



CO-ORDINATION OF NOTIFIED BODIES
PPE Regulation 2016/425

PPE-R/00.041
Version 2

RECOMMENDATION FOR USE

Number of pages: 1	Approval stage :	Approved on :	
Origin : Horizontal Committee	<input type="checkbox"/> Vertical Group	n/a	
	<input checked="" type="checkbox"/> Horizontal Committee	30/05/2018	
	<input checked="" type="checkbox"/> EU PPE Working Group	22/04/2019	
Question related to	<input checked="" type="checkbox"/> PPE Regulation	<input type="checkbox"/> EN/prEN:	<input type="checkbox"/> Other:
Article:	Annex: II, 1.2.1.1	Clause:	
Key words: information supplied by the manufacturer; sensitising or allergenic substances			
Question: Should the manufacturer of PPE display all substances with sensitising or allergenic potential in the "information supplied by the manufacturer", if the PPE is designed to get (even if only partly) in close skin contact with the user, or if parts of the PPE may be released and taken up via the inhalation route by the user?			
Solution: Yes. Annex II, 1.2.1.1 (suitable constituent materials) requires that "PPE materials and parts, including any of their decomposition products must not adversely affect user hygiene or health". In case that PPE contains substances which are known to be potentially sensitising or allergenic, the manufacturer has to display each individual relevant substance in the information supplied by the manufacturer to give a warning to all potentially concerned users.			