetics that include sunscreen filters.

5 NEXT MEETING:

The ISO/TC 217 suggested holding the next plenary meeting in October in Colombia.

Member: Heibrie le Roux
Registration Number: 2001/055088/23
Physical Address: 287 Sinovich Drive, Grootfontein Country Estate, Garsfontein Road Ext., Pretoria East
Postal Address: PO Box 39675, Garsfontein East, South Africa, 0060
Tel: +27-12-8110621 Fax: +27-12-8110510 Mobile: +27-82-9613509
E-mail: heibrie@futurecosmetics.co.za