



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Industrial Transformation and Advanced Value Chains
Advanced Engineering and Manufacturing Systems

Regulation (EU) 2016/425 on personal protective equipment (PPE):

Transition from Directive 89/686/EEC – Products in the stocks of the manufacturer before 21 April 2019

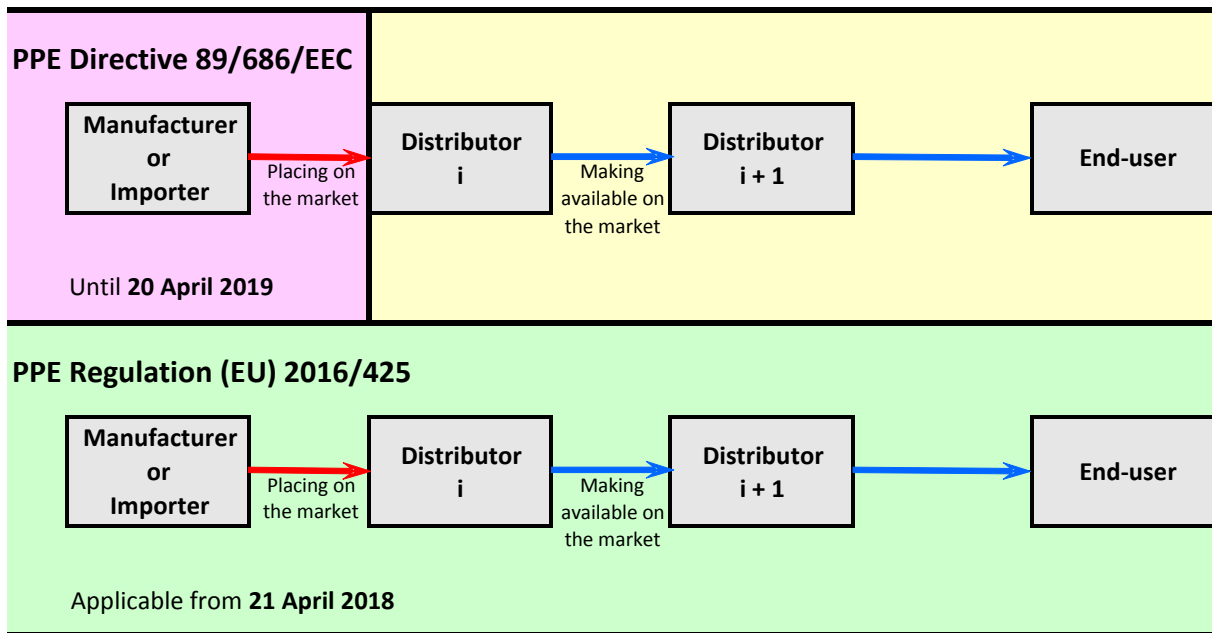
I. Background

Regulation (EU) 2016/425 (“the PPE Regulation”) became fully applicable on 21 April 2018, and on the same day, Directive 89/686/EEC (“the PPE Directive”) was repealed, according to Article 46 of the PPE Regulation. The specific transitional provisions of Article 47 of the PPE Regulation allow the placing on the market of personal protective equipment designed and manufactured in conformity with the PPE Directive during one year after the repeal date, it is to say, until 20 April 2019. As from 21 April 2019, only personal protective equipment in conformity with the PPE Regulation can be placed on the market.

Manufacturers and other economic operators expressed concerns about products designed and manufactured according to the PPE Directive, which can still be in the stocks before the end of the transitional period on 20 April 2019. In this sense, manufacturers asked for clarification on the concept of “placing on the market” with respect to such products, to find practical solutions to deal with them in an appropriate manner and to prevent unnecessary technical and administrative burdens related to the legislative transition.

II. “Placing on the market” and “Make available on the market” according to Regulation (EU) 2016/425 and to “*The 'Blue Guide' on the implementation of EU product rules*”

The different steps of placing on the market and make available on the market of products with the definitions laid down in Article 3 of the PPE Regulation and involving the different economic operators (manufacturer, importer, distributor) as well as the end-user can be represented as follows:



Placing on the market: the first making available of PPE on the Union market (Regulation (EU) 2016/425, Article 3(3))

Making available on the market: any supply of PPE for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge (Regulation (EU) 2016/425, Article 3(2))

On the other hand, sections 2.2. and 2.3. of *“The ‘Blue Guide’ on the implementation of EU product rules”*¹ explains the concepts of “making available on the market” and of “placing on the market”, stating that:

“A product is made available on the market when supplied for distribution; consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge. Such supply includes any offer for distribution, consumption or use on the Union market which could result in actual supply (e.g. an invitation to purchase, advertising campaign). [...] The concept of making available refers to each individual product, not to a type of product, and whether it was manufactured as an individual unit or in series” (pp. 17-18)

and

“A product is placed on the market when it is made available for the first time on the Union market. The operation is reserved either for a manufacturer or an importer, i.e. the manufacturer and the importer are the only economic operators who place products on the market. [...] The placing on the market is the most decisive point in time concerning the application of the Union harmonisation legislation. When made available on the market, products must be in compliance with the Union harmonisation legislation applicable at the time of placing on the market” (pp. 18, 20).

¹ OJ C 272, 26.7.2016, p. 1 <http://ec.europa.eu/DocsRoom/documents/18027/>.

To deal with the question of stocks in the transitional period from the PPE Directive to the PPE Regulation, it is especially interesting to consider the following parts of the text in section 2.3.:

“Placing a product on the market requires an offer or an agreement (written or verbal) between two or more legal or natural persons for the transfer of ownership, possession or any other property right concerning the product in question after the stage of manufacture has taken place. This transfer could be for payment or free of charge. It does not require the physical handover of the product” (p. 18).

“Placing on the market is considered not to take place where a product is: [...] in the stocks of the manufacturer (or the authorised representative established in the Union) or the importer, where the product is not yet made available, that is, when it is not being supplied for distribution, consumption or use, unless otherwise provided for in the applicable Union harmonisation legislation” (p. 19).

“The placing on the market is the most decisive point in time concerning the application of the Union harmonised legislation. When made available on the market, products must be in compliance with the Union harmonisation legislation applicable at the time of placing on the market. Accordingly, new products manufactured in the Union and all products imported from third countries – whether new or used – must meet the provisions of the applicable Union harmonisation legislation when placed on the market, i.e. when made available for the first time on the Union market. 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” (p. 20).

Per definition, placing on the market is limited to the manufacturer or the importer of a product. A product can be placed on the EU market before it is physically present there (for example, in the context of an online sale): in this sense, it is admissible that a product can be placed on the EU market and that it arrives into the EU territory on a later date.

As the moment of placing on the market determines the moment a product has to fulfil the requirements of the legislation applicable at that moment, it is important for manufacturers and importers to be able to prove that moment, when requested; in particular, for the transition from the PPE Directive to the PPE Regulation, to prove at what date the PPE has been placed on the market, even if not yet physically there, for example in case of products shipped to be imported into the EU. The economic operator does not need to provide a written agreement or contract for the placing on the market, but if the agreement was verbal, he may still have other documentary evidence such as shipment information.

III. Conclusions

Taking into account the above, it is possible to conclude that, despite being in the stock of the manufacturer, individual product items of personal protective equipment can be considered as “placed on the market” when they are effectively offered for distribution, consumption or use. While the physical handover of these products is not necessary to consider that they have been placed on the market, the offer or the transaction must refer to a quantifiable lot of product items which have been already manufactured.

According to that, products in compliance with the PPE Directive which are in the warehouse of the manufacturer, can be considered as already placed on the market before 21 April 2019 in the case that these products have been offered for sale in product catalogues, or on websites,

or in the manufacturer's own store(s) and/or online store. Therefore, these products in compliance with the PPE Directive already placed on the market before 21 April 2019 can continue to be made available on the market after 20 April 2019.

In the case of a central warehouse delivering PPE to subsidiary company's warehouse in another EU Country, or a parent company sells PPE to a subsidiary company as business operations within a corporate group, these activities can be considered as "placing on the market", provided that the central warehouse or parent company, and the subsidiary company, are separate juridical entities (legal or natural persons), and assuming that there is at least a verbal contract. If, after that, the parent company buy the products from the subsidiary company and continue selling them after 20 April 2019, the products can be considered to be in the distribution chain and therefore they can continue to be made available after 20 April 2019.

The manufacturer must be able to provide, on a case-by-case basis, the adequate proofs (documentation, justification, traceability) to demonstrate that products that have been designed and manufactured according to the PPE Directive have been legally placed on the market before 21 April 2019, because after that date, only products in conformity with the PPE Regulation can be placed on the market. In case of central warehouse or parent company and subsidiary company, it is necessary to prove that the concerned products were intended to be marketed before the circulation between the different entities of the group.

In any case, after 20 April 2019, only products in conformity with the PPE Regulation can be placed on the market (made available for the first time).