

## **EOTA: Arrangements for the transition from CPD to CPR**

### **1. Aim of this document**

This document is intended to provide information and recommendations to Approval Bodies in order to allow them to provide continuity of service to manufacturers during the transition to the CPR.

### **2. Situation on 1 July 2013**

It is highly probable that the process of preparing and issuing all current requests for European Technical Approvals by Approval Bodies under the CPD will not be completed before 1 July 2013 when all Articles of the CPR will become applicable and the CPD will be repealed. Therefore, a practical method is required for treating any European Technical Approval requests still pending at this cut-off date.

Requests pending on 1 July 2013 could belong to one of the following categories:

1. Requests for products covered by ETA Guidelines (ETAG)
  - a) Guidelines [adopted by EOTA, endorsed by the Commission and published by Member States] which can be used as EADs without changes in their content
  - b) Guidelines [adopted by EOTA, endorsed by the Commission and published by Member States] which cannot be used as EADs without amendment of their content
  - c) Guidelines adopted by EOTA, but not yet endorsed by the Commission
  - d) Guidelines or amendments thereto not completed by EOTA
2. Requests for products not covered by an ETAG  
(CPD Article 9.2 , Common Understanding of Assessment Procedure – CUAP)
  - a) Assessment procedures (CUAP) adopted by the Approval Bodies within EOTA
  - b) Assessment procedures still being drafted (CUAP not yet adopted by the Approval Bodies within EOTA)
  - c) Requests pending for EC authorisation or confirmation to issue a European Technical Approval.

Chapter 3 contains certain general principles and chapter 4 sets out the practical steps to be taken with these pending European Technical Approval requests from 1 July 2013 onwards.

### **3. General principles**

If any European Technical Approval request cannot be completed by 1 July 2013 the manufacturer has the option of informally expressing his intention to continue his request as a European Technical Assessment. This action should be made to a Technical Assessment Body (TAB) as soon as possible after this situation is recognised. It **must** be made clear that the formal process of seeking a European Technical Assessment cannot be commenced until 1 July 2013 and as such the process must be formalised from that date by the manufacturer introducing his request for a European Technical Assessment followed by a contractual agreement between the TAB and the manufacturer.

The TAB should inform the Organisation of TABs of such requests as they arise and in order to handle such transitional requests efficiently they will be introduced to the Commission by the Organisation of TABs from 1 July 2013 in accordance with Article 21.

According to Article 66(3) of the CPR, an ETAG endorsed by the Commission after Member States consultation and published by Member States may be used as European Assessment Document (EAD) – see case 1a above. For all other cases an EAD shall be established based on the CPR regime and, where applicable, drawing on all technical work done so far. The European Technical Assessment will then be issued on the basis of this EAD.

In cases where an EAD has to be drafted to continue with the procedure under the CPR, the EAD contract (CPR. Annex II (2)) must also be formalised on 1 July 2013.

To avoid any delay in this procedure, Approval Bodies are recommended with immediate effect to advise manufacturers of the transitional arrangements outlined in this document.

The decision on the European Technical Assessment format is foreseen in the CPR (Art. 26(3)) as an implementing act and can thus only be adopted after 1 July 2013. However, preparations and informal discussions about the European Technical Assessment format have been started and will be continued in order to have the format available as soon as possible, given the regulatory constraints.

#### **4. Specific measures**

European Technical Approval requests pending on 1 July 2013 are to be handled as follows:

Case	Request on the basis of	Practical steps to be taken
1a	ETAG endorsed by EC and published by Member States which can be used as EADs without changes in their content	European Technical Assessments may be elaborated using the ETAG as an EAD according to the CPR. To ensure full transparency and consistency, the parts of the ETAG applicable for elaborating the European Technical Assessment will be clearly explained to the manufacturer and advised to the Commission in writing.
1b	ETAG endorsed by EC and published by Member States which cannot be used as EADs without changes in their content	An EAD needs to be drawn up and adopted according to the CPR taking note in particular of Art. 24(3) of the CPR.
1c	ETAG adopted by EOTA but not yet endorsed by EC	
1d	ETAG or amendment thereto not completed by EOTA	
2a	CUAP adopted by EOTA	
2b	Draft CUAP not adopted by EOTA	
2c	EC authorisation/confirmation pending	An EAD needs to be drawn up if the product is not fully covered by any harmonised technical specification (Art. 19(1) and 21(1) & (2) of the CPR).

EOTA – April 2012