

Federation of the European Sporting Goods Industry

FEDERATION OF THE EUROPEAN SPORTING GOODS INDUSTRY

House of Sport

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FESI COMMENTS ON UV PROTECTIVE CLOTHING

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It has come to the attention of the Federation of the European Sporting Goods Industry (FESI) that an inconsistency has been identified in the first version of the Guidelines on the PPE Regulation (1st Edition - April 2018).

According to the PPE Guidelines, skin protection against natural UV radiation should be considered PPE Category I when protecting against natural UV radiation (Appendix, 16.6, p. 165). However, the Guidelines also indicate that *natural UV-radiation (sunlight) is not an atmospheric condition* (p. 26).

Annex I of the PPE Regulation lays down the categories of risk (Categories I-III) against which PPE is intended to protect users. A PPE can only be categorized as belonging to Category I if it is intended to protect users against a clearly defined list of exclusively included minimal risks. Atmospheric conditions that are not of an extreme nature are included in this list of Annex I.

Since natural UV-radiation is not an atmospheric condition according to the Guidelines, all UV protective clothing should – following this logic – be considered as PPE Category II. However, we believe that this decision will lead to serious consequences for both consumers and economic operators.

FESI calls the Commission and the members of the PPE Working Group to work on a solution that will not only ensure that the health, safety and economic and legal interests the PPE Regulation aims to protect are fully respected, but also that it will avoid unjustified regulatory burden and will not unnecessarily penalize either manufacturers or EU consumers.

Please find below FESI initial comments on this issue as well as the alternative solution we wish to present to the members of the PPE Working Group.

ON THE NOTION OF ATMOSPHERIC CONDITION

The source of the inconsistency is the fact that the Guidelines do not recognise natural UV-radiation as (a consequence of) an atmospheric condition.

Natural UV radiations are produced by the sun. Exposure to the sun's ultraviolet radiation has an impact on the human body and may in some circumstances entail risks for health. Those risks – although different in nature and importance – depend, on the one hand, on radiation intensity and, on the other, the duration and conditions of exposure.

While duration and conditions of exposure are directly linked to consumers' behaviors (permanence outdoors, time of day, wearing sunscreen and UV protecting clothing, etc.), radiation intensity relates to the nature of the sunlight. During a sunny summer day the UV index will be higher than when cloudy / rainy – hence increasing UV radiation to the human body. UV protective clothing provides a protection (at various levels) against potential risks indirectly caused by weather conditions.

In addition, most people adjust their daily plans and choice of clothing to the weather forecast, especially to temperature conditions and as to whether it will be sunny or it will rain. This means that consumers themselves clearly associate the potential risks entailed by natural UV radiation with specific atmospheric conditions.

Last but not least, the PPE Guidelines (page 26) state that *protection against weather (atmospheric) conditions, [includes] but [is] not limited to seasonal clothing e.g. rainwear and clothing protecting against cold that is not extreme*. Likewise, most UV protective clothing provides protection to users against <u>heat</u> that is not extreme.

Thus, the guidelines make a clear connection between weather and atmospheric conditions. Products that protect against these, when they are not extreme, are not PPE. Weather is made up of multiple parameters, including air temperature, atmospheric (barometric) pressure, humidity, precipitation, **solar radiation** and wind. Each of these factors can be measured to define typical weather patterns and to determine the quality of local atmospheric conditions.

For the above mentioned reasons, FESI urge the Commission and the members of the PPE Working group to recognise that natural UV-radiation (sunlight) is an atmospheric condition and amend the PPE Regulation Guidelines accordingly.

ON THE NOTION OF EXTREME NATURE

According to the PPE Guidelines, atmospheric conditions that are not of an extreme nature are normal weather conditions, (...) which can be expected when performing outdoor activities (...) (p. 82). Once again, most (not all) UV protective clothing is intended to be worn when performing

outdoor activities in non-extreme weather conditions (e.g. hiking, kayaking, spending a couple of hours at the beach, etc.).

This does not mean that sunlight cannot be of an extreme nature. Environmental factors can have an impact on the UV level. At higher altitudes, a thinner atmosphere filters less UV radiation. With every 1000 meter increase in altitude, UV levels increase by 10% to 12%. The closer we are to the equator, the higher the UV radiation levels. People climbing a mountain or desert trekking in the Sahara are thus likely to face atmospheric conditions of an extreme(r) nature with high levels of natural UV radiation.

It is also possible to encounter high UV radiation levels during the day time in temperate climates and at low altitudes. The World Health Organisation (WHO) has produced extensive research on UV radiation and health. They recommend following the UV index which indicates the level of UV radiation and the potential danger of sun exposure on a given day. As shown in the table below, extra protection is strongly advised when facing an UV index of 8 or higher.



In addition, the WHO has also put out <u>guidelines</u> which define what constitutes extreme atmospheric conditions. Industry acknowledges that weather conditions captured by levels 8, 9, 10, and 11 could be considered "extreme" although the WHO itself narrowly defines only level 11 as Extreme. Such conditions may be found at high altitudes or on reflective glaciers or where there is no or just a very thin ozone layer. But <u>in any case</u> below level 8, the conditions are normal atmospheric conditions (as defined in p. 82 of the Guidelines) and pose no more threat than ordinary and seasonal cold, heat, wind or rain.

| EXPOSURE CATEGORY | UVI RANGE |
|-------------------|---|
| LOW | < 2 |
| MODERATE | 3 TO 5 |
| HIGH | 6 TO 7 |
| VERY HIGH | 8 TO 10 |
| EXTREME | 11+ |
| | Table 1: UV radiation exposure categories |

Therefore, the WHO UV index demonstrates that in most circumstances, sunlight should not be considered as an atmospheric condition that is of an **<u>extreme</u>** nature.

ON THE NOTION OF MINIMAL RISKS

Category I applies to PPE intended to protect users against (specific) minimal risks. There is unfortunately no clear definition in neither the PPE Regulation nor the PPE Guidelines of the notion of minimal risks.

While we must not forget that natural UV radiations also have positive effects on the human body (by stimulating the production of vitamin D for instance), they can also trigger serious consequences. Constant, prolonged and/or repeated exposure to the sun's UV radiation induces most of the skin changes commonly associated with aging, such as wrinkling, thickening, and changes in pigmentation. Reddening of the skin (sunburn) is another direct effect of UV radiation which comes on more or less gradually depending on the exposure level and the skin type. There is also a risk of developing skin cancer, particularly in persons with fair skin.

Most risks linked to sun exposure (because of natural UV radiation) are thus minimal. However, prolonged and repeated exposure to natural UV radiation can also have more dramatic consequences, especially for young children and persons with fair skin. This segment of the population, to be efficiently protected, requires extra protection.

Nevertheless, for the vast majority of the population, simple clothing – that provides low to medium levels of protection - will suffice to protect them against the sun.

Since sunlight is, from our perspective, an atmospheric condition, and one that, in the vast majority of the cases, is not of an extreme nature, we would recommend that UV protective clothing not providing high levels of UV protection be considered as PPE category I for professional use and excluded from the scope of the PPE Regulation if designed for private use as set forth in Article 2.2 of the PPE Regulation.

FESI notes that protective benefits claimed by the manufacturer on product labels or packaging, regardless of CE marking, could still be challenged by a regulator at any time and could lead to appropriate internal/3rd-party testing.

ON THE NEED TO FIND THE PROPER THRESHOLD

While FESI believes that most UV protective clothing intended for private use should be excluded from the scope of the PPE Regulation, products especially designed to provide a very high level of protection against natural UV radiation should be considered as PPE Category II.

As stated above, in some circumstances sunlight can be perceived as an extreme atmospheric condition, significantly increasing the risks for the human body. While most such risks are minimal,

the risk of developing skin cancers cannot be ignored, particularly in some specific segments of the population (children and people with fair skin).

The UV standard 801 developed by International Test Association for Applied Protection against UV Radiation presents a table on recommended sun protection factor (SPF) by index and skin type.

| UV index | Children's skin | Skin type I | Skin type II | Skin type III | Skin type IV |
|-------------|-----------------|-------------|--------------|---------------|--------------|
| 3 - 4 | UPF 20 | UPF 20 | UPF 15 | UPF 10 | UPF 5 - 10 |
| 5 - 6 | UPF 20 - 40 | UPF 20 - 40 | UPF 20 - 40 | UPF 20 | UPF 10 |
| 7 - 8 | UPF 60 - 80 | UPF 60 - 80 | UPF 40 - 60 | UPF 40 | UPF 20 |
| 9 and above | UPF 80 | UPF 80 | UPF 60 - 80 | UPF 60 | UPF 40 |

Recommended sun protection factor (SPF) by index and skin type

By collating this information with the recommendations of the WHO, the minimum level of protection recommended for children and (very) fair skin when the UV index is 8 and above (extra protection needed) is UPF 60.

FESI would thus recommend that all UV protective clothing indicating UPF 60 or more should exclusively be considered as PPE Category II, to ensure those individuals who are most vulnerable to natural UV radiation to make an informed purchase of a a product that will adequately protect them.

Futhermore FESI believes that the UPF level should not be the only criteria dictating whether a product with UV protective properties manufactured for private use should be excluded from the scope of the PPE Regulation or be considered PPE Category II. For example, if a manufacturer chooses to market and label a product with protective claims against "exceptional/severe atmospheric conditions" as the product's prime function, such a claim would make the product Category II PPE.

FESI PROPOSAL

In light of the above, FESI would recommend the following amendments to be included in the Guidelines:

PPE designed and manufactured for private use to provide protection against weather (atmospheric) conditions, including but not limited to seasonal clothing e.g. rainwear and clothing protecting against cold **and heat** that **is are** not extreme, does not fall under the scope of the PPE Regulation. Natural UV-radiation (sunlight) is **not** also considered as an atmospheric condition

| Type of PPE | Category |
|---|----------|
| Skin protection for private use against natural UV radiation: all garments, including partial or whole body clothing, caps and helmets, gloves, and shoes, designed and manufactured to have specific UV-protective properties against natural UV radiation | |
| Except: | |
| All garments, including partial or whole body clothing, caps and helmets, gloves, and shoes which have a functional UV-protective claim of UPF 60 or more or where the manufacturer claims a protective function against exceptional/severe atmospheric conditions | |



FESI would like also to strongly encourage the European Commission, Member States and the industry to continue ongoing initiatives and develop new ones aiming at better educating consumers on the most appropriate means and level of protection available when exposed to natural UV radiation.

1. Please provide short information on your company and the products with UV-protective properties that the company manufactures.

Company A is an outdoor equipment company, designing and producing outdoor apparel for private use during outdoor activities. They sell T-Shirts, Shirts, Caps, Hats and Pants with UV Protection properties between UPF +15 and +50.

Company B is mainly known in doing outdoor and skiing garments. They are using UVprotective properties for garments like: TShirts, blouses and trousers (firstlayer).

Company C is an outdoor company that design and produce head and neck accessories for private use with UV protection properties +50. The articles with UV protecting clothing represent 50% of the total sales of the company.

2. What impact does the classification in category 1 for your products and your company have?

For **company A**, Category 1 will leade to higher costs for special labelling, information and conformity documentation, to more administrative efforts for creating technical documentation and to additional labour costs (trainings, additional staff etc.)

For **company B**, The classification in category 1 means a lot of extra work and manpower.

For **company C**, PPE Category 1 classification means higher cost to add extra labelling, user information and declaration of conformity. All of them with another extra cost due to translations into all languages where the products are sold. Additional labour cost are also foreseen (training, manufacturing, additional staff, document management for 10 yearstechnic documentation and declaration of conformity according to Regulation). A huge change will also take place in the communication strategy that affects marketing, retail, trade marketing, website. Managing of current stock of products, packaging and communication supports will also be impacted. These stocks become obsolete and must be destroyed with important financial costs. Re-label all the stock that are carried over from previous seasons and we have already in our warehouse is also foreseen.

3. What impact would a classification into category 2 have for your products and your company?

Company A: Category 2 requires certification from notified bodies which will cause extraordinary costs which cannot be forwarded to the end consumers and delays in timelines. In addition, styles are not allowed to be changed within 5 years or need new certificate or permit from NB (leading to additional costs). If all UV protective clothing are considered to be PPE category 2, we need to decide if we will further design, produce and sell garment with UV protective properties.

Company B: The classification into category 2 would have a huge impact for our company! This decision would change the whole sales strategy in a negative way. To put UVprotective garments into category 2 creates extra work and a huge effort which isn't tradeable as well as viable for our company. If UV-protective garments would be category 2 we will not promote any UV-protective properties in future.

Company C: Same answer that Company A. Certification from a notified body with a high cost for each article (every colour/print has to be tested).

4. *Why would* consumers not be better protected or informed if all garments with UVprotective properties were PPE-category 2?

Company A: UV protection is a combination of UPF garment combined with sun cream (adequate for skin type) and duration of sun exposion. UPF in textiles is given by construction, thickness and colour, UPF rate can be checked by all certified laboratories. Certification by notified bodies will only increase costs without any further benefit for brand or end consumer. Category 2 might also imply that garment can protect from all risks while doing sports outdoors.

Company B: To put UV-protective garments into category 2 is misleading the consumers. Every consumer has to evaluate its own skin protective properties and thus to choose garments that additionally protect its skin.

Company C: The UPF factor announced in our UPF products are already based on a test carried out by an external laboratory. The reports with the test are already made available to consumers in our website. We believe that the end-consumer in outdoor activities understand what UPF means but not PPE category 2 so by announcing category 2 PPE we would be giving confusing information about the product. We also agree with Company A and B answer.

FINAL REMARKS

There is undoubtedly a clear need to update the Guidelines to ensure that they do not contradict the PPE Regulation and cause confusion among economic operators, notified bodies (who need to carry out the EU type-examination procedure), market surveillance authorities and EU consumers.

One of the possibilities would be to consider all UV protective clothing as PPE Category II. FESI strongly advises the European Commission and the members of the PPE Working Group not to make that choice. In principle, all clothing provides a degree of protection against natural UV-radiation. A variety of factors can influence the level of protection provided by a garment (fiber composition and its level of woven density, color of the garment, etc.). This is factual information that can be of interest to consumers.

Once a product is a PPE, whether Category I or II, it must meet rigorous standards in order to comply with the basic health and safety requirements laid down in the PPE Regulation. The cost for

compliance is always one among many factors that manufacturers must take into account before placing a new product on the market.

Manufacturers of clothing providing a high level of protection against natural UV radiation (as one if not the primary function of the product) will very likely be willing to bear this cost – as it also has the advantage of reinforcing consumers' trust in the product. However, for the vast majority of garments providing a low to medium level of protection, economic operators will have to decide whether to go through the certification process or to simply remove this information before marketing the product. While this decision will have to be taken by each manufacturer individually, there is a risk that finding a garment providing low/medium protection against UV radiation will become more complex for consumers as they will not know whether a garment has good UV protective properties or not (unless explicitly mentioned by the manufacturer). This is not the best outcome for consumers who would be better off with adequate information on products that will provide them the *appropriate* level of protection against the sun. On the contrary, if all garments indicating a UV protective function – regardless of its level – were to be marked and marketed as PPE Category II, it would potentially mislead consumers into thinking that the garment will provide enough protection in any given circumstances.

Finally, it is key to stress that legal certainty is highly important for businesses. Before the revision of the PPE Directive guidelines, UV protective clothing have never been considered as PPE. Adapting production lines and supply chains to new legal requirements can be challenging – especially since the interpretation of the PPE Regulation keeps evolving. The content of a catalogue collection is defined at least within 18 months before the season starts. At the time of the definition of the collection, companies must know the cost implication and the legal requirements. Many sporting goods companies have started re-labeling their products as PPE Category I. This is a costly and time-consuming process. The possibility of having those products re-classified as PPE Category II in the coming months is thus even more worrying as all those efforts would have been done in vain.

Founded in 1960 FESI - the Federation of the European Sporting Goods Industry represents the interests of approximately 1,800 sporting goods manufacturers (85% of the European market) through its 12 National Sporting Goods Industry Federations and its directly affiliated member companies. 70-75% of FESI's membership is made up of Small and Medium Sized Enterprises. In total, the European Sporting Goods Industry employs over 650,000 EU citizens and has an annual turnover of some 66 billion euro