ISO TC217 working group 7, “Sun Protection Test Methods”, what’s new?

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Abstract (Maximum of 250 words)

ISO is an independent, non-governmental international organization with a membership of 167 national standards bodies.

The ISO TC217 working group 7, “Sun Protection Test Methods”, is one of the 802 technical committees and subcommittees. It was set up in 2006 and since then a lot of standardisation work has been done.

What is the current situation? The *in vivo* SPF and *in vivo* or *in vitro* UVA methods have been republished in order to take certain technical developments into account. The water resistance method has also recently been published. Thus, all the methods generally used for suncare product claims are standardized by the ISO. What about the *in vitro* methods recommended by the European Commission? The *in vitro* UVA method was published, updated in 2022 and widely used for several years. A lot of validation work has already been done for the alternative methods to *in vivo* SPF and their statistical characterization is currently being measured.

Thanks to the work of ISO TC217, the cosmetics sector can use standardized *in vivo* methods for all commonly used protection factors and for most *in vitro* methods. There is still work to be done to standardize the *in vitro* SPF method, but the future looks promising.

Keywords: ISO – SPF – UVA - Water restistance – test methods.

Introduction. ISO is an independent, non-governmental international organization with a membership of 167 national standards bodies.

With more than 24000 International standards, ISO covering today almost all aspects of technology and manufacturing. Across its 167 members representing ISO in their country, it brings together experts to share knowledge and develop voluntary, consensus-based, market-

relevant International Standards that support innovation and provide solutions to global challenges.

Discussion. The ISO TC217 working group 7, “Sun Protection Test Methods”, is one of the 802 technical committees and subcommittees [1].

As can be seen in Figure 1, 41 countries in blue have an active role and therefore can vote during the standards validation process, the 31 countries in yellow are observers, i.e. they receive information but cannot vote.

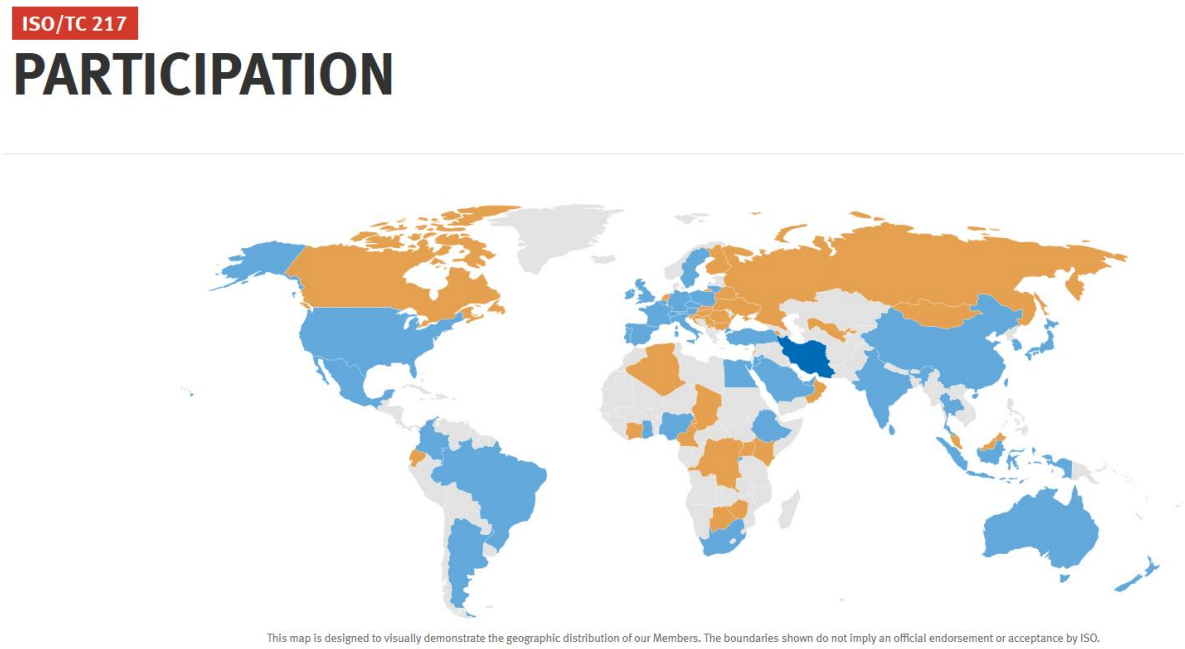

Figure 1: participating and observing countries

Working group 7.was set up in 2006. Its goal is to standardize and publish test methods for sunscreen products.

To participate in the standardization process, it is generally necessary to be an active member of the national standardization agency. It is, for example, for France the AFNOR, for England the BSI, the United States the ANSI. These national agencies meet their members upstream, discuss and take national decisions which will be commented on during meetings of the ISO working group (figure 2).

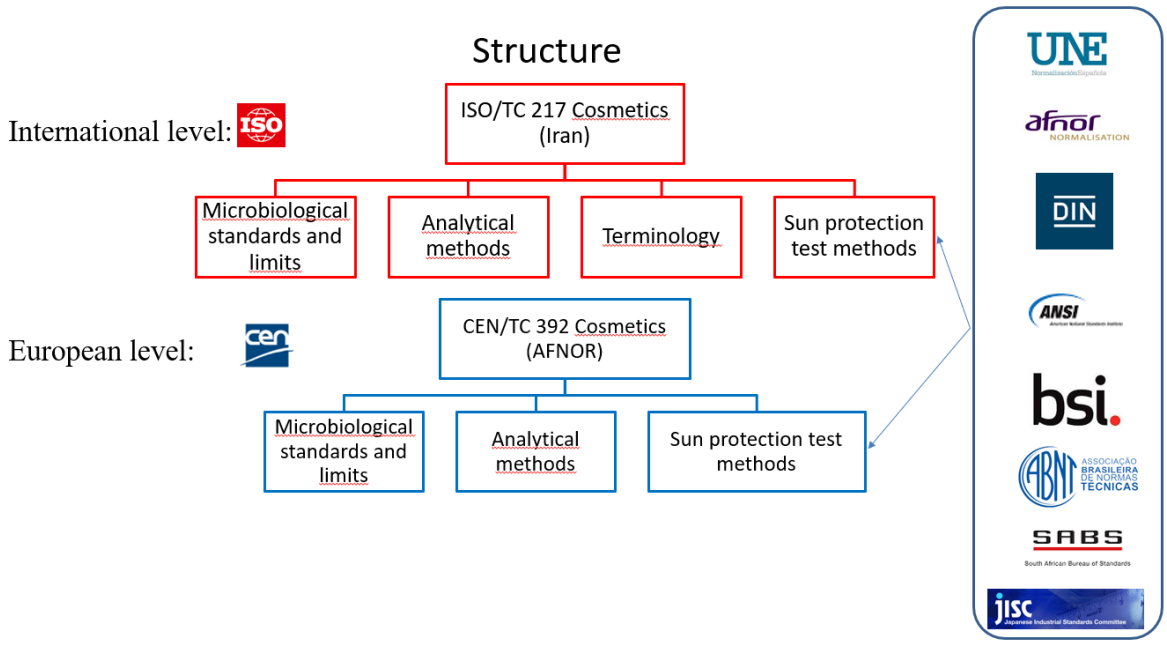

Figure 2: structure of the technical committee 217 and its links

Within the ISO working group, the same work is carried out but this time in internationally, all the experts of the member countries are able to comment on the different subjects. The goal is to find an agreement based on consensus to make recommendations which will then be validated by the ISO technical committee.

The different steps of the ISO standardization process are described in figure 3, but in general the process comprises 6 steps divided into 2 phases:

The first is to set up and develop a working draft (WD). The protocol and technique of the proposed method are discussed and improved. As it improves, the project moves from new work item proposal to WD. Note that there can be several WDs, usually 4 but it can go up to 7 or even more. These steps are validated by WG7 experts.

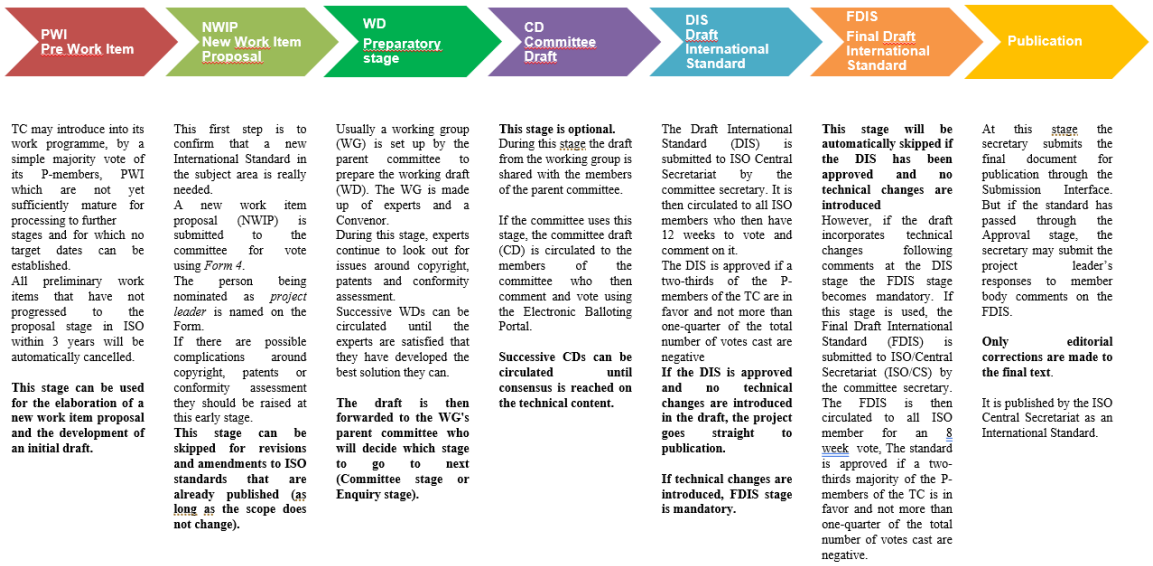

Figure 3: The different steps of the ISO standardization process

The second phases allows the working draft to gradually become a working document that will finally be published by ISO. This time these steps are validated not by the experts of the working group but by the participating member countries. Note that for these votes, one country equals one vote, regardless of the country size.

Since 2006, a lot of standardisation work has been done by the WG7 (figure 4). First, the 2 historical methods, *in vivo* SPF and UVA were published by ISO in 2010 and 2011 respectively, followed one year later by the *in vitro* UVA methods. In 2016, a systematic review of the *in vivo* SPF was launched, followed in 2017 by the *in vivo* and *in vitro* UVA

methods. At the same time (2016), the validation process of *in vivo* water resistance began.

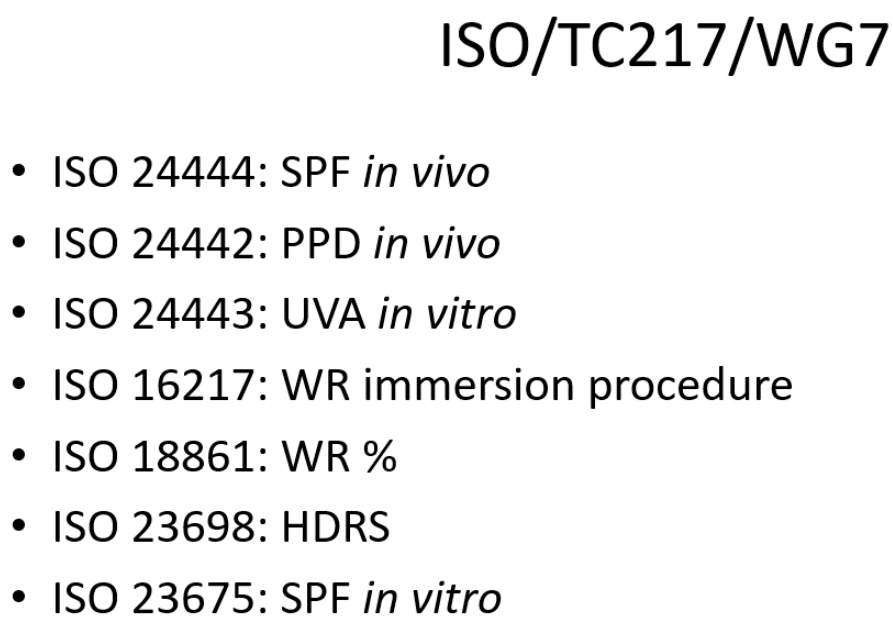

Figure 4: different ISO methods developed or published by the WG7

What is the current situation? The SPF *in vivo* ISO 24444 and UVA *in vivo* ISO 24442 or *in vitro* ISO 24443 methods have been republished in order to take certain technical developments into account. The systematic review of these methods which was initiated a few years ago has led to an improvement especially regarding repeatability and reproducibility within or between laboratories. These technical modifications do not modify the mean value calculated but make it possible to obtain lower standard deviations [2-4].

Another protection factor which is very widely used and was not standardized until 2020, is the water resistance of solar products. From the two historical methods widely used (Colipa & FDA methods), working groups 7 experts have harmonized then optimized an immersion protocol making it possible to obtain an SPF value after bath sufficiently reproducible and repeatable to make it an ISO standard. From these SPF results, another ISO method has been developed to calculate a percentage of water resistance for the countries that use it [5-6].

Some countries will only use the ISO 16217 immersion procedure to obtain the SPF after bathing, others will use ISO 16217 and 18861 in order to obtain a % of water resistance.

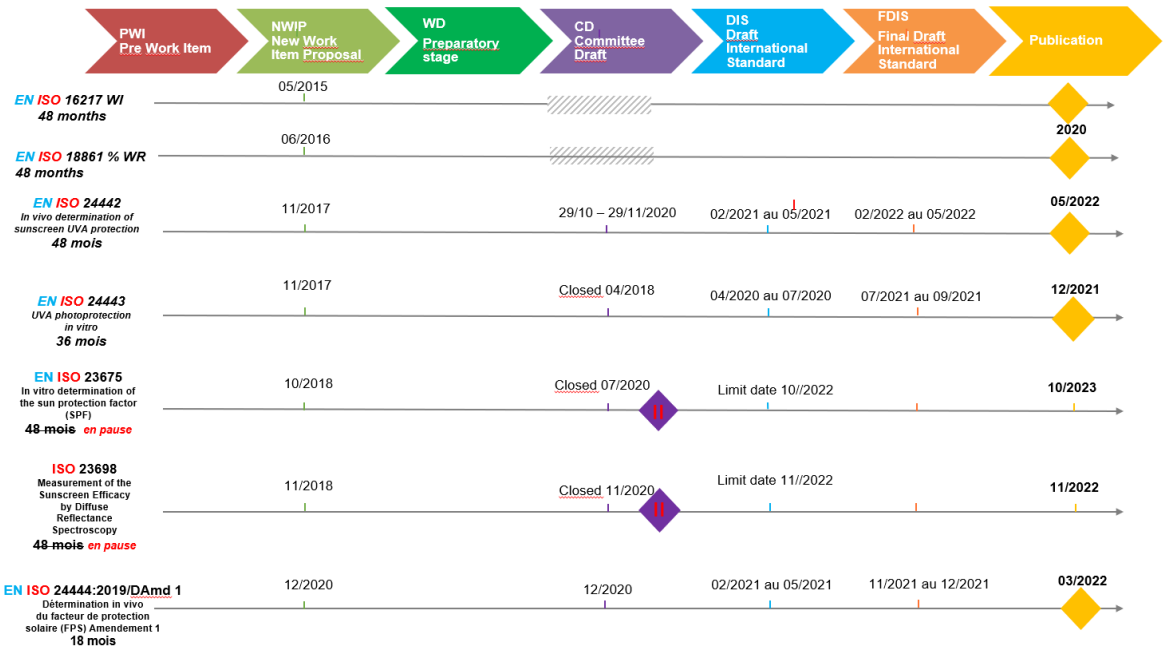

Figure 5: progress of the methods studied within the WG7

Working group 7 has done remarkable work over the past 15 years by producing 5 standards for repeatable and reproducible testing of sun protection products (figure 5). However, there is still at least one *in vitro* method to be published as recommended by the European Commission [7].

ISO already offers a harmonized method for *in vitro* UVA testing, but this is still not the case for *in vitro* SPF. Thanks to great efforts, in particular from Cosmetique Europe who has published 2 manuscripts in order to validate an *in vitro* SPF method [8-9] and from a group of researchers who has developed another method based on diffuse reflection [10] this might be overcome. ISO is currently studying these 2 alternative methods to 24444 in order to publish them probably in 2025-2026.

Only the *in vitro* water resistance method remains to be able to offer a complete alternative to the currently validated *in vivo* measurement.

Conclusion. It seems obvious nowadays that test methods must be harmonized, repeatable and reproducible, cosmetics cannot be an exception. The enormous work initiated in 2006 by ISO TC217 now allows players in the cosmetics sector to be able to use standardized *in vivo* methods for all commonly used protection factors and for most *in vitro* methods.

There is still work to be done in order to standardize the *in vitro* SPF method, but the future looks promising and we can hope to see the two methods which are currently in progress in the ISO process be published in 2025-2026.

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Conflict of Interest Statement. NONE.

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