

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.011 Version 7 20/05/2026 AdHocC2/D Meeting
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Question related to ☒ PPE Regulation ☐ EN/prEN: ☒ Other:		
Article: Annex: VII Clause: Module C2		
Key words: C2 samples and process / production dormant		
Question: What are the necessary actions where a company follows module C2 and production is dormant for a period, resulting in module C2 activities not being able to be carried out?		
Solution: It is noted that: C2 approval decision may be covered by a separate report or certificate with a validity determined and clearly stated by the notified body. The manufacturer should provide the NB with a declaration of non-production, defining the period for which there was, or will be no production. Where there is no production, production has been dormant, the NB should consider the following options: 1. Where relevant, including a restriction on the C2 approval decision, that no production occurred between date X and date Y, without additional testing of prepared specimens / materials (i.e. not production items). 2. Refraining from issuing a C2 approval decision which covers the period of inactivity. 3. Where relevant, including a restriction on the C2 approval decision, that no production occurred between date X and date Y, with additional conformity testing of prepared specimens / materials (i.e. not production items). 4. Issuing a C2 approval decision based on sampling from the Market only when agreed with the manufacturer, noting risks that the products have been outside of the control of both the manufacturer and the notified body.		