## **European Technical Assessment Regulation**

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## Introduction

The Belgian Union for Technical Approval in Construction (UBAtc asbl / BUtgb vzw) is a not-for-profit organisation under Belgian law, established on 28 October 2009.

The Belgian Union for technical approval in construction has been designated in the framework of Regulation (EU) N° 305/2011 and the Belgian Law of 21 December 2013 implementing Regulation (EU) N° 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC and repealing various provisions and the Royal Decree of 30 September regarding the technical assessment bodies authorized to establish a European Assessment Document and to issue a European Technical Assessment for construction products by the Belgian Federal Public Services Economy, SMEs, Self-Employed and Energy on 15 July 2013, for all construction products, with the exception of power, control and communication cables.

This document was presented to the Board of Directors of the UBAtc and accepted on 25 February 2019 and replaces the version accepted by the Board of Directors of the UBAtc on 13 June 2017; it is in force as of 1 March 2019. It takes into account Assessment Operators' different practices concerning adjusting cost for inflation and comprises a modified Article 92(4).

The previous version of this document was presented to the Board of Directors of the UBAtc and accepted on 13 June 2017 and replaced the version accepted by the Board of Directors of the UBAtc on 22 June 2016; it was in force since 1 July 2017. It comprised a modified Annex 1.

This document will be made available in English, French and Dutch. In case of conflicts between language versions, the English version will be considered as the reference version.

The applicable version of this European Technical Assessment Regulation is the one made available on the UBAtc website.

NOTE: Modal verbs are used in this document as follows:

- "Can" expresses ability;
- "May" expresses permission;
- "Must" expresses obligation; and
- "Will" expresses future action.

# UBAtc asbl

## **Identity of UBAtc**

The Belgian Union for Technical Approval in Construction is a not-for-profit organisation under Belgian law, established on 28 October 2009.

## **Objectives**

The purpose of the organisation is the creation, development, conservation and provision of an organisational framework:

- for the dissemination of reliable and independent technical information regarding fitness for use and quality, for the benefit of the construction sector;
- for strengthening confidence in innovative or complex materials, products, construction systems, construction kits, procedures, processes and services, and/or in those offering equivalent performance;
- that contributes to technical harmonisation and mutual awareness at the European level;
- that provides support in communicating best practices.

To achieve these objectives, the organisation organises a series of socially and collectively supported public quality declarations that are issued by third parties, the Approval, Assessment and Certification Operators, in order to control the technical risks and to improve the quality of construction work and construction processes.

Furthermore, the organisation may develop any other activity that contributes directly or indirectly to achieving predetermined not-for-profit objectives, including additional commercial and profit-making activities within the limitations prescribed by law, the revenues of which will be committed to the realisation of the not-for-profit objectives.

## **Organisation**

The UBAtc is supported by a collective of major players in the Belgian construction sector, as well as by impartial executive organisations, operating as a network.

The organisation has two types of members:

**Effective members**; those who founded the organisation or who were accepted, after its foundation, by the Assembly General on the basis of the conditions incorporated in the Statutes.

The effective members are divided into two groups:

- Category A: institutions or organisations that, on the basis of their expertise and independent and impartial functioning, may work in an autonomous manner or within the context of a collaboration agreement as Assessment, Approval and/or Certification Operators and that, as such, can assume or provide a sectoral competence or technology expertise. The institutions must satisfy the conditions outlined in the Statutes.
- Category B: organisations that represent the social groups with a specific interest in the existence, the activities and the functioning of UBAtc. These are mainly intersectoral federations, confederations and other transverse groupings that represent the interests of public or private contractors, project promoters (architects and engineers), operators, insurers, etc.

The effective members are listed on the UBAtc website.

Adherent members; organisations that have a reduced vested interest in the existence, the activities and the functioning of UBAtc, or who choose, for certain reasons, not to become effective members. Adherent members are admitted by the Board of Directors based on the criteria approved by the General Assembly. The adherent members are listed on the UBAtc website.

The organisational structure is as follows:

- A management structure, composed of the General Assembly, the Board of Directors, and two consulting commissions: an Advisory Commission and a Co-ordination Commission. The Quality Commission falls under the aegis of the Coordination Commission.
- The organisational structure, composed of the Management Committee, the UBAtc secretariat and several support services and the Technical Coordination Boards.
- An executive structure, composed of all of the Approval, Assessment and/or Certification Operators<sup>1</sup>, working together.

<sup>&</sup>lt;sup>1</sup> In the Framework of Regulation (EU) N° 305/2011, only Assessment Operators are involved in the activities of the UBAtc.

# Tasks and responsibilities of UBAtc and its Assessment Operators in the framework of Regulation (EU) N° 305/2011

## **Assessment Operators**

Assessment Operators assess the subjects for which applications have been submitted for one or more technical domains, in accordance with the rules and procedures imposed by the UBAtc. The UBAtc monitors all activities of its Assessment Operators in the framework of developing and issuing European Technical Assessments.

In the case of the joint involvement of two Assessment Operators, e.g. subjects covered by two technical domains, decisions are taken collectively. Precision may be given to indicate which Assessment Operator is competent and therefore responsible for which aspects.

The Assessment Operators base their activities on the recommendations of the Specialised Group, which must have a composition that meets the criteria imposed by the UBAtc. In the event of a difference of opinion between the Specialised Group and the Assessment Operator and if no consensus can be found, the competent Technical Co-ordination Board will act as intermediary, although ultimately the decision remains the responsibility of the Assessment Operator.

The Technical Co-ordination Boards are responsible for verifying that the composition of the Specialised Groups is in accordance with the rules of the UBAtc.

To achieve its objectives, the Assessment Operator must have, for each product family within a technical domain, a committee of experts, the Executive Bureau. The composition of the Executive Bureau is known to the UBAtc.

The Assessment Operator submits the final draft European Technical Assessment to the UBAtc secretariat. The UBAtc assumes responsibility for issuing the European Technical Assessment.

The activities of the experts come under the legal responsibility of the Assessment Operator. In order to assume this responsibility, procedures for qualification, surveillance and evaluation of the experts must be available.

#### **UBAtc**

In its role of a Technical Assessment Body, member of the European Organisation for Technical Assessment (EOTA), the final responsibility for the issuing of a European Technical Assessments and for all the tasks incumbent upon a Technical Assessment Body based on its functioning within the context of Regulation (EU) N° 305/2011, however modified or replaced, falls upon the UBAtc through its delegation of the handling of an Application to an Assessment Operator.

The requirements for the Assessment Operator regarding the planned structure, management of competences, allocation of tasks to experts and the procedures and processes have been laid down in the Organization Manual. The operator drafts the Evaluation report and the European Technical Assessment, carries out the activities referred to above and is responsible for them within organisation. It provides the organisation with a complete report on the assessment process.

Before issuing, the European Technical Assessment text is signed by both UBAtc directors and by a representative of the Assessment operator concerned.

## **European Technical Assessment**

The route to a declaration of performance in the framework of Regulation (EU) N° 305/2011 for most construction products is the harmonised standard, published by the national standardization institutes, in Belgium, the Belgian Bureau for Standardization (NBN). In cases where construction products are not covered or not fully covered by such a harmonized standard, manufacturers may CE mark on the basis of a declaration of performance issued to a European Technical Assessment. A European Technical Assessment is a document comprising a description of the construction product, the list of essential characteristics relevant for the intended use of the product, the methods and criteria used to assess the product's performance in relation to those essential characteristics and the principles of the factory production control system applied bv manufacturer to ensure the construction product's performances continuously meet those specified in the European Technical Assessment.

The essential characteristics are foreseen by the manufacturer and agreed between the manufacturer and EOTA, the organisation to which all Technical Assessment Bodies necessarily belong.

European Technical Assessments (ETA) are based on a European Assessment Document (EAD) or on European Technical Approval Guidelines (ETAG) used as European Assessment Document. European Technical Approval Guidelines used to be the basis for issuing European Technical Approvals in the framework of Directive 89/106/EEC which was repealed by Regulation (EU) N° 305/2011. European Assessment Documents, one of the two types of harmonised technical specification in the framework of the Regulation (EU) N° 305/2011 (the other being the harmonised standard), adopted by EOTA are published by the European Commission in the Official Journal of the European Union.

It continues to be possible to apply for duplicate European Technical Assessment, permitting so called "private label" products to benefit from CE marking. It is also possible, for ETA-holders that consider this beneficial to convert European Technical Approvals into European Technical Assessments.

# Process leading to a European Technical Assessment

Having received the application, the UBAtc will send applicants a notice of receipt, confirming that the application has been received in good order and providing the applicant a unique AG reference for the file. Although this is usually an easy enough task, Technical Assessment Bodies need to confirm that the subject of the application is in fact a construction product in accordance with the definition in the Regulation (EU) N° 305/2011 and need to determine whether or not the product is fully covered by a harmonised standard. Issuing European Technical Assessments is permitted until the beginning of the coexistence period as determined by the European Commission for each harmonized standard and specified in the Official Journal of the European Union. If the product is not (fully) covered by a harmonized standard, Technical Assessment Bodies may issue a European Technical Assessment.

Whereas the Regulation formally recognizes just one route to obtain a European Technical Assessment, variations do exist (see Article 9 of this document and Figure 1).

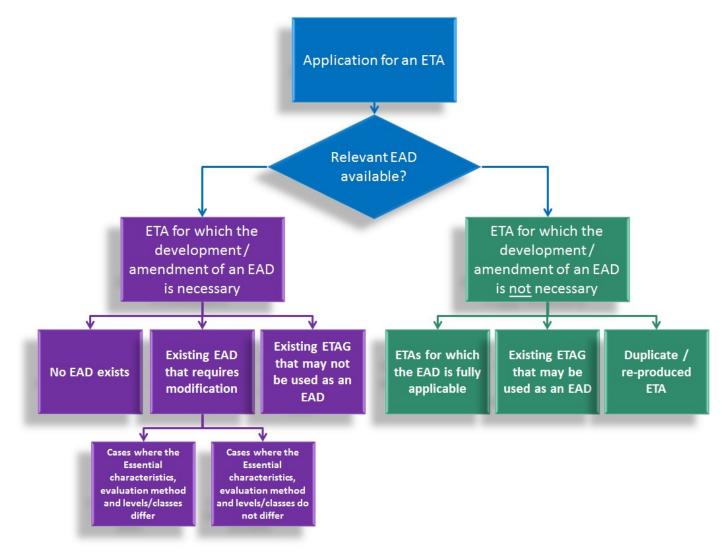


Figure 1: Routes to obtain a European Technical Assessment

The establishment of the European Technical Assessment is based on the information made available, the adopted European Assessment Document and the result of the evaluation carried out under the responsibility of the Technical Assessment Body.

The evaluation generally comprises the following elements

- The study of the subject for which the application has been submitted, mostly on the basis of the manufacturer's technical file;
- Visits to construction sites;
- Visits and controls of the production facilities, the laboratory and the warehouse(s);
- One (or more) sampling(s);
- Tests, calculations and any other evaluation techniques, as foreseen in the European Assessment Document;
- The drafting of an Evaluation Report;
- The drafting of the European Technical Assessment text(s).

The UBAtc assumes responsibility for the admissibility of applications, the coordination at European level and the issuing of European Technical Assessment. The technical work and development of European Technical Assessment texts is carried out by Assessment Operators, designated by the UBAtc.

Members of Executive Bureaus evaluate the technical reports collected and the draft European Technical Assessment text. Afterwards, the draft European Technical Assessment text is submitted to the other Technical Assessment Bodies in the framework of EOTA.

Whereas this is not foreseen by the Regulation, Technical Assessment Bodies have agreed to ensure consistency between European Technical Assessments issued by different EOTA members through the exchange of Evaluation files, comprising details of the assessment carried out, and draft European Technical Assessment texts, prior to their issuing. Public availability of the European Technical Assessment depends on the Technical Assessment Body.

All European Technical Assessments issued by UBAtc are made available on its publicly available internet website.

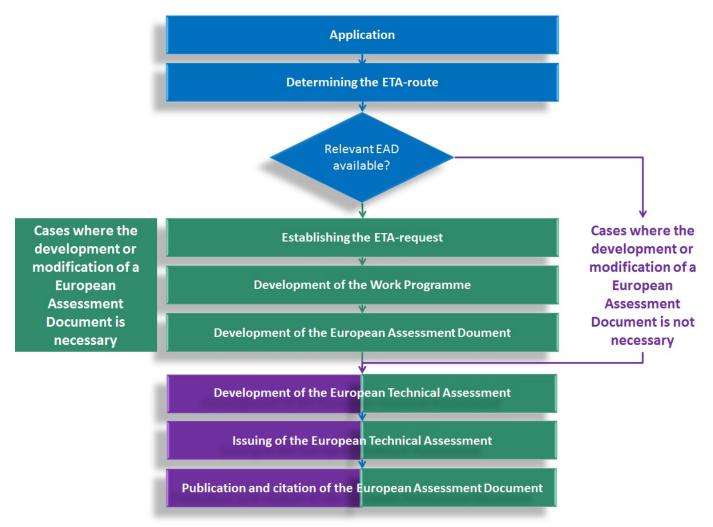


Figure 2: Main processes for the development and issuing of European Technical Assessments

## **European Assessment Document (EAD)**

Aiming at transparency, if no relevant European Assessment Document exist, Regulation (EU) N° 305/2011 requires Applicants and Technical Assessment Bodies to agree a formal contract and foresees the development of a Work Programme, ensuring applicants know exactly what their rights and obligations are and know beforehand what they may expect as content in their European Technical Assessment. This requires Technical Assessment Bodies to know exactly what the subject of the application is and what it is intended for, i.e. Technical Assessment Bodies need to obtain a complete technical file from applicants prior to starting working on the application.

In cases where the development or modification of a European Assessment Document is necessary, Technical Assessment Bodies need to agree the basic works requirements and the essential characteristics that apply, the existence of relevant existing standards, etc. regarding the application, which is done through the ETA-request consultation, and which is ultimately presented to the applicant for acceptance.

The contract between the Technical Assessment Body and the applicant comprises an Initial Work Programme, specifying the organization of work within EOTA, the composition of the workgroup which will develop the European Assessment Document and the coordination of Technical Assessment Bodies.

Once the contract, which needs to be sent to the applicant within one month after the confirmation of the ETA-request, has been signed, the Work Programme is completed (Final Work Programme) with the Assessment Programme and the timing of work to be done. The Final Work Programme needs to be sent to the European Commission within three months after the confirmation of the ETA-request. The European Assessment Document needs to be adopted by EOTA six months thereafter. Throughout this process, the applicant will be requested to complete the information about the product, its manufacture, its intended use and the factory production control elements being used during production, i.e. to complete the Manufacturer's Technical File.

After the issuing of the European Technical Assessment, the European Assessment Document may be modified taking into account experience gained and cited by the European Commission in the Official Journal of the European Union.

The European Assessment Document is published by EOTA on its website as soon as the product for which the European Technical Assessment was issued is CE marked.

It is at that time that the applicant's competitors are made aware of the existence of, can obtain and study the European Assessment Document. Until this time, the whole procedure should be kept confidential, unless the applicant decides that confidentiality is not required.

## 1 Terminology and definitions

Article 1 In addition to those specified in Regulation (EU) N° 305/2011, the following terms and definitions apply:

## Definition 1 Applicant

Legal person submitting an application for a European Technical Assessment, who may or may not be the ETA-holder

#### Definition 2 ETA-holder

Legal person identified on the cover page of the European Technical Assessment as manufacturer (see also Article 3(3))

## Definition 3 Type of application

An application may be submitted for a new, modified or extended European Technical Assessment, based on an existing European Assessment Document, an ETA-Guideline or on a European Assessment Document that still needs to be developed or the application may concern a duplicate of an existing European Technical Assessment

## Definition 4 Duplicate

European Technical Assessment text that is identical to an already issued European Technical Assessment text, in which the only changes are the name of the ETAholder and/or the trade name(s) of the subject(s) covered by the European Technical Assessment and/or the identification of the Manufacturing plant(s); A duplicate may only be issued if the original is a valid issued European Technical Assessment

NOTE: Duplicates may also be referred to as "reproduced ETA"

## Definition 5 EOTA Product area code

Technical domain used to classify subjects for which an application has been registered by the EOTA secretariat. The EOTA Product area code is identified as follows: XX.YY/ZZ.

## Definition 6 Product area

Technical domain for which Technical Assessment Bodies may be designated in accordance with Regulation (EU) N° 305/2011, Annex IV, numbered from 1 to 36, 36 being the code for products not covered by any other product area.

## Definition 7 Type of construction product

Product group according to the title of the EAD/ETAG, the Product area according to Regulation (EU) N° 305/2011, Annex IV or a generic name for the construction product that is the subject of an Applicant

#### Definition 8 Technical domain

A series of materials, products and systems dealt with by a UBAtc Specialised Group (for example, civil works, construction systems, facades, etc.).

#### Definition 9 Product families

A series of materials, products and systems dealt with by an Executive Bureau (an Executive Bureau may be responsible for more than one product family)

## Definition 10 Transfer

A European Technical Assessment transfer refers to the transfer by inheritance, donation, sale or other type of transfer of the right to manufacture or to use the subject of the European Technical Assessment. The new rightful owner can revoke the European Technical Assessment. Authorisation is given once the new rightful owner has demonstrated to have sufficient technical ability and adequate installations.

## Definition 11 Assessment Operator

UBAtc Member organisation that assumes responsibility for the functioning of one or more Specialised Groups

## Definition 12 Specialised Group

The UBAtc commission that provides recommendations to the Assessment Operator

#### Definition 13 Executive Bureau

A group of experts acting as a college, which carries out assessment activities for one or more product families, and which reports to a Specialised Group

## Definition 14 Rapporteur

A person who oversees the management of a European Technical Assessment file starting with his nomination, documented in the declaration of admissibility. Depending on the file, the rapporteur ensures the handling of the elements of the assessment process and/or coordinates the activities of the people taking part in the assessment process (for example, for establishing the Work Programme, inspections, etc.). Rapporteurs work under the responsibility of the Assessment Operator.

## Definition 15 Validity

The period for which the European Technical Assessment is valid

## Definition 16 Suspension

## Temporary cessation

NOTE: In this document, suspension relates to applications for a European Technical Assessment or the publication of a European Technical Assessment on the UBAtc website. It does not relate to the validity of the European Technical Assessment.

## Definition 17 Prolongation

Making the period of availability of the European Technical Assessment on the UBAtc website longer than the default period

#### Definition 18 Extension

Widening of the scope and/or intended use of the subject of an Application or of an issued European Technical Assessment

## Definition 19 Corrigendum

New version of a European Technical Assessment issued by UBAtc, which corrects one or more errors or ambiguities inadvertently introduced in either drafting or printing and which could lead to incorrect or unsafe application of the previous version.

## 2 Applying for a European Technical Assessment

## 2.1 Application

**Article 2** Conditions for submitting an application

(1) Legal form of the Applicant

An Application may be submitted by the manufacturer or his authorised representative established in the EEA, Switzerland or Turkey, or a legal entity submitting the Application on behalf of the manufacturer or his authorised representative, provided that legal entity has the rights over the subject for which a European Technical Assessment is being applied for.

NOTE 1: When necessary, the Applicant may be required to demonstrate that the necessary rights were obtained, by means of document FORM03B (see Article 4).

## (2) Legal rights

The Applicant must have the legal rights to all the evidence and data provided and must be able to ensure access of UBAtc representatives to the production facilities.

NOTE 2: When necessary, the Applicant may be required to demonstrate that the necessary rights were obtained, by means of the documents made available by UBAtc for this purpose (see Article 4).

(3) For each individual product (i.e. with a unique trade name) only a single legal entity may submit an Application at any one time.

**(4)** If an Application has been submitted to another Technical Assessment Body, prior to the Application being submitted to UBAtc, the Applicant must demonstrate that the Application has been withdrawn or rejected by the other Technical Assessment Body. In the latter case, the Applicant must also provide information as to why the Application was rejected.

## **Article 3** Submission of the Application

- (1) The application for a European Technical Assessment, including applications for revision or modification, is made by means of forms provided by the UBAtc for this purpose (see Article 4) and includes the following information, among others:
- the identity of the Applicant;
- the identity of the ETA-holder (to be);
- the type of Application (see Definition 3);
- the type of construction product (see Definition 7 );
- the trade name(s) of the subject(s) of the Application;
- the intended use(s) of the construction products (as far as relevant for the Application);
- Justification of the Application according to Regulation (EU) N° 305/2011, Article 19 (see Article 16, e, ii);
- the identification of the production facility(ies);
- the essential characteristics that should be covered in the European Technical Assessment and, as far as known to the Applicant, the country in which these characteristics are regulated and the expected performances;
- the contact person dealing with the Application;
   and
- the accounting data.

A technical file, the contents of which are specified in Article 20, must be included with the Application.

- **(2)** An application may only be submitted through the UBAtc or one of the Assessment Operators.
- (3) The name or trade name or mark and the address of the ETA-holder, i.e. the company identified on the cover page of the European Technical Assessment, relates to one of the following:
- where the manufacturer is established in the Community and he has no authorised representative - the details are those of the manufacturer;
- where the manufacturer is established in the Community and he has an authorised representative - the details must be those of either the manufacturer or his authorised representative;

- where the manufacturer is not established in the Community but he has an authorised representative - the details must be those of the authorised representative;
- where the manufacturer is not established in the Community and he has no authorised representative so established - the details must be those of the importer into the Community.
- (4) The name and address details of the ETA-holder are required to enable enforcement authorities to take follow-up action. Any abbreviation of the above details may only be made as long as the manufacturer or authorised representative or importer, as appropriate, can be identified. A company's trade name or mark may appear with the full name and address. However, the trade name or mark may only appear as an alternative to the full name provided such trade name or mark enables the manufacturer or authorised representative or importer to be identified by enforcement authorities.

## Article 4 UBAtc Application forms

Valid Applications must be submitted using forms provided by the UBAtc for this purpose. The following forms must be used, as far as relevant:

- a) Application form for a European Technical Assessment referred to in Article 26 of the Regulation (EU) N° 305/2011 (FORM01B)
- b) Request for transfer (FORM02B)
- Authorisation for an assessment application by a company that does not itself manufacture the subject of the assessment (FORM03B)
- d) Authorisation for the application for a duplicate assessment (FORM04B)
- e) Authorisation for the use of test (and similar) reports (FORM05B)
- f) Authorisation for carrying out (an) inspection(s) (FORM06B)
- g) Request to reuse test reports (FORM07B)

NOTE 1: UBAtc forms are made available on the UBAtc website and may also be obtained at the UBAtc secretariat (info@ubatc.be).

NOTE 2: Applicants should either type entries or complete the forms in clear legible block capitals

## **Article 5** Application for duplicate(s)

(1) An Applicant or ETA-holder may authorise the issuing of a separate European Technical Assessment.

- NOTE 1: Unless the Applicant or holder of the original European Technical Assessment submits the Application, an Application for (a) duplicate(s) must be accompanied by (a) declaration(s) in which the holder(s) of the original European Technical Assessment(s) confirm(s) that the duplicate European Technical Assessment(s) may be issued, by means of the document FORMO4B made available by UBAtc for this purpose (see Article 4).
- (2) A duplicate European Technical Assessment may be issued on the basis of an existing European Technical Assessment in cases where an application only concerns the modification of one or more of the following elements of the original European Technical Assessment:
- manufacturer (CPR, Articles 2 (19) and 15),
- trade name of the construction product and/or
- manufacturing plant, provided the manufacturer's production method and FPC leads to products with performances that correspond to those in the original European Technical Assessment, as judged by UBAtc or its Assessment Operator(s).
- (3) Prior to the submission of the Application for a duplicate European Technical Assessment, an agreement between the holder of the original European Technical Assessment and the potential holder of the duplicate European Technical Assessment must exist. This agreement must at least specify that, upon the issuing of a modified or extended version of the original European Technical Assessment:
- the holder of the duplicate European Technical Assessment must discontinue using the duplicate European Technical Assessment; or
- a corresponding revised duplicate European
   Technical Assessment must be applied for.

If the duplicate European Technical Assessment has been issued for a "private label" product, the agreement must specify that in case the product does not any longer correspond with the European Technical Assessment, the holder of the duplicate European Technical Assessment must discontinue using that duplicate European Technical Assessment.

NOTE 2: For duplicates based on European Technical Approvals, issued in the framework of directive 89/106/EEC, see Article 107.

**Article 6** Commitments accepted by the applicant by submitting the application

By submitting an application, the applicant agrees to:

respect the obligations imposed by these present regulations; and

— pay the compensation of 1000 € or 5000 € (see Annex 1) to UBAtc for consulting other Technical Assessment Bodies for the preliminary consultation that is required; this compensation is due if the application does not lead to the issuing by UBAtc of a European Technical Assessment for the subject of the Application (see Annex 1).

## 2.2 Registration of the Application

Article 7 Registration of the Application and Notice of receipt

When the Application has been received, the UBAtc secretariat will send the Applicant a Notice of receipt, which comprises some of the information from the Application, and which includes the registration reference of the file (AG registration reference).

NOTE 1: The Notice of receipt merely confers the information that an Application has been received by UBAtc in good order; Applicants cannot derive any right from this document.

NOTE 2: UBAtc is obliged to inform EOTA and the European Commission (Article 21(2)) about every application it receives.

## **Article 8** AG Registration reference

The AG registration reference (typically A/G XXXXXX-E) must be mentioned by the Applicant in all official communications with the UBAtc and with the Assessment Operator; it is recommended to use this AG registration reference in all communications related to the Application.

# 3 Determining the ETA-route and ETA-request

## 3.1 Determination/confirmation of the ETA-route

Article 9 Routes to a European Technical Assessment (ETA-routes)

(1) Whereas the Regulation formally recognizes just one route to obtain a European Technical Assessment, the Applicant must indicate in his Application(s), as far as known to the Applicant, which. The UBAtc, possibly after consulting the other Technical Assessment Bodies, confirms the appropriate route.

(2) The following possibilities exist:

- European Technical Assessment for which the development/amendment of a European Assessment Document (EAD) is necessary
  - No EAD exists
  - Existing EAD that requires modification
  - Existing ETAG that may not be used as an EAD

- ETA for which the development/amendment of an EAD is not necessary
  - Existing ETAG that may be used as an EAD
  - ETAs for which the EAD is fully applicable
  - Duplicate ETA

**Article 10** Determination/confirmation of the ETA-route and verification of the completeness of the technical file

(1) The UBAtc and/or the Assessment Operator(s) concerned will examine Applications received.

NOTE 1: When an Assessment Operator has been designated for the technical domain concerned, this Assessment Operator will carry out the admissibility examination and determine or confirm the ETA-route. The decision is confirmed and registered by the UBAtc and communicated by the UBAtc secretariat to the Applicant. NOTE 2: When an Assessment Operator has not yet been designated for the technical domain concerned, the UBAtc, together with the relevant Technical Co-ordination Boards, will solicit one or more Assessment Operator(s) and invite it/them to take over the responsibility. All the Assessment Operators are informed of this type of application.

NOTE 3: When it is unable to find an Assessment Operator that can declare the application admissible, the UBAtc will inform the Applicant accordingly.

(2) In a first phase,

- the technical and administrative admissibility of the Application (see Article 16),
- the product area (CPR, Annex IV)
- the ETA-route (see Article 9) and
- the composition of the technical file (see Article 20)
   are examined.

## **Article 11** Confirmation of the ETA-route

NOTE 1: In case of an Application for a duplicate European Technical Assessment (see Article 5), this article does not apply.

NOTE 2: In case there is no need for the development or modification of an EAD, or in case the Application and accompanying information permits UBAtc to decide that the development of an EAD is necessary, the confirmation of the ETA-route may be presented as part of the Declaration of Admissibility.

- **(1)** The UBAtc secretariat will send the Applicant a Confirmation of the ETA-route, confirming:
- that a European Technical Assessment may be issued;
- the route that may be followed;
- indicative costs for the procedure and the issuing of the European Technical Assessment.

requesting the Applicant to sign and return the document.

(2) Taking into account the examination of the Application and accompanying information having been performed, additional information to complete the manufacturer's technical file (see Article 20) may be requested.

NOTE 2: In case a European Assessment Document needs to be developed, the UBAtc's opinion on the above may be challenged during an EOTA consultation (see clause 3.2), possibly leading to a revised Confirmation of the ETA-route being issued.

(3) The Applicant confirms his agreement with the Confirmation of the ETA-route by signing and returning the document and provides, if relevant, the required information to complete the manufacturer's technical file.

## 3.2 Development of the ETA-request

**Article 12** Development of the ETA-request

NOTE: This article is only relevant in case a European Assessment Document needs to be modified or developed

- (1) On the basis of the signed Confirmation of the ETA-route (where relevant), additional information provided by the Applicant to complete the technical file and after consulting the other Technical Assessment Bodies designated for the relevant product area, the UBAtc secretariat will send the Applicant a UBAtc Consultation form, comprising, amongst others, the following information:
- the ETA-route that may be followed;
- the Assessment and Verification of Constancy of Performance system(s) that apply(ies) (see Article 28 of Regulation (EU) N° 305/2011);
- the essential characteristics that apply (see Article 24),

requesting the Applicant to sign and return the document.

- (2) Taking into account the reactions from other Technical Assessment Bodies designated for the relevant product area, additional information to complete the manufacturer's technical file (see Article 20) may be requested.
- (3) The Applicant confirms his agreement with the UBAtc Consultation form by signing and returning the document and provides, if relevant, the required information to complete the manufacturer's technical file.
- **(4)** Once the Applicant confirms his agreement with the UBAtc Consultation form, the UBAtc secretariat confirms the ETA-request by sending the Applicant a Declaration of Admissibility (see clause 3.3).

## 3.3 Admissibility examination

**Article 13** Admissibility examination

- (1) The admissibility examination is generally carried out by the competent Executive Bureau, which operates under the responsibility of the Assessment Operator.
- **(2)** The decision on admissibility is endorsed by the Assessment Operator and the UBAtc management.
- **(3)** The Application may be addressed by the Assessment Operator as soon as the Applicant signs the declaration of admissibility and pays the indicated deposit.
- (4) The availability of a declaration of admissibility indicates the technical and administrative possibility of issuing a European Technical Assessment. It is possible that during the assessment process, missing information and/or observations could make the issuing of the European Technical Assessment not (yet) possible. The declaration of admissibility does not itself constitute a guarantee of the issuing of a European Technical Assessment.
- (5) When a European Technical Assessment cannot be issued on the basis of Article 16, the UBAtc will inform the Applicant that a declaration of admissibility cannot be issued and will communicate the reasons for this inadmissibility (see Article 17).

Article 14 Declaration of Admissibility (confirmation of ETA-request)

The UBAtc secretariat will send the Applicant a Declaration of Admissibility, comprising the following information:

- The Assessment Operator(s) responsible for the file
- The rapporteur(s) taking charge of the file (see Definition 14)
- The cost involved
- In case the Application requires the development of a European Assessment Document (see Article 9): the ETA-route to be followed
- In case the Application does not require the development of a European Assessment Document (see Article 9), as relevant:
  - The applicable European Assessment Document, in case this document has already been adopted by EOTA
  - The applicable European Technical Approval Guideline, which will be used as a European Assessment Document, indicating the applicable parts of the Guideline and the manner in which NPD-options will be used, as far as relevant (see Article 49)

The European Technical Assessment the duplicate will be based on

NOTE 1: The UBAtc secretariat may generally provide support to the Applicant by indicating which operator(s) will be involved, so that the potential Applicant, together with the Assessment Operator(s) can come up with an estimate of the expected costs and/or obtain an indicative quote before the Application is submitted. An indicate quote prior to the ETA-route having been confirmed does not bind the UBAtc or its Assessment Operators.

NOTE 2: The Declaration of Admissibility confers the message that UBAtc accepts the task of assessing the product for which an Application has been submitted. Applicants cannot derive any other right from this document. The declaration does not give any anticipation on a favourable result in the assessment.

Article 15 Commitments entered into by the Applicant by the signing and returning of the declaration of admissibility

By returning a signed declaration of admissibility, the Applicant agrees to the following:

- to respect the obligations imposed by these present regulations;
- to submit to controls, sampling and testing of workshops, factories, laboratories or worksites, as judged necessary for the assessment examination;
- to provide all necessary information within the context of the assessment examination;
- to pay the compensation specified in these regulations, according to R6, and reiterated in the declaration of admissibility.

**Article 16** Reasons for which issuing a European Technical Assessment may not be possible

- a. the Applicant has not satisfied the conditions laid out in Article 2.
- the Application form made available by UBAtc (see Article 4) has not been fully completed and/or the attached technical file is incomplete or information is missing.
- c. the Applicant has not paid, in a timely manner, the indicated costs specified in the Declaration of admissibility (see clause 17).
- d. the Applicant does not, or not in a timely manner, provide the UBAtc or the Assessment Operator with the technical file, or has provided an incomplete file (see Article 20).
- e. The Applicant does not, or not in a timely manner, allow the evaluation or provide the UBAtc or the Assessment Operator with the results of the evaluations deemed necessary to assess the subject of the Application

- f. the subject of the Application:
  - is not a construction product according to Regulation (EU) N° 305/2011, Article 2(1);
  - ii. is fully covered by an existing harmonised standard in the framework of Regulation (EU) N° 305/2011, i.e. possibilities a, b and c of Article 19 of Regulation (EU) N° 305/2011 do not apply;
  - falls outside the competence of the UBAtc;
  - iv. is not suitable for the use for which it is intended.

## **Article 17** Declaration of inadmissibility

If a European Technical Assessment cannot be issued by the UBAtc, the Applicant will receive a Declaration of inadmissibility, comprising the following information:

- Reason(s) why a European Technical Assessment cannot (yet) be issued
- Motivation, as far as relevant

By having issued the Declaration of inadmissibility, the UBAtc will consider the Application as terminated.

## 3.4 Suspension and termination of an Application for a European Technical Assessment

**Article 18** Suspension of an Application for a European Technical Assessment

(1) In the event that the Applicant does not pay within a reasonable time period following the declaration of admissibility, the Assessment Operator may, with the agreement of Executive Bureau, propose to suspend the Application. Such proposal requires confirmation by the UBAtc.

Should the Applicant wish to re-launch the Application, the UBAtc, having consulted the Assessment Operator, will communicate in writing the conditions under which it may be reactivated.

- (2) In order to prevent the UBAtc and/or the Assessment Operator from spending unnecessary time on files unduly regarded as active, files may be considered to be suspended when the Applicant has failed to provide the requested information after several repeated requests by the Assessment Operator.
- **(3)** The Assessment Operator will communicate in writing to the Applicant the decision to suspend and determine, on a case-by-case basis, the conditions under which the file may be reactivated.

- **Article 19** Termination of an Application for a European Technical Assessment
- (1) Should the Applicant wish to terminate an assessment procedure after making the payment required following the declaration of admissibility, 50% of the total expected assessment costs will in all cases be retained by UBAtc.

NOTE: UBAtc and its Assessment Operator(s) will evaluate expenses made and inform the Applicant accordingly.

- **(2)** The wish to terminate an assessment procedure must be communicated in writing to the UBAtc and the Assessment Operator.
- (3) All the related tasks carried out before the decision to terminate the assessment process was made known to the UBAtc and the Assessment Operator must in any case be compensated by the applicant.

# 3.5 Requirements for the (manufacturer's) technical file

Article 20 Availability of the technical file

- (1) The technical file will be completed throughout the assessment procedure. The Applicant is responsible for ensuring that the information is made available in a timely manner, preventing the undue slowing down of the assessment process.
- (2) The Applicant is responsible for ensuring that the technical file contains all relevant information regarding the manufacture of the product, the FPC system used during manufacturing, the product and its intended use(s).
- (3) The UBAtc and its Assessment Operators cannot be held responsible for errors in judgement and/or assessment due to omissions in the technical file.
- (4) If the technical file is not completed by the Applicant within the three months following the UBAtc's request to do so with the information requested, the Application may be declared inadmissible.
- (5) If it is impossible to provide the requested information within the three month period, the Applicant must inform the UBAtc and/or the Assessment Operator during this period and a limited extension may be agreed to for one time only.

### **Article 21** Content of the Technical file

(1) Annex 1 of the UBAtc's General approval and certification regulations covers in detail the contents of the technical file that accompanies the Application. It must include, amongst other things:

- where required or relevant, a copy of the relevant industrial or commercial property titles, patents, licenses, trade registry or memorandum of organisation of the company, certification of registration in the trade name registry.
- a complete description of the subject of the European Technical Assessment, including its structure, composition, form, production method, tools necessary for installation or incorporation, means and conditions of installation or incorporation, as well as maintenance and repair guidelines.
- Reports, in so far as available, relating to the subject for which the Application has been submitted (for example, test results, calculations and references) and which demonstrate the sustainable fitness for use for the intended use;
- the description of the means used to ensure the regularity of the properties and performance of the product or the use, including, but not limited to, the control methods the producer has at its disposal;

NOTE: The FPC requirements depend on the family of the products that are the subject of the submitted Application. However, there are a certain number of rules that are imposed on every Applicant. These rules are indicated in Annex 2 of the UBAtc's General approval and certification regulations.

- a declaration demonstrating that the Applicant obtained the rights necessary for this purpose:
  - from the ETA-holder (in the event of (an) Application(s) for (a) duplicate(s));
  - the rights to the trade name (in the case that the Applicant is not the trade name owner; for example, a distributor or an importer);
  - a declaration that the Applicant gives the UBAtc or its agent access to the production facilities (in the case that the Applicant is not the owner).
- (2) European Assessment Documents may provide additional guidance or the minimum requirements regarding the contents of the technical file necessary for the evaluation of the admissibility of the Applications.
- (3) At some point during the assessment process, the technical file must be supplemented by whatever additional documentation the Assessment Operator or its representative(s) judge necessary, in addition to what is mentioned above.

# 4 Development of the Initial and Final Work Programme, the ETA-contract and the European Assessment document

NOTE: This clause is only relevant in case a European Assessment Document needs to be modified or developed.

# 4.1 Development of the Initial Work Programme and ETA-contract

**Article 22** Development of the Initial Work Programme and ETA-contract

- (1) After consulting the other Technical Assessment Bodies designated for the relevant product area, the UBAtc secretariat will send the Applicant the ETA-contract and Initial Work Programme, comprising, amongst others, the following information:
- reference to the applicable European Technical Assessment Regulation
- reference to the Declaration of admissibility
- the organisation of work within EOTA,
- the composition of the EOTA workgroup,
- the coordination of Technical Assessment Bodies requesting the Applicant to sign and return the document (Regulation (EU) N° 305/2011, Annex II (2)).
   (2) The Applicant confirms his agreement with the ETA-
- contract by signing and returning the document.

# 4.2 Development of the Final Work Programme and the European Assessment Document

**Article 23** Development of the Final Work Programme

Asking further information to complete the technical file, when and if relevant, the UBAtc completes the Final Work Programme and consults other Technical Assessment Bodies designated for the relevant product area. The EOTA secretariat will submit the Final Work Programme to the European Commission (Regulation (EU) N° 305/2011, Annex II (3)).

NOTE: UBAtc cannot be held responsible for the activities of EOTA or the lack thereof.

Article 24 Content of the European Assessment Document

The content of the European Assessment Document complies with Article 24 of Regulation (EU) N° 305/211. In the absence of guidance from the European Commission and/or EOTA, requirements regarding the Essential characteristics that may be covered are those that applied in the framework of directive 89/106/EEC.

Article 25 Development of the European Assessment Document

- (1) Having consulted other Technical Assessment Bodies designated for the relevant product area, the UBAtc secretariat sends the final draft European Assessment Document to the Applicant (Regulation (EU) N° 305/2011, Annex II (4)), asking for comments and suggestions to improve the document.
- (2) Within 15 days after receipt, the Applicant responds by providing comments and/or suggestions, using the form made available by the UBAtc.
- (3) Having consulted other Technical Assessment Bodies, having adopted the draft European Assessment Document and informed the European Commission accordingly, the EOTA secretariat informs the Applicant how his comments, if any, were taken into consideration (Regulation (EU) N° 305/2011, Annex II (7)a).
- (4) Having taken into consideration possible comments from the European Commission, the EOTA secretariat provides the Applicant a copy of the Adopted European Assessment Document (Regulation (EU) N° 305/2011, Annex II (7) last paragraph).

NOTE: UBAtc cannot be held responsible for the activities of the EOTA secretariat, or the lack thereof. Applicants may contact the UBAtc secretariat in case it is perceived that the EOTA secretariat does not act according to the provisions of Regulation (EU) N° 305/2011. Nevertheless, the Applicant must accept that EOTA's obligations in accordance with Article 25 (3) and (4) may also be fulfilled by the UBAtc informing the Applicant.

## 5 Development of the European Technical Assessment

## 5.1 Assessment examination

**Article 26** Examination of the Application

- (1) The assessment examination itself begins once the technical file has been completed and the down payment made.
- (2) The rapporteurs involved and the members of the concerned Executive Bureaus will respect the absolute confidentiality of the information contained in the technical file.
- (3) Draft European Technical Assessment texts, Evaluation reports and corresponding comments handling documents are only made available to the Applicant in English.
- **(4)** The assessment examination generally includes the following elements:

- The study of the subject for which the Application has been submitted, mostly on the basis of the technical file (see Article 20);
- Visits to the references and/or construction sites;
- Visits and controls of the production facilities, the laboratory and the warehouse(s) (see Article 27);
- One (or more) sampling(s) (see Article 28);
- Tests (see Article 32), calculations (see Article 33) and any other evaluation techniques;
- The drafting of an Evaluation Report (see Article 36);
- The drafting of the assessment text(s) (see clause 6.4).

NOTE 2: Depending on the subject for which the Application has been submitted, deviations from the above-mentioned elements are possible.

## 5.2 Audits, site visits and inspections

**Article 27** Audits, site visits and inspections within the context of the assessment examination and the initial acceptance inspection

(1) Audits, site visits and inspections within the context of the assessment examination are organised in conjunction with the Applicant. The Applicant must therefore provide free access during working hours to the production facilities, self-control laboratory and warehouses, as well as allowing the manuals and control registers to be checked.

NOTE: The reason for such verification is that a European Technical Assessment is only issued by the UBAtc when the Applicant has demonstrated that he is able to manufacture the subject for which the Application has been submitted, in a controlled and consistent way, so that production always has the same properties and performances.

- (2) In the case that a European Technical Assessment examination with an Assessment and Verification of Constancy of Performance system that does not make provision for certification (systems 3 or 4), initial inspection of FPC as part of the assessment examination is performed by a UBAtc representative.
- (3) In the case that a European Technical Assessment examination with an Assessment and Verification of Constancy of Performance system does provide for certification (systems 2+, 1 or 1+), the manufacturer has to determine which notified certification body to involve. However, the Applicant is advised to have the initial inspection of FPC carried out simultaneously by the UBAtc and by the notified certification body selected by the Applicant. The FPC inspection as part of the assessment examination is in any case carried out by or under the responsibility of the UBAtc representative.

NOTE: In the latter case (2), the Applicant must ensure that the selected certification body is notified in accordance with article 39 of Regulation (EU) N° 305/2011 for the relevant European Assessment Document or the ETA-Guideline used as a European Assessment Document.

## 5.3 Sampling and testing

## Article 28 Independent sampling

- (1) Sampling within the context of the European Technical Assessment examination is always carried out by the Assessment Operator, or under the Assessment Operator's responsibility, e.g. by an independent party recognised by the Assessment Operator, and always on the basis of a wide selection of potential samples offered by the Applicant.
- (2) Unless the subject of the Assessment is clearly identified by the Applicant in the premises where sampling is to take place as not conforming, any of the products that are the subject of the Application and available in the premises may be included for sampling.

## Article 29 Representative sampling

The samples will be representative of the subject for which the Application has been submitted.

## Article 30 Sampling report

- (1) Sampling is accompanied by a sampling report which is signed off after sampling by the person responsible for taking the sample and by a representative of the Applicant.
- (2) The sampling report accompanies the samples to the laboratory where the tests will take place. In its report, the laboratory will refer to this sampling report. NOTE: Annex 3 of the UBAtc's General approval and certification regulations specifies the minimum content requirements which sampling reports must satisfy.

**Article 31** Criteria imposed on laboratories that carry out the tests

For the European Technical Assessment examination, distinction should be made between tests for which, within the context of the Assessment and Verification of Constancy of Performance, it is necessary to use a notified laboratory and those tests for which this is not necessary:

a) Tests for which, due to the Assessment and Verification of Constancy of Performance system (system 3), the involvement of a notified laboratory is necessary. In order to prevent the Applicant from the necessity of repeating the tests after the issuing of the European Technical Assessment, a notified laboratory is preferably used for the assessment tests. b) Tests for which, due to the Assessment and Verification of Constancy of Performance system (systems 1+, 1, 2+ or 4) the involvement of a notified laboratory is not necessary. In this situation, accredited laboratories must be used insofar as is possible. Often, the tests performed in the framework of an assessment examination deviate from frequently-performed tests. In these cases, laboratories that work in conformance with NBN EN ISO/IEC 17025, or according to its principles, must be used.

NOTE: In the former case (a), the Applicant must ensure that the selected laboratory(ies) is/are notified in accordance with article 39 of Regulation (EU) N° 305/2011 for the relevant European Assessment Document or the ETA-Guideline used as a European Assessment Document and the test method(s).

(2) It is possible that the Assessment Operator may formulate specific requirements regarding the laboratories that may carry out the tests as specified in the European Assessment Document. The Assessment Operator will provide more detailed information on this topic.

## Article 32 Test reports

- (1) In order to be accepted, the reports provided by the Applicant must at least comply with the requirements specified in Annex 3 of the UBAtc's General approval and certification regulations.
- (2) Should the reports not satisfy the requirements specified, the Assessment Operator has the right to refuse them.
- (3) All reports must be transmitted to the Assessment Operator in their full and complete form.

NOTE 1: Annex 3 of the UBAtc's General approval and certification regulations specifies the minimum content requirements which test reports must satisfy.

NOTE 2: This Article refers in particular to test reports. Similar requirements apply for reports relating to other types of evaluation (see Annex 3 of the UBAtc's General approval and certification regulations).

### 5.4 Calculation

## Article 33 Calculation controls

- (1) When calculations must be carried out within the context of the Assessment examination, these must be carried out either by an external organisation or by the Applicant.
- **(2)** The Assessment Operator will verify calculations presented.

## Article 34 Calculation reports

- (1) In order to be accepted, the reports provided by the Applicant must comply with requirements similar to those specified in Annex 3 of the UBAtc's General approval and certification regulations.
- **(2)** Should the reports not satisfy the requirements specified, the Assessment Operator has the right to refuse them.
- **(3)** All reports must be transmitted to the Assessment Operator in their full and complete form.

NOTE: Annex 3 of the UBAtc's General approval and certification regulations specifies the minimum content requirements which calculation reports must satisfy.

**Article 35** Criteria imposed for external organisations carrying out the calculations

Depending on the Assessment and Verification of Constancy of Performance system(s) and the importance of the calculations, the Assessment Operator may require use of an external organisation to perform calculations. When necessary, criteria may be imposed by the Assessment operator.

NOTE: Similar to the situation for laboratories (see Article 31), the Applicant must ensure that, where relevant, the selected laboratory(ies) is/are notified in accordance with article 39 of Regulation (EU) N° 305/2011 for the relevant European Assessment Document or the ETA-Guideline used as a European Assessment Document and the calculation method(s).

## 5.5 Evaluation Report

Article 36 Establishment of the Evaluation report The necessary evaluations having been carried out, the Assessment Operator's rapporteur will establish an Evaluation report, making use of and, where relevant, referring to, as relevant:

- Report of the study of the manufacturer's technical file (see Article 20)
- Construction site/reference visit reports
- Factory, production facilities, warehouse, internal laboratory and FPC inspection reports (see Article 27)
- Sampling reports (see Article 30),
- Test reports (see Article 32),
- Calculation reports (see Article 34),
- Declarations and certificates made or made available by the Applicant, and
- Any other relevant document intended to demonstrate that the evaluation is in accordance with the provisions of the relevant European Assessment Document.

## **Article 37** Use of the Evaluation report

The Evaluation Report will form the basis of the European Technical Assessment text and will be used to demonstrate to the members of the Executive Bureau and other Technical Assessment Bodies that all necessary evaluations were conducted and that performances specified in the European Technical Assessment have been determined in accordance with the European Assessment Document and any other reference document that may apply.

NOTE: The Evaluation report must be treated confidentially. Only the Assessment Operator will keep a copy. The document may be used in discussions in the Executive Bureau and must be used to inform other Technical Assessment Bodies.

## 6 Issuing of the European Technical Assessment

# 6.1 Handling within the Specialised Group

NOTE: This clause is a summary of the Internal Regulations for Specialised groups. These Internal Regulations apply in case of conflict.

## **Article 38** Statute of the Specialised Groups

A Specialised Group is an advisory body addressing a specific technical domain; it reaches decisions using consensus. The Assessment Operator responsible for the Specialised Group concerned submits the European Technical Assessment texts to the UBAtc, taking the advices of the Specialised Group into consideration.

**Article 39** Composition of the Specialised Groups A Specialised Group may be made up of:

- Executive Bureau members who are relevant to the Specialised Group concerned;
- representatives of manufacturers', distributors' and importers' federations, building contractors, architects and project owners;
- representatives of the public institutions;
- representatives of building societies and insurers;
- representatives of the laboratories carrying out the tests within the framework of the assessment activities.

Article 40 Membership of the Specialised Group

- (1) The Assessment Operator is responsible for selecting the members. Potentially, other interested parties may present their candidature for membership to the Assessment Operator responsible for the Specialised Group concerned; the Assessment Operator will request a recommendation on the candidature from that Specialised Group.
- **(2)** Each member of the Specialised Group must sign a commercial secrecy and confidentiality agreement.

## **Article 41** Conflicts of interest

For each draft European Technical Assessment, the composition of the Specialised Groups is examined for possible conflicts of interest. The members may not have any direct or indirect personal interest in the business being addressed to them.

Article 42 Working method and tasks of the Specialised Groups

The working method of the Specialised Groups is described in the UBAtc internal regulation for the Specialised Groups.

The tasks of the Specialised Groups in the framework of the UBAtc's activities regarding Regulation (EU) N° 305/2011 are:

- to provide comments and suggestions with a view to optimize European Assessment Documents that have been
  - developed by UBAtc and having been used to issue a European Technical Assessment
  - adopted by EOTA and cited in the Official Journal of the European Union.

NOTE: European Assessment Documents adopted by EOTA, but not yet cited in the Official Journal of the European Union are considered as confidential documents and may not be distributed to parties that are not members of a UBAtc Specialised Group.

## 6.2 Proofreading ("30 days procedure")

## **Article 43** Purpose of the proofreading

Following the validation by the operator, the European Technical Assessment text is presented to the Applicant. The purpose of this procedure is to give the Applicant the opportunity to check the contents of the European Technical Assessment text before it is to be signed, at which point it will become definitive. At the same time, the text is made available to the Assessment Operator and the management of the UBAtc.

## **Article 44** Time period for proofreading

The proofreading period continues until all the parties concerned have provided their comments or given their agreement. When no reaction is received within a maximum period of 30 days, all the parties involved are considered to have given their tacit agreement for the signing and thus for the finalisation and publishing.

# 6.3 Issuing European Technical Assessments

Article 45 Decision to issue a European Technical Assessment

The decision to issue a European Technical Assessment is taken after confirmation by the Assessment Operator concerned and the UBAtc.

### Article 46 Parties involved

European Technical Assessment texts are signed by:

- The Assessment Operator(s); and
- The UBAtc.

## Article 47 Significance of the signature

- (1) By signing the European Technical Assessment text, the Assessment Operator confirms its agreement with the technical contents of the text.
- (2) By signing the European Technical Assessment text, the UBAtc confirms that the necessary monitoring was carried out to ensure that the procedures in force are being respected, that the Assessment Operator(s) have satisfied the requirements of the organisation and assumes responsibility for the issued European Technical Assessment.

## 6.4 European Technical Assessment text

Article 48 Commission Implementing Regulation 1062/2013 of 30 October 2013on the format of the European Technical Assessment

The European Technical Assessment text must be in compliance with the Commission Implementing Regulation 1062/2013 of 30 October 2013 on the format of the European Technical Assessment, taking into account relevant EOTA guidance.

**Article 49** Use of the No-Performance-Determined option

Subject to the implementation of Article 6, 3(c) and Article 27 of Regulation (EU) N° 305/2011, manufacturers may use the NPD-option in their Declaration of Performance in those cases where 'No Performance Assessed' has been used by the Technical Assessment Body in the European Technical Assessment.

Article 50 Number of European Technical Assessment texts

In the case that an Application includes more than one subject or type of construction product and/or this/these subject(s) is/are suitable for more than one intended use, the Executive Bureau must evaluate whether it is necessary to make provision for one or more European Technical Assessment texts.

In this case, the following are taken into consideration in particular:

- the basic principle that a European Technical Assessment text should preferably deal with one subject or type;
- the necessity of avoiding any misunderstanding resulting from describing, in a single text, several subjects or types and/or uses with different performances and/or different installation or incorporation, maintenance and repair guidelines;
- the limitation that only similar subjects and/or types with similar intended uses may be described within a single European Technical Assessment text.

## 6.5 Dissemination (publication)

**Article 51** Issuing of the ETA-reference

- (1) The EOTA secretariat is responsible for making available the ETA-reference
- (2) UBAtc cannot assume any responsibility with regard to the ETA-reference other than communicating it to the Applicant, using it in the European Technical Assessment text and any publication related to that European Technical Assessment.
- (3) The ETA-reference is made known after the signing of the European Technical Assessment text.
- (4) The ETA-reference is made up of the two last digits of the year during which the draft European Technical Assessment was distributed for consultation in EOTA and a registration number.

EXAMPLE: ETA 99/9999

**(5)** The ETA-reference is only modified when the subject of the European Technical Assessment changes in such a way as to cause possible confusion amongst users if the same ETA-reference were to be used.

NOTE: new versions of the European Technical Assessment include an overview of modifications made since its original (or previous) version.

## **Article 52** Dissemination

(1) After being issued (see clause 6.3) the European Technical Assessment text is transmitted electronically to the Applicant.

- **(2)** The UBAtc has the right to publish the European Technical Assessment text on its website, at the expense of the ETA- holder.
- (3) The UBAtc has the right to discontinue publication of the European Technical Assessment text on its website (see Article 68).
- (4) Publication will at least be in English. If requested by the Applicant and once available translations will also be published.
- **(5)** This publication may only be reproduced in its entirety, in the format determined by the UBAtc, without any additions or omissions.
- **(6)** The ETA-holder can obtain from the UBAtc paper copies of the European Technical Assessment text printed at the UBAtc's rates.

## **Article 53** Methods and form of dissemination

- (1) European Technical Assessments must be published in English and may be published, upon request by the Applicant, in both French and Dutch.
- (2) French and Dutch versions are optional, but when the Applicant decides on this possibility, both languages must be included
- (3) Translations must be provided through the UBAtc's services.
- (4) Publication refers to the publication of the European Technical Assessment text(s) on the UBAtc website.
- **(5)** Printing of European Technical Assessment is optional.
- **(6)** Images and photos that are to be integrated in the European Technical Assessment text must be provided by the Applicant in a separate electronic file, i.e. not integrated into a Word document.
- (7) When necessary, images must be supplied with a legend, so that the same images may be used in different linguistic versions. The legend must be transmitted separately from the image.
- (8) For a European Technical Assessment text that will not be printed, photos must be provided in a minimum resolution of 72 dpi, i.e. 150 pixels x 125 pixels. When the European Technical Assessment text is to be printed, the minimum resolution required is 300 dpi, i.e. 600 pixels x 450 pixels.
- **(9)** The UBAtc does not provide or publish documents in or translate texts from or to any other languages than Dutch, English and French.
- (10) The UBAtc has the right to authorise EOTA to publish on its site bibliographic information on the European Technical Assessments issued by the UBAtc as well as the complete European Technical Assessments text.

(11) The UBAtc has the right to make all necessary information regarding issued European Technical assessments available to third parties (for example, the EOTA secretariat, the European Commission, the designating and enforcement authorities, etc.).

## 7 Amendment of the European Assessment Document

Article 54 Amendment of the European Assessment Document

After the issuing of the European Technical Assessment, the Assessment Operator will verify whether experiences gained through the examination process lead to the need to adapt the European Assessment Document and, if so, the UBAtc secretariat will take the necessary steps for EOTA to consider the proposal prior to the European Assessment Document being formally adopted. Once adopted, EOTA has the right to publish the European Assessment Document and in accordance with Regulation (EU) N° 305/2011, the European Commission will cite the adopted European Assessment Document in the Official Journal of the European Union.

## 8 Publication of the European Assessment Document

Having been cited by the European Commission in the Official Journal of the European Union (http://eurlex.europa.eu/JOIndex.do) and the ETA-holder having made known that the product covered by the European Technical Assessment for which the European Assessment Document has been established was CE marked (see Article 59), the EOTA secretariat has the right to publish the European Assessment Document on the EOTA website (www.eota.eu).

NOTE: UBAtc cannot be held responsible for the activities of the European Commission and/or EOTA or the lack thereof.

## 9 Obligations of the European Technical Assessment holder

- Article 55 Compliance with legal and regulatory provisions, including, without limitation, national and European legislation on the safety of products and services
- (1) The European Technical Assessment holder guarantees that the product(-s) to which the assessment relates, is/are produced and marketed in accordance with and comply with all applicable legal and regulatory provisions, including, without limitation, national and European legislation on the safety of products and services.
- (2) The ETA-holder must inform the UBAtc immediately in writing of any circumstance affecting the aforementioned guarantee. Consequently, the ETA-holder should refrain from using the European Technical Assessment as the basis for his declaration of performance and the UBAtc may withdraw the European Technical Assessment from the UBAtc website and consider the European Technical Assessment as having been withdrawn by the ETA-holder (see Article 68).
- (3) European Technical Assessments are being issued under the condition that the aforementioned guarantee by the ETA-holder will be continuously observed.

## **Article 56** Continued conformity of the products

- (1) Pursuant to Article 11(3) of Regulation (EU) N° 305/2011, manufacturers must adequately take into account changes in the product-type and in the applicable harmonised technical specifications. Therefore, when the contents of the issued European Technical Assessment do not any longer correspond to the product-type, the manufacturer should refrain from using this European Technical Assessment as the basis for their declaration of performance.
- (2) The ETA-holder must inform the UBAtc immediately in writing that the contents of the issued European Technical Assessment do not any longer correspond to the product-type. Consequently, the UBAtc may withdraw the European Technical Assessment from the UBAtc website and consider the European Technical Assessment as having been withdrawn by the ETA-holder (see Article 68).

## **Article 57** Instructions and safety information

According to Regulation (EU) N° 305/2011, Article 11(6), when making a construction product available on the market, the manufacturer must ensure that the product is accompanied by instructions and safety information in a language determined by the Member State concerned which can be easily understood by users. These instructions and safety information should fully correspond with the technical information about the product and its intended use which the manufacturer has submitted to the UBAtc when applying for a European Technical Assessment.

## **Article 58** European Technical Assessment text and ETA-reference

An Applicant may only use the European Technical Assessment text and/or ETA-reference with the permission of the UBAtc either in writing or by the publication of the European Technical Assessment text on the website of the UBAtc.

## **Article 59** Announcement of CE marking

- (1) In accordance with Annex II (8) of Regulation (EU) N° 305/2011, the ETA-holder is obliged to inform the UBAtc that the product covered by the European Technical Assessment for which the European Assessment Document was established is being CE marked.
- (2) UBAtc may remind the ETA-holder that he is obliged to inform the UBAtc that the product covered by the European Technical Assessment for which the European Assessment Document was established is being CE marked.
- (3) If the ETA-holder neglects to inform UBAtc accordingly, UBAtc has the right to inform the enforcement authorities.

## Article 60 Publicity

- (1) European Technical Assessment holders may not use the terms "BUtgb", "UBAtc", the BUtgb and/or UBAtc mark, any mark used by UBAtc in the framework of its other services, the European Technical Assessment text or the ETA-reference to claim performances that do not conform to the European Technical Assessment and/or that relate to subjects and/or properties or characteristics that are not part of the European Technical Assessment.
- (2) The European Technical Assessment text issued may be reproduced by the holder in its documentation, publicity (including the holder's Internet website) and promotional materials as long as the European Technical Assessment text is used in its entirety, exactly as it appears on the UBAtc website.

(3) Information that is made available by the European Technical Assessment holder or the person designated by it in any way, whether for (potential) users of the subject of the European Technical Assessment (for example, project owners, building contractors, prescribers, etc.) may not contradict the contents of the European Technical Assessment text or the information to which the European Technical Assessment text refers.

## Article 61 Mark usage

The ETA-holder must respect the mark usage specifications regarding the shape, utilisation and protection of any mark used by UBAtc in the framework of its other services and the BUtgb and UBAtc and EOTA marks.

NOTE 1: Marks used by UBAtc in the framework of its other services are registered trade names. The usage rules for those marks are specified in the Regulations for the Use and protection thereof.

NOTE 2: The BUtgb and UBAtc marks are registered. The usage rules for the two marks are laid out in the Internal Regulations of the UBAtc.

NOTE 3: The EOTA mark is registered.

## 10 Conformity with and validity of issued European Technical Assessments

**Article 62** Conformity of the product with the issued European Technical Assessment

- (1) Under the provisions of Regulation (EU) N° 305/2011, UBAtc is not authorized to check whether the provisions of European Technical Assessments are met once these have been issued.
- (2) The responsibility for the continued and permanent conformity of the performances of the products covered by a European Technical Assessment with the provisions thereof and the suitability of the products for the intended use remains with the holder of the European Technical Assessment.
- (3) In the event that the UBAtc becomes aware that a European Technical Assessment should be modified or withdrawn, it may inform the ETA-holder (see Article 73).

**Article 63** Validity of European Technical Assessments

- (1) Under the provisions of Regulation (EU)  $N^{\circ}$  305/2011, the validity of European Technical Assessments is not specified.
- (2) If UBAtc is made aware that the basis for issuing the European Technical Assessment has been modified in a way that affects the correctness of an already issued European Technical Assessment, the UBAtc may inform the ETA-holder (see Article 73).

Article 64 Serious infringements regarding issued European Technical Assessments

The following are considered serious infringements which may lead to sanctions:

- actions that run contrary to the present Regulations or the non-respect of the conditions imposed by the European Technical Assessment;
- use of the subject of the European Technical Assessment for a different utilisation than that mentioned in the European Technical Assessment, while claiming conformity therewith;
- the placing on the market or the making available of another product or use of another production facility of method using the same references as the subject of the European Technical Assessment
- the provision of incorrect information, even in good faith, in the Application or in the information transmitted to the UBAtc within this context;
- non-conformity with new, existing or revised European Assessment Documents;
- default of timely payment of costs for the European Technical Assessment;
- modifications to the subject of the European Technical Assessment and/or the production methods, without prior submission of an Application for a revised European Technical Assessment.

### **Article 65** Emergency procedure

- (1) When the UBAtc considers that the situation is urgent, publication of the European Technical Assessment on the UBAtc website may be suspended immediately as soon as an infringement is observed.
- (2) The emergency procedure is applied in particular in the case of (potential) serious faults in essential parts of the construction<sup>2</sup>.

<sup>&</sup>lt;sup>2</sup> "Serious faults in essential parts of the construction" in this context means those for which decennial liability exists, in accordance with Articles 1792 and 2270 of the Belgian Civil Code and in accordance with the related doctrine and jurisprudence.

## **Article 66** Duration of the suspension

Suspension measures with regard to Article 65 are imposed for a maximum duration of three months. They may be prolonged to allow for additional inquiry. After the suspension sanction, the European Technical Assessment may be withdrawn entirely from the list of European Technical Assessments issued by the UBAtc published on the UBAtc website.

## Article 67 Notification

- (1) The decision to suspend or withdraw publication on the UBAtc website includes the motivation.
- (2) The arrangements that must be taken for on-going construction works in order to protect the interests of the parties using the subject of the European Technical Assessment are mentioned in the motivation. These arrangements must be communicated immediately to these parties by the ETA-holder.
- Article 68 Withdrawal of the publication of the European Technical Assessment from the UBAtc website
- (1) If UBAtc is being informed by the ETA-holder in accordance with Article 55 or Article 56 that the subject of the European Technical Assessment does no longer comply with legal and regulatory provisions and/or that the product no longer complies with the provisions of the European Technical Assessment, the UBAtc may withdraw the European Technical Assessment from its list of issued European Technical Assessment.
- (2) If UBAtc is (made) aware that Article 62, Article 63 and/or Article 64 apply to a European Technical Assessment that it has issued, and having informed the ETA-holder according to Article 73, to no avail, the UBAtc may decide, as sanction, to withdraw the European Technical Assessment from its list of issued European Technical Assessments.
- (3) Unless the ETA-holder requests a prolongation, which is granted in writing, the UBAtc may withdraw European Technical Assessment texts from its list of issued European Technical Assessments 5 years after the issuing thereof.

# 11 Modifying and extending already issued European Technical Assessments

**Article 69** Modifications to the subject of the already issued European Technical Assessment

The ETA-holder must inform the UBAtc of any modifications to the subject of the European Technical Assessment, the production process and/or its installation/incorporation method(s) and any new production sites in which the subject of the European Technical Assessment will be manufactured.

Article 70 Modification or extension of a European Technical Assessment on the demand of the ETA-holder (renewal)

When the ETA-holder intends to modify or extend the subject, it must request a modification or an extension. The technical file to be submitted for this purpose may be limited to a detailed explanation of the proposed modifications or extension. The assessment process takes place just as for a new Application.

**Article 71** Transfer of a European Technical Assessment

When the manufacturing or exploitation rights of the subject of the European Technical Assessment are transferred by inheritance, donation and sale or in any other way, the new rightful owner may continue to use the European Technical Assessment as long as it has the authorisation of the UBAtc. This authorisation is accorded after the new rightful owner has demonstrated that he has sufficient technical aptitude and adequate facilities.

NOTE: Demands for transfer are submitted using the forms provided for this purpose by the UBAtc or by one of the Assessment Operators.

- Article 72 Relocation of production sites and/or transfer of (a) production line(s) or unit(s)
- (1) When the relocation of the production site or the transfer of (a) production line(s) or unit(s) is no more than the moving of the production facility and results in no changes to the production methods, the production control system and/or the subject of the European Technical Assessment, the Applicant or the ETA-holder must simply inform the UBAtc Assessment Operator(s) concerned.

(2) When the relocation of a production site and/or the transfer of (a) production line(s) or unit(s) does or could potentially result in a change to the production method, production control system and/or the subject of the European Technical Assessment and/or its performances, or when it relates to a change of ownership, the Applicant or the ETA-holder must inform the UBAtc Assessment Operator(s) concerned of this fact before the change is accomplished.

In this event, the following information must be communicated:

- In the case of a change of ownership, an application for transfer (see Article 71 and form FORM02B);
- An application for a modification of the issued European Technical Assessment (see Article 70)
- (3) In case the steps to be followed are not clear, the Assessment Operator will explain which steps must be followed.

## Article 73 Revision on the demand of the UBAtc (updating)

## (1) In the event that

- the continued and permanent conformity of the performances of the products covered by a European Technical Assessment with the provisions thereof and/or the suitability of the products for the intended use is guestioned; or
- the basis for issuing the European Technical Assessment has been modified in a way that may affect the correctness thereof,

the UBAtc may invite the ETA-holder to modify or withdraw the European Technical Assessment and motivate why.

**(2)** UBAtc cannot be held responsible if the ETA-holder does not modify or withdraw the European Technical Assessment accordingly.

## Article 74 Corrigendum

In case a corrigendum (see Definition 19) is necessary, the ETA-holder must contact the UBAtc secretariat or the Assessment Operator or both.

Note: It continues to be possible to issue corrigenda for European Technical Approvals, issued by UBAtc in the framework of directive 89/106/EEC

## 12 Copyrights

## Article 75 Copyrights

- (1) By their collaboration, all interested parties renounce any rights to the European Technical Assessment text(s), Evaluation reports, Comments handling documents, European Assessment Documents, information sheets and related documents, and concede them exclusively and irrevocably to the UBAtc, without their names being mentioned in the utilisation thereof.
- (2) This renunciation and concession of rights does not exclude the person/people concerned from using their contribution for their own purposes, as long as this does not in any way affect the above-mentioned use by the UBAtc.
- (3) In the event that the person/people concerned do not have the rights over their contribution, this must be communicated to the UBAtc or its representative(s).

# 13 Commercial secrecy and confidentiality

**Article 76** Issuing commercial secrecy and confidentiality agreements

Assessment Operators, individual rapporteurs and other UBAtc representatives do not sign commercial secrecy and confidentiality agreements with individual Applicants.

**Article 77** UBAtc commercial secrecy and confidentiality agreement

- (1) The UBAtc and its Assessment Operators may not communicate confidential information and documents that they have taken knowledge of within the context of an assessment examination to a third party, including after the completion of the examination.
- (2) The UBAtc and its Assessment Operators must only use the confidential information and documents for the examination and issuing of European Technical Assessments and for the related activities, where relevant (for an overview of the services provided by the UBAtc, see the General Approval and Certification Regulations), and may not communicate them to a third party without express written authorisation (an email is acceptable) from the Applicant or his/her delegate. All persons other than the Applicant, the UBAtc or its Assessment Operators or their representatives are considered to be third parties. The UBAtc and its Assessment Operators must ensure that any employees and advisors they call upon are also held to the above-mentioned points.

- **Article 78** Commercial secrets and confidential information and documents
- (1) The term 'Commercial secrets and confidential information and documents', as used herein, means information that is:
- a) of a technical or business nature; and
- b) of practical value and provides economic benefits; and
- c) secret and unknown to the public, provided in any way by the Applicant within the context of the European Technical Assessment Application.
- **(2)** Non-secret and non-confidential information is information for which the UBAtc may document that:
- The information was already available publicly before the UBAtc was made aware of it; or
- the information was made public afterwards, without this dissemination being attributed to the UBAtc; or
- the information was published by a third party in a legitimate way and without violating the confidentiality obligations of this third party.

## Article 79 Exceptions

An exception to the confidentiality agreement is applicable when the nature of the Application submitted by the Applicant leads the UBAtc or its Assessment Operators to exchange information with other Technical Assessment Bodies, the organisation of such bodies and/or public authorities (the European Commission and/or notifying and enforcement authorities) in accordance with the regulatory provisions and/or the rules of the organisations concerned. When the Applicant objects to this exchange of information, it must inform the UBAtc or the rapporteur in writing (an e-mail is acceptable).

NOTE: When this occurs, it may be necessary to end the assessment examination by mutual consent.

## Article 80 Legal status and disputes

- (1) Implementation of Article 76, Article 77, Article 78 and Article 79 and any possible disputes related to those articles are subject to Belgian law.
- (2) All disputes that may arise as a result of these articles will be submitted to the UBAtc Appeals Commission. When the dispute continues after the ruling of this Commission, the issue will be referred to the Brussels (Belgium) court system.

## 14 Complaints

- Article 81 Complaints regarding the subject of the European Technical Assessment
- (1) When a written complaint is lodged with the UBAtc or the Assessment Operator regarding the subject of the European Technical Assessment, an assessment of the admissibility of the complaint will be carried out.
- **(2)** When the complaint is admissible, the Assessment Operator must examine its foundation, based on available information.
- (3) The Assessment Operator will inform the assessment holder in writing of the admissibility of the complaint. Where relevant, the Assessment Operator may involve the ETA-holder in addressing the complaint received and may, where relevant, attempt to convince the ETA-holder into withdrawing the European Technical Assessment and/or to submit an application for a modification of the issued European Technical Assessment.
- (4) The Assessment Operator will inform the complainant in writing of the admissibility and basis of the complaint, and will inform them of the results of the inquiry and the measures taken, if any. Only information that belongs legally to the complainant regarding the subject of the complaint is communicated.
- **(5)** When the complaint is determined not to be well-founded, the Assessment Operator may recover all or part of the costs from the complainant.
- Article 82 Complaints concerning the services provided by the UBAtc and/or (an) Assessment Operator
- (1) When a written complaint is lodged with the UBAtc or the Assessment Operator regarding possible deficient services provided by the UBAtc and/or one or more of the Assessment Operators() concerned, the admissibility of the complaint is assessed by the UBAtc Legal Service.
- (2) When the complaint is found admissible, the UBAtc will take the measures necessary, within the limits authorised by its Statutes.
- Article 83 Informing the designating authority Having submitted a complaint in accordance with Article 81 or Article 82 and not being satisfied with the follow-up provided by the UBAtc or the Assessment operator(s), a written complaint may be submitted to the Belgian designating authority.

## 15 Decision review process

## Article 84 Decision review process

- (1) If an applicant disagrees with (a) decision(s) taken by the UBAtc and/or (an) Assessment Operator(s), he may request a hearing.
- (2) If the hearing does not lead to the desired effect, the applicant may introduce an appeal petition and ultimately introduce higher appeal.

## Article 85 Hearing

- (1) When the Applicant disagrees with (a) decision(s) or (a) sanction(s) imposed by the UBAtc and/or (an) Assessment Operator(s), the Applicant has the right to be heard by the UBAtc and/or the Assessment Operator(s).
- (2) The request for such a hearing must be introduced in writing.
- (3) The request for a hearing does not suspend the decision(s) taken or the sanction(s) imposed by the UBAtc and/or the Assessment Operator(s).

## Article 86 Appeal

- (1) If, after the hearing referred to in Article 85, the Applicant continues to disagree with (a) decision(s) or (a) sanction(s) imposed by the UBAtc and/or (an) Assessment Operator(s), the Applicant has the right to submit a request for appeal against this decision with the Appeals Commission of the Assessment Operator(s).
- (2) The submission of a request for appeal is carried out by registered letter within 10 working days following the announcement of the decision(s) or sanction(s).
- (3) The submission of a request for appeal does not suspend the decision(s) taken or the sanction(s) imposed by the UBAtc and/or the Assessment Operator(s).

## Article 87 Higher appeal

- (1) If, after the appeal procedure referred to in Article 86, the Applicant disagrees with the ruling of the Appeal Commission of the Assessment Operator(s), the Applicant has the right to submit a request for higher appeal to the President of the UBAtc's Technical Coordination Board regarding the form and procedure followed, if the Applicant considers that faults in the form and/or procedure were committed during decision-making.
- (2) Higher appeal may only be lodged regarding the faults and errors described above, as far as it relates to the issuing or non-issuing of a European Technical Assessment by UBAtc that was the subject of an Application submitted by the Applicant.

- (3) Any introduction of a higher appeal must be received within 60 days following the notification to the Applicant of the decision(s) that is the subject of the higher appeal. A higher appeal that is not introduced in a timely manner may be rejected by the LIBAtc
- **(4)** A legitimately-submitted higher appeal includes at least the following elements:
- A detailed declaration regarding the decision(s) that is/are the subject(s) of the higher appeal;
- A detailed declaration regarding the foundation of the higher appeal (for example test results, references, technical specification, etc.);
- (where relevant) a reference to legislation, regulations, guidelines, standards, criteria, etc. that have a bearing within the context of the higher appeal.
- **(5)** A request for higher appeal is submitted to the UBAtc secretariat.
- **(6)** The costs of the higher appeal are invoiced by the UBAtc secretariat to the Applicant, and must be paid before the procedure begins.

## **Article 88** Appeals Committee

- (1) The UBAtc secretariat will inform the President of the Technical Co-ordination Board concerned, who will set up an Appeals Committee which may comprise:
- a representative of the public authorities,
- a representative of the building contractors,
- a representative of the Assessment Operators and
- a representative of the architects,
- and must comprise a representative of the manufacturers.
- (2) The members of the Appeals Committee must sign a confidentiality agreement provided by the UBAtc and send it back within 10 calendar days to the UBAtc secretariat.
- (3) The members of the Appeals Committee may not be involved in the UBAtc's Assessment processes and are not permitted to participate in the handling of the appeals process:
- if they have any personal interest in it,
- if they have been involved previously in the handling as the representative of one of the parties or
- if they have played a role in the decision being appealed.
- **(4)** The Appeals Committee is presided over by the representative of the manufacturers.

## **Article 89** Hearing by the Appeals Committee

- (1) The President of the Appeal Committee will indicate to the UBAtc and to the Applicant launching the appeal, the date, place and time of the hearing. The hearing will take place at the earliest 60 days and at the latest 90 days after the president of the Technical Coordination Board has been informed by the UBAtc secretariat.
- (2) The UBAtc and the Applicant launching the appeal have up to 30 calendar days before the hearing to provide written evidence that may be taken into consideration by the president of the Technical Coordination Board concerned, who will transmit this information within 10 calendar days following its receipt to the members of the Appeals Committee and to the opposing party.
- **(3)** The UBAtc and the Applicant launching the appeal may present additional information during the hearing.

#### **Article 90** Draft decision and decision

- (1) In order to arrive at a proposal for a decision, the president of the Appeals Committee may carry out the deliberations with the Appeals Committee. Within the 30 days following the hearing, the president of the Appeals Committee will indicate a proposal for a decision to the members of the Appeals Committee, to the president of the Board of Directors of the UBAtc and to the Applicant launching the appeal.
- **(2)** A representative of the Board of Directors of the UBAtc will make provision for addressing the appeal procedure during a regular or extraordinary meeting of the Board of Directors of UBAtc. The Board of Directors:
- confirms the proposal for a decision put forward by the president of the Appeals Committee
- charges the president of the Appeals Committee with the organisation of an additional hearing, in accordance with Article 89, or
- takes the decision not to confirm the proposal put forward by the president of the Appeals Committee.

and indicates its motivated decision in writing, to the members of the Appeals Committee, the Management Committee of the UBAtc and the Applicant who launched the appeal.

## 16 Disputes

## Article 91 Disputes

- (1) The Applicant or the ETA-holder and the Assessment Operator, undertake that all possible disputes arising from the execution or interpretation of the regulatory provisions will be dealt with definitively in accordance with the Arbitration Rules of the Belgian Centre for Mediation and Arbitration (CEPANI) by one or more arbitrators, nominated in accordance with these Arbitration Rules.
- (2) The arbitration tribunal will consist of an arbitrator. The procedure will take place in Brussels. The language of the arbitration will be that used in the license demand (Dutch or French).
- (3) The parties explicitly exclude any appeal petition to nullify the decision resulting from the arbitration.

## 17 Assessment costs

## 17.1 General provisions

### **Article 92** Determination of the tariffs

- (1) The costs associated with the Application, the examination, European consultation and collaboration, the UBAtc Specialised group consultation and information, issuing, translation and publication of the European Technical Assessment texts are determined by the UBAtc and its operators.
- **(2)** Payment of the costs is the responsibility of the Applicant of the European Technical Assessment.
- (3) The tariffs and fees may be adjusted once a year if necessary based on, amongst other things, the consumer price index published by the Federal Public Service Economy, SMEs, Self-Employed and Energy.
- (4) The UBAtc and the Assessment Operators are entitled to modify the tariffs pending an annual review. Assessment operators may use another index to adjust prices for inflation.
- (5) Unless otherwise specified, as a general rule all the tariffs, fees and quotes of the UBAtc and the Assessment Operators are excluding VAT (see Annex 1).

#### Article 93 Additional activities

(1) The costs for additional activities, other than those mentioned in this document will be communicated in advance to the Applicant.

- (2) Any costs resulting from the modification of the subject of the Application during the examination, or the submission of variants that result in modifications to the presentation of the European Technical Assessment after its issuing are to be paid by the Applicant.
- (3) For additional activities, the tariff that applies is the one in force at the moment that the modification or variant is made known to the UBAtc, not the tariff in force at the moment of the European Technical Assessment Application.
- **Article 94** Determination of the price and invoicing
- (1) In the declaration of admissibility, the amount to be invoiced by the relevant Assessment Operator is indicated, including a detailed breakdown of the costs (see Article 14).
- (2) The basis for the costs is specified in Article 96, which may be supplemented with the costs determined by the Assessment Operator(s), as far as relevant.
- **(3)** By returning the declaration of admissibility, the Applicant indicates agreement with the amount specified for the services to be provided.

## Article 95 Payment

- (1) The Assessment Operator designated by the UBAtc will handle the invoicing.
- (2) After receiving the duly signed and dated declaration of admissibility, the operator concerned will send an invoice to the Applicant, in which half of the total amount will be required as a prepayment. Amounts less than €4500 are charged in one time.
- (3) The prepayment paid is in no case reimbursable.
- (4) After validation of the draft European Technical Assessment by the Assessment Operator, an invoice with the balance of the total cost, in which any discounts are taken into account, will be sent to the Applicant. This invoice must be paid before the European Technical Assessment is issued.
- **(5)** The payment of costs must be made within 30 days after the date of the invoice.
- **(6)** Notwithstanding the preceding conditions, the Assessment Operator designated by the UBAtc has at all times the right to stipulate payment terms or the provision of a prepayment, a deposit or a bank guarantee from the Applicant or ETA-holder.

- (7) When the Applicant or ETA-holder does not pay the amount invoiced in a timely manner, the UBAtc or the Assessment Operator designated by the UBAtc may suspend the handling of the application or ensure the suspension and ultimately withdrawal of the European Technical Assessment text(s) issued from its website as a sanction (see Article 68).
- (8) Costs left unpaid to third parties involved in the assessment process may also lead to the sanctions mentioned above by the UBAtc and/or the Assessment Operator designated by the UBAtc.
- (9) In the event that payment has not been made after three reminders, the UBAtc and/or the Assessment Operator designated by the UBAtc may proceed to enforce the payment through any legal means.

## 17.2 Costs for specific services

Article 96 Costs to obtain a European Technical Assessment

The costs to obtain a European Technical Assessment, depending on the type of Application, cover the activities and are determined as foreseen in Table 1.

Table 1: Overview of costs and their structure

Activity	Flat fee	Cost per day, line or page
Registering and processing the Application*	Х	
Issuing a notice of receipt*	Х	
Determining/confirming the ETA-route*	X	
Development of the ETA-request*	Х	
Admissibility examination*	Х	
Issuing a declaration of admissibility	Х	
Verifying the completeness of and maintaining the manufacturer's technical file throughout the assessment examination		X
Development of the Initial and Final Work Programme, if relevant	Article 97	
Dossier costs	Article 97	
Study of the Application		Х
Assessment examination, comprising the elements as listed in Article 26 (6)		Х
Travelling and accommodation, if relevant		Article 98

Development of the Evaluation report  Development of the European Technical Assessment text, incl. x proof reading  Issuing of the new, modified or extended European Technical X Assessment  Making available the European Technical Assessment  Making available the European Technical Assessment on the X UBAtc website  Translations  Printing of texts  Article 100  European Co-ordination, split into:  — cases where an existing EAD may be used; and — cases where an EAD may be developed or modified  EOTA fee per issued European Technical Assessment  Article 101	Activity	Flat fee	Cost per day, line or page
Technical Assessment text, incl. x proof reading  Issuing of the new, modified or extended European Technical X Assessment  Making available the European Technical Assessment on the X UBAtc website  Translations  Printing of texts  Article 99  Printing of texts  European Co-ordination, split into:  — cases where an existing EAD may be used; and — cases where an EAD may be developed or modified  EOTA fee per issued European Technical Assessment  Article  Anneals	•	Х	
extended European Technical X Assessment  Making available the European Technical Assessment on the X UBAtc website  Translations  Printing of texts  European Co-ordination, split into:  — cases where an existing EAD may be used; and — cases where an EAD may be developed or modified  EOTA fee per issued European Technical Assessment  Article  Article	Technical Assessment text, incl.	X	
Technical Assessment on the X UBAtc website  Translations  Printing of texts  European Co-ordination, split into:  — cases where an existing EAD may be used; and — cases where an EAD may be developed or modified  EOTA fee per issued European Technical Assessment  Article	extended European Technical	Х	
Printing of texts  Printing of texts  European Co-ordination, split into:  - cases where an existing EAD may be used; and - cases where an EAD may be developed or modified  EOTA fee per issued European Technical Assessment  Article	Technical Assessment on the	X	
Printing of texts  European Co-ordination, split into:  — cases where an existing EAD may be used; and — cases where an EAD may be developed or modified  EOTA fee per issued European Technical Assessment  Article	Translations		
into:  — cases where an existing EAD may be used; and — cases where an EAD may be developed or modified  EOTA fee per issued European Technical Assessment  Anneals  Article	Printing of texts		
may be used; and  — cases where an EAD may be developed or modified  EOTA fee per issued European Technical Assessment  Appeals  Article			
developed or modified  EOTA fee per issued European Technical Assessment  Appeals  Article	_	Х	
Technical Assessment X  Anneals Article	•		
Anneals	·	Х	
	Appeals		

<sup>\*</sup> These costs will be deducted from the overall costs if the applicant continues the process and obtains an ETA

#### **Article 97** Dossier costs

(1) These costs cover the following activities:

- Management of the Application by the operator;
- Treatment within the Executive Bureau;

The Applications are assigned to categories (simple, normal, complex or special) depending on their complexity, by the UBAtc together with the Assessment Operators designated by the UBAtc.

Note: This complexity depends, amongst other, on

- the significance of the technical deviation from existing specifications, technical complexity and/or innovative nature of the product or its intended use;
- the use of methods and criteria, that may be incorporated as parts of the European Assessment Document, to assess the performance of (some of) the essential characteristics of the product, in accordance with Regulation (EU) N° 305/2011, Article 24, if those existing methods and criteria have already been
  - established in other harmonised technical specifications; or
  - established in ETA-Guidelines; or

- used in accordance with Article 9 of Directive 89/106/EEC before 1 July 2013 in the context of issuing European Technical Approvals,
- and are (still) appropriate.
- the availability and applicability of a decision specifying the relevant Assessment and Verification of Constancy of Performance system

## **Article 98** Travelling and accommodation

In normal situations, travelling and accommodation are included in the work of the rapporteurs and are not charged separately.

NOTE: The number of visits and samplings depends on the subject for which the Application has been submitted.

In the event that additional visits or samplings are necessary, these may be charged separately by the Assessment Operator designated by the UBAtc. The costs are determined by the Assessment Operator designated by the UBAtc on the basis of an hourly or daily tariff.

Any travel and accommodation costs (travel and stayrelated) will be added as a flat fee or will be based on the distance

These costs will be invoiced separately from those referred to above.

### Article 99 Translation

Costs for translation are determined by the UBAtc by line or by page and are determined after the issuing of the European Technical Assessment.

These costs will be invoiced separately from those referred to above.

## **Article 100** Printing of texts

Costs for printing are determined by the UBAtc by page and are determined after the issuing of the European Technical Assessment.

These costs will be invoiced separately from those referred to above.

## **Article 101** Costs of appeals

These costs must be borne by the appellant in accordance with Article 87 (6).

These costs will be invoiced separately from those referred to above.

## **Article 102** Costs for testing, calculation and other evaluations

The costs for tests, calculations or other evaluations necessary during the Assessment examination are determined and invoiced by the laboratory/organisation responsible for carrying out the evaluation.

**Article 103** Costs related to Assessment and Verification of Constancy of Performance

The costs for Assessment and Verification of Constancy of Performance are to be determined and invoiced by the organisation responsible for carrying out the tasks in accordance with Regulation (EU) N° 305/2011.

### Article 104 Cost increases and reductions

The costs specified in this document assume that an Application covers one product, intended for one specified use, manufactured in one production facility. Cost reductions or increases may be required for specific Applications in case these cover several products with one or several intended uses and/or products that are produced in several facilities or lines.

# 18 Termination of the non-profit organization (asbl)

**Article 105** Termination of the non-profit organization (asbl)

In the event that the UBAtc is voluntarily dissolved, the European Technical Assessment holders may continue to use the European Technical Assessments issued by UBAtc, but the documents may no longer be available on the UBAtc website.

## 19 Transitional measures

- Article 106 Transitional measures related to the period in which the implementation of Regulation (EU) N° 305/2011 has not yet been finalized and EOTA procedures and documents are under development
- (1) Whereas fundamental changes in the processes and documentation are not expected at the date of issuing this version of the European Technical Assessment Regulation, readers and especially applicants should take into consideration that changes may occur. The UBAtc will make applicants aware of significant changes as soon as possible, in particular when these changes lead to increased costs for the applicants.
- Article 107 Transitional measures related to European Technical Approvals issued in the framework of directive 89/106/EEC Converting a European Technical Approval into a European Technical Assessment
- (1) It is impossible to issue European Technical approvals in the Framework of Regulation (EU) N° 305/2011. Consequently, UBAtc cannot issue duplicate European Technical approvals.

- (2) Duplicate European Technical Assessments may only be issued if the original European Technical Approval has been re-issued as a European Technical Assessment.
- (3) Provided no technical changes are necessary, due to:
- Regulations having changed since the issuing of the European Technical Approval; or
- the product, production and/or FPC system having changed since the issuing of the European Technical Approval,

converting European Technical Approvals into European Technical Assessments is possible.

The Applicant needs to demonstrate that the product, production and/or FPC system did not change.

If the European Technical Approval is not based on

- an existing ETA-Guideline that may be used as a European Assessment Document; or
- an existing European Assessment Document a European Assessment Document must be developed before the European Technical Assessment may be issued.



## **Annex 1: Tariff**

Table 2: Registering application, examination of the ETA-route and general costs

Activity	Cost (€)
Administration (registering and processing the Application, issuing a notice of receipt and declaration of admissibility	
Determining/confirming the ETA-route	
Development of the ETA-request	
Admissibility examination	
In case an adopted EAD is not available or may not be used for the application concerned	5000
All other cases	1000
Travelling and accommodation, if relevant	p.m.
Translations*	p.m. + 100
Printing of texts	p.m.
Appeals	5000

## Table 3: Issuing duplicates

Activity	Cost (€)
Administration	315
Verifying the completeness of and maintaining the manufacturer's technical file throughout the assessment examination and studying it	0
Dossier costs	265
Development of the European Technical Assessment text, incl. proof reading	525
Issuing of the duplicate European Technical Assessment	265
European Co-ordination	420
EOTA fee per issued European Technical Assessment, incl. duplicates	315
Total	2105

Table 4: Converting European Technical Approvals into European Technical Assessments (Article 107 (3))

Activity	Cost (€)				
	Without any modification of the content	In case of technical modification of the content		opean Assessm ds to be develo	nent Document oped*
Administration			315		
Verifying the completeness of and maintaining the manufacturer's technical file throughout the assessment examination and studying it			0		
Dossier costs			265		
Study of the Application	0		525		525**
Development of the Initial and Final Work Programme	0	0	1050	2105	3155**
Development of the European Technical Assessment text, incl. proof reading		525			525**
Issuing of the European Technical Assessment			265		
European Co-ordination			420		
EOTA fee per issued European Technical Assessment, incl. duplicates			315		
Total	2105	2630	3680	4735	5785
* Depending on complexity of the file (see Article 9	7)				

<sup>\*\*</sup> Applicants may be informed if Operator efforts exceed 4 working days, leading to additional costs

Table 5: Development and issuing European Technical Assessments for products for which an existing ETA-Guideline may be used as EAD or for which an adopted EAD is available, incl. modified and extended European Technical Assessments

Activity			Cost* (€)		
Administration			630		
Verifying the completeness of and maintaining the manufacturer's technical file throughout the assessment examination and studying it		525			525**
Dossier costs			840		
Study of the Application		525			525**
Assessment examination, comprising the elements as listed in Article 26 (6)	1050	2105	3135	4205	5255**
Development of the Evaluation report		525			525**
Development of the European Technical Assessment text		525			525**
Issuing of the new, modified or extended European Technical Assessment			265		
European Co-ordination			1575		
EOTA fee per issued European Technical Assessment			315		
Total	6775	7830	8860	9930	10980

Table 6: Development and issuing European Technical Assessments for products for which an adopted EAD is not available or may not be used for the application concerned

Activity	Cost* (€)				
Administration			630		
Verifying the completeness of and maintaining the manufacturer's technical file throughout the assessment examination and studying it		525			525**
Dossier costs			840		
Study of the Application		525			525**
Development of the Initial and Final Work Programme*	1051	1575	2105	2630	3135**
Assessment examination, comprising the elements as listed in Article 26 (6)	4205	5255	6305	7350	8410**
Development of the Evaluation report		525			
Development of the European Technical Assessment text, incl. proof reading		525			525**
Issuing of the new, modified or extended European Technical Assessment			265		
European Co-ordination			1575		
EOTA fee per issued European Technical Assessment			315		
Total	10980	12555	14135	15705	17270

<sup>\*\*</sup> Applicants may be informed if Operator efforts exceed 13 working days, leading to additional costs