



CO-ORDINATION OF NOTIFIED BODIES
PPE Regulation 2016/425

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Version 3

RECOMMENDATION FOR USE

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Article:	Annex: VII	Clause:	RfU sheet 00.007, 2B(iii) and 2B(iv)
	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 not being able to be carried out?			
Solution: 1. C2 approval is covered by a separate report or certificate with a 1 year validity. 2. Where the C2 approval does not have a validity period. Either: C2 supervision / sampling cannot be carried out due to no production, certificate remains valid and C2 process is activated when production starts or restarts, manufacturer to inform NB. C2 process to be satisfactorily completed before product is allowed to be placed on the market. Or: C2 supervision / sampling cannot be carried out due to no production, certificate remains valid and C2 process is activated when production starts or restarts, manufacturer to inform NB. Product is allowed to be placed on the market while the C2 assessment is organised / carried out.			