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Subject: Proposal for a Regulation of the European Parliament and of the Council
on personal protective equipment
- Preparation for the informal trilogue

I. INTRODUCTION

1. The Commission presented the above proposal on 1 April 2014.¹
2. The Council Working Party on Technical Harmonisation has examined the proposal on seven occasions under the Hellenic and Italian Presidencies since April 2014.

¹ doc. 8453/14 + ADD1.

3. The Council agreed on a General Approach on this file on 4 December 2014². At this occasion, the Presidency was also mandated to enter into informal negotiations with the representatives of the European Parliament and the European Commission in order to explore the possibility of an agreement at first reading. It has to be pointed out that to a large extent, the text of the General Approach includes standard provisions already adopted for the files of the "Alignment Package" agreed in 2013.
4. The European Parliament Internal Market and Consumer Protection Committee (IMCO) adopted its report on the proposal on 23 April 2015. This report contains 157 amendments to the text of the original Commission proposal. The Council Working Party on Technical Harmonisation examined these amendments in detail in May 2015.

II. STATE OF PLAY

5. Informal contacts with the representatives of the European Parliament and the European Commission have resulted in a consensus on most of the text. Furthermore, during a first informal trilogue on 11 May 2015 which focused on the Cableways dossier, a short exchange of views on the Personal Protective Equipment file has already taken place.
6. The Council Working party on Technical Harmonisation has regularly been informed of the progress in the negotiations with the European Parliament. At the meeting on 29 May, the Working Party confirmed that most of the text seems to be acceptable. The acceptable parts of the text can be found in the four-column-document (in the right column / green shaded) which is set out in Addendum 1 to this note.

² doc. 15735/1/14 REV 1 + COR 1.

The few open issues can be divided in three groups.

- A. Firstly, horizontal provisions which are largely identical in the regulations on "Personal Protective Equipment", on "Cableways" and on "Appliances burning Gaseous Fuels". These issues should be dealt with at the occasion of a trilogue on 16 June. The Presidency will defend the text of the General Approach in its entirety as these provisions follow exactly what was adopted on the Alignment Package in 2013 and should, therefore, not be altered.
- B. Secondly, there are issues of secondary importance where either the texts of the European Parliament and the Council are close to each other and the final compromise can be found at technical level or where the representatives of the European Parliament are still discussing internally whether the Council wording can be accepted. These issues are still presented as "yellow-shaded" in the four-column-document. For these issues the Presidency does not propose any new compromise text to the Committee and will maintain the substance of the General Approach.
- C. Thirdly, there is a group of issues of a more political nature, shaded either in yellow or red and set out in section III below, which remain open. On these the Presidency would like to receive guidance from the Committee.

III. OUTSTANDING ISSUES

a) **Scope of the Regulation, clarifying the exclusions (Recital 9, Article 2 (2))**

8. The Council General Approach followed the original Commission proposal regarding the scope of products covered by the Regulation. Several IMCO amendments, however, seek to exclude some products for private use, in particular dishwashing gloves and oven gloves, from the scope and/or try to clarify the borderline to decorative products in a different wording.

In order to find a compromise the Presidency suggests that dishwashing gloves for private use be excluded from the scope, that oven gloves be maintained in the scope of the Regulation, and that the legal situation of different kinds of decorative products (including decorative gloves and clothing with fluorescent elements) should be clarified in the recitals. This compromise would present a balance and a middle point between the positions originally taken by both institutions.

The necessary modifications to the text of the General Approach would be as follows:

Recital 9: Some products on the market that provide a protective function to the user are excluded from the scope of Directive 89/686/EEC. In order to ensure as high level of protection for the user of those products as for the PPE covered by Directive 89/686/EEC, the scope of this Regulation should include PPE for private use against ~~damp, water and heat~~ **high temperature environments** (e.g. ~~dish washing gloves,~~ oven gloves), in line with similar PPE for professional use which is already covered by Directive 89/686/EEC. Artisanal products, such as handmade gloves, designed for decorative purposes and not intended to fulfil a protective function are not personal protective equipment; **and they are** therefore not concerned by this inclusion. **Clothing intended for private use with reflective or fluorescent elements which are exclusively included for reasons of design or decoration are not personal protective equipment and therefore not covered by this Regulation. In the case of products intended for private use to protect against atmospheric conditions that are not of an extreme nature or to protect against damp and water, including but not limited to seasonal clothing, umbrellas and dishwashing gloves, these should be outside of the scope of this Regulation.** It is also appropriate to clarify the exclusion list set out in Annex I to Directive 89/686/EEC by adding a reference to products covered by other legislation and therefore are excluded from the PPE Regulation.”

Article 2 (2) (c):

2. This Regulation shall not apply to PPE:

(a) specifically designed for use by the armed forces or in the maintenance of law and order;

(b) designed to be used for self-defence with the exception of PPE intended for sporting activities;

(c) designed for private use to protect against:

(i) atmospheric conditions that are not of an extreme nature;

(ii) damp and water not of an extreme nature;

(iii) heat if the risk involved for the user is not classified higher than risk category I as set in Annex I for which the manufacturer has provided clear information on the product, its packaging or accompanying documents that it can only be used in low temperature environment.

b) Field tests (Recital 10a (new) and various IMCO amendments)

9. Both the Commission and the Council consider field tests as being outside the scope of this Regulation since field tests do not serve the purpose of testing products with regard to their health and safety requirements. In general, products used in field tests have to be safe and have already undergone a relevant conformity assessment procedure. The European Parliament, however, finds it important that the legal situation of products undergoing field tests is clarified.

In order to find a compromise, the Presidency suggests that the Council continues to object to the inclusion of field tests in the articles, but that the Council accepts amendment 7 (recital 10a) revised as follows:

(10a) **Field test can be carried out on PPE that meets the health and safety requirements set out in this Regulation.** During ~~field demonstrations and~~ field tests, adequate measures should be taken to ensure the protection of persons. Field tests should not be designed to test the protection performance of the PPE but to evaluate, **for a limited period only,** ~~other non-protective aspects such as comfort, ergonomics and design.~~ All concerned parties, ~~for instance the employer as well as the wearer or the consumer,~~ should be informed in advance concerning the scope and purpose of the test.

c) **Simplified procedure to renew certificates (Recital 24, 24a, Annex V (Module B, 6.1 and 7.4, 7.5., 7.5a))**

10. The examination in the Working Party showed that the Council would be in a position to accommodate the European Parliament's wishes to restrict the maximum validity period of EU-type examination certificates to five years. Therefore, the changes to recital 24 and Annex V, section 6.1. as proposed by IMCO (AMs. 19 and 141) should be acceptable. As a consequence of this shortening of the maximum validity period, IMCO also introduced in amendments (AMs 20 and 145) a simplified procedure for renewal of EU-type examination certificates. The Council Working Party has shown some degree of flexibility also to these amendments. Therefore, the Presidency suggests to adapt recital 24a, Annex V, sections 7.4, 7.5 and 7.5a of the text of the General Approach in order to integrate the new provisions proposed by the European Parliament. :

Recital 24a (new):

(24a) A simplified procedure should be applied for ~~re-certification~~ **review** of the EU-type examination certificate when **the manufacturer has not modified the approved type and the product,** ~~applied~~ harmonised standards or other technical ~~solutions~~ **specifications** applied by the manufacturer have not been changed and continue to meet the essential health and safety requirements in the light of the state of the art., **In such cases** ~~making additional tests or technical examinations~~ **should be** unnecessary and ~~thereby keeping~~ the administrative burden and related costs **should be kept** to a minimum.

Annex V, sections 7.4, 7.5 and 7.5a (new):

7.4. The manufacturer shall ask the notified body to review the EU type-examination certificate:

- (a) in case of a modification to the **PPE-approved type** referred to in point 7.2;
- (b) in case of a change in the state of the art referred to in point 7.3;
- (c) at the latest, before the date of expiry of the certificate.

The manufacturer shall ensure that his application is submitted on time in order to allow the notified body to fulfil its tasks before the expiry date of the EU type-examination certificate, but not more than 12 months before that date.

7.5. The notified body shall examine the PPE type and carry out any tests necessary to ensure that the **PPE-approved type** continues to fulfil the applicable essential health and safety requirements. In that case, it shall renew the EU type-examination certificate. **The notified body shall ensure that the review procedure is finalised before the expiry date of the EU type-examination certificate.**

7.5a ~~At the earliest 12 months and at the latest 6 months prior to the expiry date~~ **Where the conditions of points (a) and (b) of point 7.4 are not met,** the manufacturer may ~~inform~~ **ask** the notified body ~~that a~~ **to apply a** simplified **review** procedure ~~shall apply for the review, as no modification to the PPE referred to in point 7.2 has occurred.~~ The manufacturer shall supply the notified body with the following ~~information~~:

- (a) ~~confirmation of the current company~~ **his** name and address **and data identifying the EU type-examination certificate concerned;**
- (b) confirmation that there has been no modification to the ~~product~~ **approved type as referred to in point 7.2,** including materials, sub-components or sub-assemblies, nor to the ~~solutions applied in the relevant harmonised standards or in other technical specifications~~ **applied;**
- (c) ~~where not already supplied, copies of current product drawings and photographs, product marking and information supplied by the manufacturer~~ **confirmation that there has been no change in the state of the art and no modification to the approved type as referred to in point 7.3;** and
- (d) for category III products, information on the ~~status~~ **results** of the **supervised** product ~~verification~~ **checks at random intervals carried out in accordance with Annex VII or on the results of audits of his** quality assurance of the production process **system carried out in accordance with Annex VIII.**

When the notified body has confirmed that no change in the state of the art **and no modification to the approved type** referred to in point 7.3 has occurred, the ~~EU type-examination laid down~~ **examinations and tests referred to** in point ~~4~~ **7.5** of Annex V shall not be carried out and the notified body shall renew the EU-type examination certificate. ~~The notified body shall ensure that the simplified procedure for renewal is finalised before the expiry date of the EU type-examination certificate. The reference of the certificate will remain unchanged.~~

~~The costs associated with that renewal shall be proportionate to the administrative burden of the simplified procedure.~~

~~If any of the information is missing or if~~ **the notified body finds that** a change in the state of the art referred to in point 7.3 has occurred, the procedure in point 7.5 shall apply.

d) Small units (Article 8 (7) and 10 (4)):

11. The European Parliament finds it important to clarify that all instructions which should accompany PPE should accompany the smallest commercially available units thereof. Both the Commission and the Council seem to take the view that an addition to the articles is unnecessary and only states the obvious. Nevertheless, in order to facilitate an overall compromise, the Presidency asks the Committee to receive a mandate to meet the European Parliament's concern by incorporating the last sentence of IMCO amendments 58 and 64 into the text of the Regulation as follows (identical wording for Articles 8 (7) and 10 (4)):

"Where PPE is available in package containing multiple units, such instructions shall accompany each smallest commercially available unit".

e) Annex II (Preliminary remark 4):

12. The European Parliament accepts the text ("Preliminary remarks") inserted by the Council following the example of similar dossiers. However, regarding point 4, the European Parliament wants to replace "all the risks" by "foreseeable risks". The Presidency does not believe that the European Parliament suggestion would have any significant practical consequences. Therefore, the Presidency asks the Committee for flexibility to amend the text as proposed by the European Parliament, if necessary, to achieve an overall agreement, for example, by deleting the word "all".

f) Penalties and Entry into force and application (Article 39 and 42)

13. The Presidency asks the Committee to endorse the text of Article 39 (AM 99) on penalties, which was agreed horizontally for the proposals on "Cableways", "Appliances burning Gaseous Fuels" and with some adaptations, for this proposal, and consequently also the so-amended text regarding entry into force and application (Article 42, AM 100). The text would read as follows:

Article 39

Penalties

(1) Member States shall lay down the rules on penalties applicable to infringements by economic operators of the provisions of this Regulation ~~and shall take all measures necessary to ensure that they are enforced~~. Such rules may include criminal penalties for serious infringements. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by [one month prior to the date of application of this Regulation] at the latest and shall notify it without delay of any subsequent amendment affecting them.

(2) Member States shall take all measures necessary to ensure that their rules on penalties applicable to infringements by economic operators of the provisions of this Regulation are enforced.

Article 42

Entry into force and application

(1) This Regulation shall enter into force on the twentieth day following its publication in the Official Journal of the European Union.

(2) It shall apply from [two years after entry into force].

(3) By way of derogation from paragraph 2:

(a) Articles 19 to **35** and Article 38 shall apply from [six months after entry into force].

(b) **Paragraph 1 of Article 39 shall apply from [1 year and 11 months after entry into force].**

IV. CONCLUSION

15. The Committee is invited to

- to agree to the Presidency compromises as suggested in section III;
 - to mandate the Presidency to continue the informal trilogues with the representatives of the European Parliament and the Commission, on the basis of the four-column-document set out in Addendum 1 to this note, in view of an agreement at first reading.
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