CTPA Webinar New ISO Methods to Measure SPF of Sun Products – Written Q&A

General (both ISO 23675 and 23698)

- **What are the recommended testing methods to measure the Sun Protection Factor (SPF) of sun protection products?**

The UK and EU Cosmetics Regulations do not prescribe specific testing methods to measure the Sun Protection Factor (SPF) of sunscreen products. However, the EU Commission Recommendation on sun products, which also applies in the UK, provides a list of recommended test methods to measure the SPF of sun protection products. These are test methods published by the International Organisation for Standardisation (ISO). The Recommendation states that preference should be given to *in vitro* testing methods delivering equivalent results, as *in vivo* methods raise ethical concerns.

Cosmetics Europe Recommendation No.26 on the use of alternative methods to the *in vivo* SPF testing method, ISO 24444.2019, recommends that preference should now be given to the new non-invasive reference methods, ISO 23675.2024 (double plate method) and ISO 23698.2024 (HDRS method).

- **Acceptability of the methods in other markets**

Methods approved by ISO are generally accepted at international level. However, not all countries directly implement the new methods. In fact, some countries specifically reference the ISO standards in their regulation; therefore, the methods can be used in these countries once the national legislation is updated. For countries that to do not specifically refer to the ISO standards in their regulation, new methods can be implemented and used at any time.

There is no specific timeframe for the implementation of these new methods in countries that require updates to their legislation. Engagement with the relevant regulators is currently ongoing.

- **If a formulation was already tested with ISO 24444, does it need to be retested using the new methods?**

If a formulation was already tested with ISO 24444, it does not need to be retested using the new methods. Companies will also have a weight of evidence, rather than just one measurement, to support the SPF value labelled on pack. The existing data are valid.

- **Does a laboratory need to be ISO certified for its results to be acceptable?**

No, a testing laboratory does not need to be certified by ISO. But it is important to assess the quality control processes of the lab; for example, in relation to the certification of the

plates, reference formula, training of staff, maintenance of the equipment and other aspects.

- **What type of products were included in the ring tests for both the ISO 23675 (double plate method) and ISO 23698 (HDRS) methods?**

The ring test was carried out for both ISO23675 and ISO23698, on a total of 32 products (each was tested twice in 4 different laboratories). Products included in the ring test were emulsions, lotions, creams of different viscosity, alcoholic sprays, emulsion with only inorganic filters. All the SPF levels were included (from 6 to 50+).

- **What type of products are the new methods suitable for?**

ISO 23675 (double plate method)	ISO 23698 (HDRS)
Emulsion O/W and W/O, mono-phase alcoholic formulations Stick, oil formulations work in products Not suitable for powders Bi-phase products can be treated as an emulsion, but it is important for the product to be shaken properly to emulsify the product and perform the test quickly, to avoid separation of the emulsion	All product types except powders

- **We found discrepancies in the SPF values when comparing the results from the DPM, HDRS and *in vivo* methods. How should these discrepancies be interpreted?**

The observed discrepancies in SPF values between DPM, HDRS, and *in vivo* methods should be interpreted in light of the inherent variability in SPF measurements. The experts' assessment, conducted on nearly 200 products including replicate measurements, demonstrates a strong correlation among all three methods.

A given SPF value from the DPM or HDRS methods will fall within the same result interval as that obtained with the *in vivo* method. This prediction interval is crucial, as it accounts for the significant variability, particularly with the *in vivo* method, where it can range from 10% to 50% of the SPF value depending on the product.

Therefore, the differences observed between methods largely reflect this established variability, which is an intrinsic characteristic of current SPF measurement techniques. It is important to note that the newer DPM and HDRS methods are being developed precisely to reduce this variability, having already demonstrated superior reproducibility compared to the traditional in vivo standard.

In the possibility that products on the market originally tested with the *in vivo* method may, in time, be retested by a third party using a different method leading to discrepancies in results compared with the original test, Cosmetics Europe recommends the following approach in its Recommendation 26:

- A product, originally tested with a validated test method A to support its SPF claim, is retested by a third party with a validated test method B in laboratory X…
    - Scenario 1: The test result does not show any significant discrepancy with the claimed SPF → No further testing is necessary.
    - Scenario 2: The test result with method B is significantly lower than the claimed SPF → In this case, a final conclusion should only be taken after re-retesting the product following method A in a testing laboratory different from laboratory X and taking into account company data supporting the on-pack SPF. If this re-retesting result, does not show significant discrepancy with the claimed SPF, then no further action is necessary.
- For any testing or retesting, it is important to:
    - work with a capable laboratory which is experienced with the method being used and keeps up to date with its amendments and therefore is able to provide reliable testing results;
    - work with laboratories that ensure traceability and are available to provide scientific rationale in the event of result discrepancies;
    - avoid possible bias, therefore results from previous testing should not be provided to the laboratory doing retesting.

Double Plate Method (DPM) ISO 23675

It is extremely important that the method is performed exactly as described in the ISO Standard, in every single step and detail. The method should not be adapted, making certain parameters different from how they are described in the ISO Standard. It is important to check with CROs that the method is performed exactly as described.

- **Is it normal to have a high Coefficient of Variation (COV) on an individual plate – as the spreader is not delivering a totally uniform spread, with striations on the plate?**

The spreader is delivering a reproducible spread. This is not perfectly homogeneous because the homogeneity of the spread will depend on the product. That's why it is important to cover a large part when measuring, and to have a precise repositioning which is the same independent of the plate and product.

- **Can you reject plates if they don't look as if they have spread? The ISO 23675 states a minimum of three valid plates of each type is required. What makes a valid plate (ie. are there SD and COV criteria that each plate needs to achieve)?**

A plate is valid when all the steps of the ISO DPM were performed properly: the correct quantity of product, no issue with the spreading/fingercot creasing, the correct temperature, the correct irradiation time. There are no specific criteria to reject a plate from intra-plate parameter. If you suspect an issue with the performance of the method, it is better to reject the plate.

- **When does a study start and finish? For example, if I have performed a test that didn't work at three paired plates and went on to do a further three paired plates do I need to report all three or just once the CI confidence is in specification. For example, if the fourth plate brings the CI in spec do I conclude the study (even if the fifth and sixth plates then take CI out of spec)**

Consider all your data,but have a critical view on it. If you are borderline and inconsistently reaching the CI criteria, it could mean that there is a technical issue. Reflect and analyse the issue, and re-do everything if needed. Question your practice and equipment when performing the method, but also the product.

- **What is the best practice to keep the weighing and spreading process within the required time limit?**

It is important to optimise the lab layout, to ensure all the relevant equipment is close to each other. The scale and the robot should be no more than a few meters apart. It is also important to practice and training to gain a good mastery of the tasks.

- **During the plate preparation step, can a loss of weight of plates occur when they are left in the oven?**

This has never been observed by the method developers. This is being investigated by the method developers.

- **Should the sandblasted plate be wiped before use? And how should the plate be wiped, very gently or with enough pressure to get rid of the dust that accompanies them?**

The plate should be wiped gently.

Relevant Publications

On 1 September 2025, leading experts in sun protection published a series of papers outlining the comparison and statistical analysis of five methods to test the Sun Protection Factor (SPF) of cosmetic products. These papers are publicly accessible from the International Journal of Cosmetic Science. Below is the list of published papers.

- Are there alternatives to the traditional in-vivo SPF test (ISO 24444)? Comparison and statistical analysis of 5 proposed methods - https://onlinelibrary.wiley.com/doi/epdf/10.1111/ics.70026
- Colson et al., Test design and results of a method performance characterization study for SPF and UVA-PF testing - https://onlinelibrary.wiley.com/doi/epdf/10.1111/ics.70019
- Cole et al., The variability of in vivo sunscreen sun protection factor values - https://onlinelibrary.wiley.com/doi/epdf/10.1111/ics.70000
- Pouradier et al., Performance assessment of the Double Plate method(ISO23675) in ALT-SPF Consortium: A highly reproducible and accurate in vitro method to determine SPF - https://onlinelibrary.wiley.com/doi/epdf/10.1111/ics.13088
- Ruvolo et al., Performance of hybrid diffuse reflectance spectroscopy(HDRS- ISO 23698) methodology for assessment of sunscreen protection in the ALT-SPF Consortium validation study - https://onlinelibrary.wiley.com/doi/epdf/10.1111/ics.13089
- Kunze et al., The ALT-SPF ring study—Correlation in silico versus in vivo SPF ISO24444 and in vitro UVA-PF ISO24443 - https://onlinelibrary.wiley.com/doi/epdf/10.1111/ics.13086
- Reble et al., Characterization of LED-based hybrid diffuse reflectance spectroscopy method for determination of SPF and UVA-PF in blinded multi-centre study (ALT-SPF) - https://onlinelibrary.wiley.com/doi/epdf/10.1111/ics.70007
- Acker et al., The ALT-SPF ring study – in vitro determination of the SPF & UVA-PF by the fused method - https://onlinelibrary.wiley.com/doi/epdf/10.1111/ics.70015
- Ferrero, L., Pissavini, M., Dehais, A., Marguerie, S. and Zastrow, L. Importance of substrate roughness for In Vitro sun protection assessment. IFSCC 9(2), (2006) https://onlinelibrary.wiley.com/doi/epdf/10.1111/j.1467-2494.2007.00340_2.x
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- Fageon, L., Moyal, D., Coutet, J. and Candau, D. Importance of sunscreen products spreading protocol and substrate roughness for In Vitro sun protection factor assessment. Int. J. Cosmet. Sci. 31(6): 405–418 (2009) https://pubmed.ncbi.nlm.nih.gov/19627381/

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- Pissavini, M., Marguerie S., and Doucet, O. "SPF tests reveal no ideal In Vitro substrate exists", Cosm & Toil, April 11, 2016 https://www.researchgate.net/publication/309135992_SPF_Tests_Reveal_No_Ideal_In_vitro_Substrate_Exists
- Miksa S, Lutz D, and Guy C. In vitro UV testing-robot vs. human spreading for repeatable, reproducible results. Cosmet. Toil, 128, 742-752 (2013) https://www.cosmeticsandtoiletries.com/testing/sun-protection/article/21835994/in-vitro-uv-testingrobot-vs-human-spreading-for-repeatable-reproducible-results
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