Federation of the European Sporting Goods Industry

FESI POSITION ON PPE GUIDELINES

FEDERATION OF THE EUROPEAN SPORTING GOODS INDUSTRY

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The Personal Protective Equipment (PPE) Regulation is of key importance to the sporting goods industry to ensure that safe protective equipment can be marketed in all EU Member States. It defines legal obligations to ensure that PPE on the European market provides the highest appropriate level of protection against hazards.

FESI welcomes the publication of an FAQ document and the decision of the European Commission to draft guidelines on the PPE Regulation. We strongly believe that clarifications are needed to ensure the uniform and harmonised application of the Regulation in all the Member States.

Please find below elements of the new Regulation which from our perspective should require further clarifications to ensure that safe sport equipment can be sold throughout the EU and that compliant manufacturers can rely on a clear and streamlined legal framework.

Transitional period (1)

FAQ document
Q: Until which date is it possible to issue EC type examination certificates according to Directive 89/686/EEC?

A: In principle EC type-examination certificates can be issued until the end of the transitional period, i.e. 20 April 2019. However, issuing EC-type examination certificates in the transition period may divert resources needed for the recertification of products according to the Regulation. The Commission recommends issuing only EU type examination certificates after 21 April 2018.

FESI is strongly concerned by the wording proposed by the Commission in the FAQ document as it goes against the spirit of Article 47 of the PPE Regulation which states that (…) *Member States shall not impede the making available on the market of products covered by Directive 89/686/EEC which are in conformity with that Directive and which were placed on the market before 21 April*

2019. The purpose of a transitional period is to provide companies with sufficient time to adapt their delivery chain to the new requirements of the Regulation. The Commission's approach tends to *de facto* nullify a key element of the transitional period.

FESI proposal: FESI would recommend the deletion of this provision.

Transitional period (2)

Concerns have emerged among stakeholders regarding the various interpretations made of the transitional provisions. FESI urges the European Commission to further clarify Article 47 of the PPE Regulation in the guidelines to ensure a transition from the Directive to the Regulation as smooth as possible.

Article 47.1 states that *Member States shall not impede the making available on the market of products covered by Directive 89/686/EEC which are in conformity with that Directive and which were placed on the market before 21 April 2019*. It is thus fundamental to make clear in the guidelines that individual products in compliance with the PPE Directive and put on the market before 21 April 2019 can be sold without any time limits.

It is worth noting that provisions of the 2016 Blue Guide (§2.3) are in line with this interpretation of Article 47.1: "*Compliant products once they have been placed on the market may subsequently be made available along the delivery chain without additional considerations, even in case of revisions to the applicable legislation or the relevant harmonised standards, unless otherwise specified in the legislation".*

FESI proposal for a timeframe to be included in the FAQ document and in the guidelines:

21 April 2018: Entry into force of the PPE Regulation and start of the transitional period of one year: Notified Bodies can certify PPEs against both the former Directive and the new Regulation.

21 April 2019: End of the transitional period: Notified Bodies can certify PPEs only against the new Regulation. PPEs certified against the Directive and which have been placed on the market before 21 April 2019 can remain on the market. EC type-examination certificates delivered before 21 April 2019 remain valid until 21 April 2023 unless they expire before that date. If an EC type examination certificate does not have an expiry date, it remains valid until 21 April 2023.

21 April 2023: Products certified under the PPE Directive must be recertified under the PPE Regulation, except for each individual PPE product that was already **placed*** on the market before 21 April 2019, which may subsequently be further **made available*** along the delivery chain without additional considerations, even in case of revisions to the applicable legislation or the relevant harmonised standards, unless otherwise specified in the legislation.

*For the concepts of "placing on the market" and "making available on the market", see Blue Guide 2016, par. 2.2 and 2.3.

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Harmonised standards

FAQ document

Q: Are new lists of references of PPE harmonised standards to be published on the OJEU in the date of applicability of the new Regulation?

A: (…) The goal is to publish a list of references of PPE harmonised standards before 21st April 2018; when products are not covered by harmonised standards cited in the OJEU under the PPE Regulation, their conformity will need to be assessed directly to the essential health and safety requirements of the Regulation. Harmonised standards may or may not cover all applicable Essential Health and Safety Requirements (EHSRs); in the latter case the manufacturer has, in addition to the application of these standards, to assess the conformity to the EHSRs not covered by using other relevant technical specifications and test methods (…)

To ensure legal certainty and predictability for both manufacturers and notified bodies, the list of standards which comply with the new Regulation must be published as soon as possible – especially standards harmonised under the PPE Directive for which the relevant ESHRs have not been modified under the PPE Regulation. FESI would encourage the European Commission to provide CEN and other stakeholders that may be in charge of the assessment and the potential revision of harmonised standards all help and resources needed to meet this tight deadline.

If the complete list cannot be finalised before the Regulation enters into force, the Commission must inform stakeholders and notified bodies that a harmonised standard complies with the Regulation as soon as it has been confirmed by the relevant authorities. The publication in the Official Journal of the European Union of each harmonised standards individually is strongly encouraged as it is the only way to provide a presumption of conformity with the ESHRs and other requirements it aims to cover.

FESI would also like to reiterate its concerns regarding the Commission's statement that the conformity of products should be assessed directly to the essential health and safety requirements of the Regulation if they are not yet covered by a harmonised standard under the PPE Regulation. Distributors and consumers tend to rely on standards to make an informed purchase. The Commission's approach might thus create unnecessary confusion among distributors and consumers.

FESI proposal to be included in the FAQ document and in the guidelines:

FAQ document

A: (…) The goal is to publish a list of references of PPE harmonised standards before 21st April 2018; ~~when products are not covered by harmonised standards cited in the OJEU under the PPE Regulation, their conformity will need to be assessed directly to the essential health and safety requirements of the Regulation. Harmonised standards may or may not cover all applicable Essential Health and Safety Requirements (EHSRs); in the latter case the manufacturer has, in~~

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~~*addition to the application of these standards, to assess the conformity to the EHSRs not covered by using other relevant technical specifications and test methods .*~~ ***If the complete list cannot be finalised before the Regulation enters into force, the Commission will inform stakeholders and notified bodies that a harmonised standard complies with the Regulation as soon as soon as it has been confirmed by the relevant authorities. The European Commission will publish in the Official Journal of the European Union each harmonised standards individually if needed*** *(…).*

Declaration of conformity – transitional period

FAQ document

Q: From which date a manufacturer has to mention the new PPE Regulation for his EU declaration of conformity?

A: Before 21 April 2018 all the EC declarations of conformity for PPE products placed on the EU market for the first time must be in line with Directive 89/686/EEC. PPE placed on the EU market during the transitional period (21 April 2018 to 20 April 2019) can either be accompanied by a declaration of conformity to Directive 89/686/EEC or by a declaration of conformity to the new Regulation (if all the requirements of the Regulation are complied with). According to Article 47 products that are already in the distribution chain before 21 April 2019 can continue to be made available with the EC declaration of conformity referring to Directive 89/686/EEC, as they have already been lawfully placed on the EU market. Declarations of conformity (EC or EU) remain valid according to the legislation in force when the product is placed on the EU market (= made available on the EU market for the first time). There is no need to change legislative references in documents accompanying the product. For products placed on the EU market as of 21 April 2019, the EU declaration of conformity must be in accordance with the new PPE Regulation (EU) 2016/425. Please note that placing on the market always refers to the single item, not to a series or to a type of product.

FESI supports the approach of the European Commission. Products that are already in the distribution chain **before 21 April 2019** can continue to be made available with the EC declaration of conformity referring to Directive 89/686/EEC, as they have already been lawfully placed on the EU market. There is no need to change legislative references in documents accompanying the product.

Address of the manufacturer - translation

FAQ document

Q: How to implement the requirement that the contact details shall be in a language easily understood?

A: The address does not have to be translated. The characters of the language must allow identifying the origin and the name of the company. This is not possible with certain alphabets.

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Problems may emerge when marketing products in Member States not using Latin script such as Bulgaria and Greece. In such scenario, Latin script may be used to indicate the contact details as the Latin script is the standard method of writing in most European languages and it can be easily understood by consumers based in countries which do not use this alphabet.

FESI proposal to be included in the FAQ document and in the guidelines:

A: The address does not have to be translated. The characters of the language must allow identifying the origin and the name of the company. This is not possible with certain alphabets. ***Latin script may be used to indicate the contact details as the Latin script is the standard method of writing in most European languages and it can be easily understood by consumers based in countries which do not use this alphabet.***

Request from a competent national authority

Q: How long should it take for distributors to provide the necessary documents, taking into account the fact that even the smallest distributor should provide the information?

A: There is not specific time limit in the Regulation for a "reasonable period". This period has to be assessed by the authorities on a case-by-case basis, taking into account the level of urgency/seriousness of risk and the efforts for the economic operator to follow-up the request.

While we understand the Commission's objective to privilege flexibility and to allow authorities to decide on a case by case basis, FESI would nonetheless appreciate the inclusion of indicative timeframe. We would recommend 3 business days for an issue identified by the regulator as a serious issue and 10 business days for other issues. A balance must be found between ensuring legal certainty / predictability for manufacturers and providing a flexible and efficient mechanism allowing national authorities to swiftly react to different situations.

FESI proposal to be included in the FAQ document and in the guidelines:

A: ~~There is not specific time limit in the Regulation for~~ ***Distributors shall provide the necessary documents within*** *a "reasonable period"* ***of time****. This period* ***may vary and*** *has to be assessed by the authorities on a case-by-case basis, taking into account the level of urgency/seriousness of risk and the efforts for the economic operator to follow-up the request.* ***3 business days for an issue identified by the regulator as serious and 10 business days for other issues shall be considered as a reasonable period of time under this Regulation.***

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Reflective elements for reason of design

Recital 10 - PPE Regulation
(…) *clothing intended for private use with reflective or fluorescent elements included for reasons of design or decoration is not personal protective equipment and is therefore not covered by this Regulation (…).*

There needs to be a dividing line between garments with reflective but not PPE, and garments with (a substantial degree of) reflective that are PPE.

Innovation in design has always been the heartbeat of the sporting goods industry and for decades manufacturers and suppliers have included various reflective elements to enhance the visual appearance of their products. In most cases, the product is clearly not meant for protective wear and the consumer is in no way led to believe that this is the case. No product sold by our members claim to contain safety features if it is not PPE.

Ideally, the definition of "design" would include design that "enhances conspicuity" short of being PPE. "Design" does not preclude that the design is functional. If the provisions of the new PPE Regulation are defined very narrowly such that any garment seen to "signal the user's presence" is viewed as PPE, then manufacturers will remove reflective components entirely for fear of running afoul of the law.

Only garments that are marketed and marked as PPE should be regarded as PPE.

FESI proposal to be included in the guidelines:

Clothing intended for private use with reflective or fluorescent elements included for reasons of design or decoration should be considered PPE if and only if they claim to fulfil a protective function. Products should not be considered PPE on the sole ground that they are meant to enhance conspicuity.

Exemptions - products designed and manufactured for private use

Article 2.1 – PPE Regulation
2. This Regulation does not apply to PPE:
- (…)
- (c) designed for private use to protect against:
    (i) atmospheric conditions that are not of an extreme nature,

The Regulation does not apply to PPE designed for private use to protect against atmospheric conditions that are not of an extreme nature. Concerns have emerged that authorities may consider PPE products designed for private use which are bought by professionals (e.g. a ski

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school buying 15 jackets for their ski instructors while this product has been initially designed for private use).

FESI would appreciate the opinion of the European Commission on this issue. A lack of clarifications of Article 2.1c could in a hypothetical worst-case-scenario imply that all products designed for private use to protect against atmospheric conditions that are not of an extreme nature could be considered as PPE since professionals might use them.

To ensure that notified bodies, market surveillance authorities and manufacturers can rely on a clear and streamlined legal framework, FESI would also support the inclusion of a definition of **extreme nature** in the guidelines.

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Founded in 1960 FESI - the Federation of the European Sporting Goods Industry represents the interests of approximately 2,400 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.

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