Cosmetics Europe
the personal care association

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Cosmetics Europe Recommendation On the Use of Alternative Methods to ISO24444:2019

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For decades, Sun Protection Factor (SPF) values have been determined on the skin of human volunteers *in vivo*. The current *in vivo* SPF test method used in Europe (ISO24444:2019) has been developed within the International Standards framework by a large number of global experts and is used widely for substantiation of labelled protection claims or in-market control.
Supported by the European Commission (who explicitly encouraged the development of alternatives to *in vivo* SPF testing in its Recommendation 2006/647/EC[1]**), the sun protection industry has for many years innovated continuously to develop new SPF test methods and Cosmetics Europe has largely supported these efforts, notably through the development of the *In Vitro* 'Double Plate' Method (ISO 23675:2024).**

It is essential that any alternative method demonstrates a sufficiently high statistical correlation with the current gold-standard *in vivo* SPF test method (ISO24444:2019). Predicting *in vivo* SPF test results using alternative methods has, however, proved an extremely hard scientific challenge.

Several alternative methods were proposed and subsequently investigated to varying degrees. Of these, five methods have undergone statistical characterisation vs the gold standard ISO24444:2019 method in a multi-stakeholder technical consortium (ALT-SPF). Two of those methods have extensive ring-study data on a high number of sun protection products, evaluating their correlation with ISO24444:2019, the results of which have been published in peer-reviewed journals. **Both methods have progressed through the complete, formal process of standardisation in the ISO/TC217[2] and are now published as full, international ISO standards:**

1) the ***In Vitro* 'Double Plate' Method** (ISO 23675:2024) [3]

2) **Hybrid Diffuse Reflectance Spectroscopy or 'HDRS'** (ISO 23698:2024) [4]

Preference should now be given to these new non-invasive reference methods, where possible, in line with the European Commission Recommendation of 2006.

Considering that correct use of these two methods requires adequate training and experience, we strongly recommend that CE members (and the test laboratories with whom they work) familiarise themselves accordingly as soon as possible and start to phase in the use of these new methods for SPF testing as preferred alternatives to ISO24444:2019.

It is important to acknowledge that, **scientifically robust SPF values of products currently on the market that have been assessed with the *in vivo* method** (ISO 24444:2019, the only standard available until recently) **remain valid and compliant with regulatory requirements. There is no expectation that**

[1] https://eur-lex.europa.eu/eli/reco/2006/647/oj/eng
[2] https://www.iso.org/committee/54974/x/catalogue/p/0/u/1/w/0/d/0
[3] https://www.iso.org/standard/76616.html
[4] https://www.iso.org/standard/76699.html

these products would require retesting with one of the new alternative methods. However, in the future it can be expected that for new products, SPF values will be determined preferentially by using one of the two new alternative methods.

Due to inherent variability of SPF testing, it can happen that retesting of products on the market by external stakeholders may lead to different test results. This has been the case in the past when products tested with the *in vivo* method were retested with the same *in vivo* method by a third party. It must be stressed that manufacturers have to retain a well document dossier of information to support the labelled SPF. With the publication of the alternative SPF test methods, there is 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. In the event of the retesting of a product by external stakeholders leading to discrepancies in results compared with the original test, Cosmetics Europe recommends the following approach:

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: 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.

When UVAPF is measured using a new alternative method instead of ISO 24443:2021 or ISO 24442:2022, a similar rationale to that described above should be followed.