



CO-ORDINATION OF NOTIFIED BODIES
PPE Regulation 2016/425

PPE-R/00.009
Version 2

RECOMMENDATION FOR USE

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Article:	Annex: VII Module C2	Clause: 2B(iv)	RfU sheet 00.007, 2B(iii) and
Key words: Failure of C2 samples			
Question: What are the necessary actions following failures when samples are taken as required by recommendation for use sheet 00.007, sections 2B(iii) and 2B(iv), assessment of non-homogeneity?			
Solution: The following steps should be taken: 1. Manufacturer asked to investigate the failure(s) and advise the notified body of their findings. 2. The manufacturer must inform the notified body whether or not they consider the product acceptable without modification or if the product is to be modified, and how. 3. Notified body to then determine what level of additional testing is required 4. Additional samples requested from the manufacturer and tested under the authority of the notified body 5. If additional samples pass the required testing, C2 considered completed. 6. If additional samples fail, steps 1 to 4 repeated. 7. If second set of additional samples fail, C2 certification to be withdrawn / not re-issued. NOTE: 1. If the module C2 body is not the module B body, module B body to be kept informed throughout the process. 2. Notifying authorities to be informed of failures.			