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Subject:	REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL on the exercise of the power to adopt delegated acts conferred on the Commission pursuant to Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment

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Delegations will find attached document COM(2023) 196 final.

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**REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND  
THE COUNCIL**

**on the exercise of the power to adopt delegated acts conferred on the Commission  
pursuant to Regulation (EU) 2016/425 of the European Parliament and of the Council  
on personal protective equipment**

# **REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL**

## **on the exercise of the power to adopt delegated acts conferred on the Commission pursuant to Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment**

### **1. INTRODUCTION**

Regulation (EU) 2016/425<sup>1</sup> lays down requirements for the design and manufacture of personal protective equipment (PPE) to ensure the protection of the health and safety of users and establish rules on the free movement of PPE in the Union.

To take into account technical progress and knowledge or new scientific evidence, Article 42(1) of the Regulation empowers the Commission to adopt delegated acts to amend Annex I by reclassifying the risk against which PPE is intended to protect users, moving it from one category to another.

### **2. LEGAL BASIS**

This report is required under Article 43(2) of Regulation (EU) 2016/425. Pursuant to that article, the power to adopt delegated acts is conferred on the Commission for a period of 5 years from 21 April 2018, and the Commission is required to draw up a report on the delegation of power no later than 9 months before the end of every 5 years.

Article 43(2) of the Regulation states that the delegation of power shall be tacitly extended for periods of identical duration, unless the European Parliament or the Council opposes their extension no later than 3 months before the end of each period.

### **3. EXERCISE OF THE DELEGATION**

Since the entry into force of Regulation (EU) 2016/425, the Commission has not used the empowerment. No delegated act has been adopted yet.

The PPE risk categories listed in Annex I to the Regulation are still up to date. However, the reasons, for which the co-legislators conferred the power to adopt delegated acts on the Commission, remain valid and the Commission may need to use the empowerment in the future.

### **4. CONCLUSION**

The Commission believes that, although to date it has not adopted any delegated act, the delegation of power as stated in Article 42(1) of Regulation (EU) 2016/425 should be tacitly extended for 5 years, in accordance with Article 43(2) of the Regulation.

The need to reclassify the risks by moving them from one category to another may arise in the future. It is important to maintain the necessary flexibility in the legal framework, to take into account technical progress and knowledge or new scientific evidence in order to protect the health and safety of users.

The Commission invites the European Parliament and the Council to take note of this report.

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<sup>1</sup> Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51)