



GD 01
July 2017

GD 01 – ETA Process + EAD DP

- Step-by-Step in brief – Quality panels -
- T01 letter models -

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1 FOREWORD

This Guidance Document is part of the EOTA Consistency System Manual.

2 ETA PROCESS & EAD DP IN BRIEF

Process Stage	Art 21 (1) b – Action (What?)	Art 21 (1) c – Action (What?)	Who is involved?	Annex II to the CPR
Stage 1 (stg 1)	<p>Application (ETA request) A manufacturer presents a request for an ETA.</p> <p>RTAB gives guidance about of applicability of a harmonised technical specification (hEN, EAD or ETAG used as EAD).</p> <p>RTAB gives quotation, service agreement/general terms/confidentiality agreement.</p>	<p>Application (ETA request) A manufacturer presents a request for an ETA.</p> <p>RTAB gives guidance about of applicability of a harmonised technical specification.</p> <p>RTAB gives quotation, service agreement/general terms/confidentiality agreement.</p>	RTAB & Manufacturer	Annex II.1
Stage 2 (stg 2)	<p>Registration of the ETA Request in EOTA and Information of the European Commission</p> <p>Consultation on the draft ETA</p>	<p>Registration of the ETA Request in EOTA and Information of the European Commission</p> <p>Consultation on the initial work and assessment programme</p>	<p>RTAB & EOTA Secretariat</p> <p>RTAB & EOTA ETA/EAD Service & All TABs designated in the relevant product area acting jointly</p>	Annex II.2
Stage 3 (stg 3)		<p>Outcome of the consultation including the Work programme and assessment programme agreed, PT group (TAB experts acting jointly)</p> <p>and , if necessary, consultation in EOTA (i.e. Amendment of the work programme), and information of the European Commission</p>	<p>RTAB & Manufacturer</p> <p>All TABs designated in the relevant product area acting jointly</p>	Annex II.3

Stage 4 (stg 4)		Drafting the 1 st drEAD (several intermediate versions are possible – v1, v2...)	RTAB (and, if available PT group)	Annex II.4
Stage 5 (stg 5)		Adoption of draft EAD (1 st drEAD) Comments could lead to 2 nd until 4 th drEAD consultation	All TABs designated in the relevant product area acting jointly EC consultantManufacturer	Annex II.5
Stage 6 (stg 6)		Finalisation of EU legislative procedures (e.g. Delegated Acts, Art 27 (4) agreements	European Commission, SCC, Council, European Parliament	Annex II.6
Stage 7 (stg 7)		EC observations and adoption of EAD (final EAD)	European Commission	Annex II.7
Stage 8 (stg 8)	Issuing of ETA on the basis of ETAG used as EAD, adopted or published EAD, and Publication of ETA reference in ETA Public Database	Consultation on the draft ETA Issuing of ETA on the basis of adopted EAD, and Publication of ETA reference in ETA Public Database, and EAD announcement on EOTA Website Publication of EAD reference in OJEU and NANDO-IS, and full text EAD on EOTA website	RTAB & All TABs designated in the relevant product area RTAB EOTA Secretariat European Commission & EOTA Secretariat	Annex II.8

3 GENERAL PRINCIPLES/RULES IN BRIEF

Reference: Art 20 (1) of Regulation (EU) No 305/2011; TB 13/77-CPD/2.1; TB 13/01/4.4; TB 16/14/10

1. **mandatory consultation periods:** 1st consultation = 1 month (for EAD DP, 1st drEAD, 1st drETA); all subsequent consultations = 2 weeks; EC consultations – 3 weeks (15 working-days) = 21 calendar days
2. **communication-to-all** = to the concerned **and** the entire WG in copy
3. **circulation of comprehensive CHD throughout the whole process** = detailing TAB/EC consultant comments and RTAB answers
4. **commitment of all TABs** concerned = those in the designated product area, and where applicable, in related product areas

4 EOTA QUALITY PANELS

Reference: EOTA Statutes and Internal Regulations; Regulation (EU) No 305/2011; ExBo 14/08/6.1

The following working groups/bodies are available for advice and decisions in EOTA in case of difficulties within an EAD DP:

	Working Group	Composition	Mission/tasks	How to contact?
1.	EOTA PT 1 – Technical Management	Team of senior experts of TABs (technical staff), TB Chair, and EOTA Secretariat	any guidance in case of technical questions within an EAD DP; supportive, but not decisive	Write a letter to PT 1 members and describe the problem and ask a question; written consultation;
2.	EOTA TB – Technical Board	Nominated TAB Representatives and Spokesbodies of Member States; EC	The creation of working groups; working procedures for EAD DP WGs; coordination of EAD DP WGs; adoption of EADs, TRs; any other technical issue related to EADs and ETAs	Information to TB Chair and EOTA TM (tb@; ead@) and request to endorse agenda item for TB meeting
3.	Ad hoc group for EOTA IR Clause 16 procedure	EOTA President, TB Chair, Secretary General	Settlement of disputes with regard to the interpretation of EOTA documents (EADs etc.)	EOTA President, TB Chair, and Secretary General via tb@
4.	EOTA General Assembly	Nominated EOTA Representatives and Spokesbodies of Member States	Adoption of EADs for which no agreement can be achieved in the Technical Board.	Information to President and EOTA SG (tb@) and request to endorse agenda item for GA meeting
5.	Art 23 of the CPR resolution	EC	Dispute resolution in cases of disagreements between TABs which cannot be resolved in EOTA	EC directly or EC through EOTA

5 MODELS LETTERS (T01) FOR ETA PROCESS AND EAD DPs

Due to the involvement of various parties in the ETA Process and the EAD development projects, the different steps need specific tasks with regard to completeness of the information and the transparency to the parties involved at a certain step.

EOTA has agreed on model letters which help aligning the communication internally in EOTA and hence the collaboration at EU level.

Note: The model letters are subject to regular modifications related to different new situations or new agreements with the concerned parties in order to keep the process smart.