

European Organisation for Technical Approvals Europäische Organisation für Technische Zulassungen Organisation Européenne pour l'Agrément Technique

Established pursuant to Annex II of the Council Directive 89/106 of 21 December 1988 on the approximation of laws, regulations and administrative provisions of Member States relating to construction products (Construction Products Directive)

## **ETAG 026**

## GUIDELINE FOR EUROPEAN TECHNICAL APPROVALS

for

## Fire Stopping and Fire Sealing Products

## Part 1 General

Edition September 2012

This Guideline for European Technical Approval is established and published in accordance with Article 11 of the Construction Products Directive as a basis for the preparation and issue of European technical approvals in accordance with Article 9.1 of the Construction Products Directive.

European Technical Approvals are issued by approval bodies authorised and notified in accordance with Article 10 of the Construction Products Directive. These bodies are organized in EOTA.

The European Technical Approval, according to the Construction Products Directive, is a favourable technical assessment of the fitness for use of a construction product and the technical specification of the assessed product, serving as basis for the CE marking of this product when and where a harmonised standard according to the Directive is not or not yet available.

Due to technical innovation and the progress of the state of the art, guidelines for technical approval might not reflect the latest developments and experiences gained in approval procedures. The reader of this Guideline is therefore advised to check with an EOTA member whether there are further provisions which have to be taken into account in the use of the Guideline.

Note: The copy right refers to the English reference version established by EOTA. For publications in accordance with Article 11.3 of the Construction Products Directive the national laws, regulations and administrative provisions of the Member State concerned are applicable.

This edition replaces edition January 2008 of ETAG 026-1

**EOTA** Kunstlaan 40 Avenue des Arts

B - 1040 BRUSSELS

Table o	of conte	nts F	age
1	Scope	of the ETAG	3
	1.1	Definition of the construction product	3
	1.2	Intended use of the construction product	
	1.3	Assumed working life of the construction product	
	1.4	Terminology	5
		1.4.2 Specific terms used in this ETAG	
	1.5	Procedure in the case of a significant deviation from the ETAG	
•		•	
2	<b>Assess</b> 2.1	sment of fitness for use	6
	2.1	Elements of the assessment of fitness for use	
	2.3	Relationship of requirements to the product characteristics and methods of verification and	0
	2.0	assessment	7
	2.4	Product characteristics which are relevant for the fitness for use	
		2.4.1 Reaction to fire	
		2.4.2 Resistance to fire 2.4.3 Air permeability	
		2.4.3 Air permeability	
		2.4.5 Release of dangerous substances.	
		2.4.6 Mechanical resistance and stability	
		2.4.7 Resistance to impact / movement	
		2.4.8 Adhesion	
		2.4.9 Airborne sound insulation	
		2.4.10 Impact sound insulation     2.4.11 Thermal insulation	
		2.4.11 Therma insulation  2.4.12 Water vapour permeability	
		2.4.13 Durability and Serviceability	
•	Fuelue		
3	Evalua 3.1	tion and attestation of conformity and CE marking	
	3.1	Tasks and responsibilities for the manufacturer and Notified Bodies.	I∠ 13
	0.2	3.2.1 Tasks for the manufacturer	13
		3.2.2 Tasks for Notified Bodies	
		3.2.3 Special methods of control and testing used for the evaluation	
	3.3	CE marking and accompanying information	15
4	Assum	ptions under which the fitness for the intended use is assessed	.16
	4.1	Manufacture of the product	
	4.2	Packaging, transport, storage of the product	16
	4.3	Installation of the product in the works	
	4.4	Use, maintenance, repair	
	4.5 4.6	Components in kits	
	4.0	Biological attack	
_			
5		cation of the construction product	. 17
	5.1	Means of identification	
		5.1.2 Components in kits	
	5.2	Product characteristics which are relevant for identification checking	
6	Format	of Etas issued on the basis of the ETAG	
7		nce documents	
	7.1 7.2	General EC Documents	-
	7.2 7.3	Test methods and classification standards	-
	7.3 7.4	Others	
A			
ANNEX		nmended Checklist For Initial Inspection of Factory, Factory Production Control and the uing Surveillance of Factory Production Control	20

#### **Foreword**

## Background of the ETAG

This Guideline has been prepared by the EOTA Working Group 11.01/04 "Fire Stopping, Fire Sealing and Fire Protective Products".

This Guideline specifies the performance requirements, the verification methods used to examine the various aspects of performance, the assessment criteria used to judge the performance for the intended use and the presumed conditions for the design and execution of the fire stopping or fire sealing products in the works. Since fire stopping and fire sealing products are based on different materials, which necessitate additional specific verification and/or assessment, these products are divided into 4 families of products and kits, dealt with in specific parts of this ETAG 026.

This ETAG 026, Part 1 – "General" shall be used in conjunction with one of the specific parts for a family of products.

The general assessment approach of the Guideline is based on relevant existing knowledge and testing experience.

#### **Updating conditions**

**EOTA Comprehension Documents** permanently take on board all useful information on the general understanding of this ETAG as developed when delivering ETAs by consensus among the EOTA members. Readers and users of this ETAG are advised to check the current status of these documents with an EOTA member.

EOTA may need to make alterations/corrections to the ETAG during its life. These changes will be incorporated into the official version on the EOTA web-site <a href="www.eota.eu">www.eota.eu</a> and the actions will be listed and dated in the associated <a href="Progress Files">Progress Files</a>.

Readers and users of this ETAG are asked to check the current status and content of this document with that on the EOTA web-site. The front cover will indicate if and when an amendment took place.

## 1 SCOPE OF THE ETAG

#### 1.1 Definition of the construction product

This ETAG shall be used to deliver European Technical Approvals for fire stopping and fire sealing products<sup>1</sup>. These products are intended to prevent or restrict the passage of fire and/or smoke between elements or components, or to maintain the integrity and insulation performance of a penetrated or discontinuous fire separating element for a specified duration.

This ETAG "Fire Stopping and Fire Sealing Products" is divided into the following specific parts:

- Part 1: General
- Part 2: Penetration Seals
- Part 3: Linear Joint and Gap Seals
- Part 4: Air Transfer Grilles
- Part 5: Cavity Barriers

The ETAG does not cover ducts, casings and mechanical dampers<sup>2</sup> or the use of fire stopping and fire sealing products in construction works where special extreme fire scenarios apply (e.g. traffic tunnels, nuclear plants).

<sup>&</sup>lt;sup>1</sup> In all parts of ETAG 026, the term "product" means "product or kit"

If the English term "damper" is used in the sense of air transfer grilles, based on intumescent materials, and used in openings in walls, partitions or in ducts then these forms of "damper" are included in the Guideline

## 1.2 Intended use of the construction product

The wide variation in European climatic conditions and in the user stresses imposed on structures depending on the type of structure and use intensity will make it necessary for fire stopping and fire sealing products to be restricted in their usage to defined situations allowing them to achieve the predicted working life.

In general fire stopping and fire sealing products will be influenced with regard to their working lives and durability by different degradation factors which shall be taken into account in the scope for the fire stopping and fire sealing products, if relevant (see the relevant specific parts of this ETAG). These could be:

- temperature
- freeze/thaw
- humidity (water vapour)
- rain/liquid water
- UV exposure
- pollution (e.g. for industrial regions: high SO<sub>2</sub>, H<sub>2</sub>S, NO<sub>x</sub>; for coastal regions: high chloride levels)
- biological attack.

These possible degradation factors that affect the true working life and/or the durability of "Fire Stopping and Fire Sealing Products" shall be defined by "use categories" in accordance with the EOTA GUIDANCE DOCUMENT 003 "Assessment of working life of products". If further degradation factors of importance exist, they are considered in the specific parts of this ETAG.

The following use categories are defined for the fire stopping and fire sealing products – and shall be used as a basis for assessment.

#### **OUTDOOR USE**

- EXPOSED TO RAIN AND UV
- NOT EXPOSED TO RAIN AND UV

#### INDOOR USE

It depends on the different products (described in the specific parts of this Guideline) whether further subdivisions - as referred to in the EOTA GUIDANCE DOCUMENT 003 - of the internal and external use categories are necessary or not. The specific parts deal with detailed methods of durability assessment.

Whether the fire stopping and fire sealing product is assessed for indoor and/or outdoor use or for more than one of the use categories depends on the applicant's demand.

## 1.3 Assumed working life of the construction product

The provisions and the verification and assessment methods included or referred to in this ETAG have been written based upon the assumed working life of the fire stopping or fire sealing products for the intended use of 10 years or 25 years<sup>3</sup> when installed in the works, provided that the single fire stopping or fire sealing product is subject to appropriate use and maintenance (see clause 4.4). These provisions are based upon the current state of the art and the available knowledge and experience.

"Assumed working life" means that, if an assessment following the ETAG provisions is made, and if this working life has elapsed, the true working life may be - in normal use conditions - considerably longer without major degradation affecting the Essential Requirements.<sup>4</sup>

The declaration of the working life of the construction product cannot be interpreted as a guarantee given by the product manufacturer or the Approval Body issuing the ETA, but could be regarded as a tool for choosing the appropriate product in relation to the expected economically reasonable working life of the works (see clause 5.2.2 of the Interpretative Documents).

<sup>&</sup>lt;sup>3</sup> For details see the part of this ETAG which is relevant for a specific product (family).

<sup>&</sup>lt;sup>4</sup> The real working life of a product incorporated in a specific works depends on the environmental conditions to which that works is subject and the particular conditions of the design, execution, use and maintenance. This ETAG assumes certain conditions but, if the conditions in use are different, it cannot be excluded that in these cases the real working life of the product may also be shorter than the assumed working life.

## 1.4 Terminology

#### 1.4.1 Common terms

For the meaning of these terms see the EOTA website.

## 1.4.2 Specific terms used in this ETAG

### 1.4.2.1 Ablative materials:

Materials designed not to expand significantly when heated but which may consume energy through chemical or physical processes.

#### 1.4.2.2 Air transfer grille:

A product that allows air movement through elements of construction

#### 1.4.2.3 Boards/Panels:

Rigid product of rectangular shape and cross section, in which the thickness is uniform and substantially smaller than the other dimensions

### 1.4.2.4 Cavity Barrier:

A barrier, used to close or separate a concealed space, the purpose of which is to restrict the spread of smoke and/or fire and to keep the fire resistance of the construction element. Cavity barriers can vary in size and type from 'small' which, for example, would be used within a cavity brick wall, to 'large' which can be over 2 m by 2 m used to divide large enclosed spaces, for example within ceiling voids.

#### 1.4.2.5 Intumescent materials:

Materials which expand, creating a foam or char, when exposed to heat in the conditions of fire

#### 1.4.2.6 Linear Joint/Gap:

A gap with a width not exceeding 150 mm and with a length at least 10 times its width

#### 1.4.2.7 Linear Joint/Gap Seal:

Seals designed to maintain the fire resistance at structural discontinuities which may occur between and within fire separating elements. There are several types of Linear Gap Seals, which may be classified by their construction: with/without backing material, with/without cover material, with/without support material.

## 1.4.2.8 Penetration seal:

The system used to maintain the fire resistance of a separating element at the position where there is provision for services to pass through the separating element.

#### 1.4.2.9 Reactive material:

The generic term for materials which react chemically or physically if exposed to heat generated by a fire. The term includes both intumescent and ablative materials.

#### 1.4.2.10 Slab:

Semi-rigid product of rectangular shape and cross section in which the thickness is uniform and substantially smaller than the other dimensions

## 1.5 Procedure in the case of a significant deviation from the ETAG

The provisions of this ETAG apply to the preparation and issue of European technical approvals in accordance with the CPD, Art. 9.1 and with section 3.1 of the Common Procedural Rules.

In cases in which a certain provision of this ETAG is not or not fully applicable or a particular aspect of a product and/or intended use to be assessed is not or not sufficiently covered by the methods and criteria of the ETAG, the procedure of the CPD, Art. 9.2 and of section 3.2 of the Common Procedural Rules applies with regard to the deviation or aspect concerned.

## 2 ASSESSMENT OF FITNESS FOR USE

## 2.1 Meaning of "fitness for use"

"Fitness for (the intended) use" of a construction product means that the product has such characteristics that the **works** in which it will be incorporated **can**, if properly designed and built,

- satisfy the Essential Requirements when and where such works are subject to regulations containing such requirements (CPD Art. 2.1) and
- 2. **be fit** for their intended use, account being taken of economy, **and** in this connection **satisfy** the Essential Requirements for an economically reasonable working life, if normally maintained (see CPD Annex I, sentence 1 and 2).

## 2.2 Elements of the assessment of fitness for use

The assessment of the fitness of a construction product for its intended use includes:

- the identification of the characteristics of the product which are relevant to its fitness for use (in the following referred to as "regulatory" characteristics);
- the establishment of methods for the verification and assessment of the regulatory product characteristics and the expression of the respective product performances;
- the identification of regulatory characteristics to which the option "No Performance Determined" applies for the reason that in one or more Member States they are not relevant for the fulfilment of the requirements applicable to the works;
- the identification of regulatory characteristics for which limit values (threshold values) have to be respected for technical reasons.

# 2.3 Relationship of requirements to the product characteristics and methods of verification and assessment

The product characteristics, methods of verification and assessment criteria which are relevant for the fitness of fire stopping and fire sealing products for the intended use referred to in 1.2 are given in Table 1. For the different fire stopping and fire sealing products see the relevant other parts of this ETAG.

Table 1 - Product characteristics and methods of verification and assessment

No	Product characteristic	Option "No Performance Determined"	Method of verification and assessment	Expression of product performance	
Essen	tial Requirement 1: Mechanica	al resistance and stability	J.		
	None				
Essen	tial Requirement 2: Safety in c	ase of fire		,	
1	Reaction to fire	Permitted: Class F according to EN 13501-1	2.4.1	Classes A1-F according to EN 13501-1	
2	Resistance to fire 4.2.3 Limitation of generation and spread of fire and smoke within construction works	Not permitted	2.4.2	Classification according to EN 13501; Part 2, 3, 4 or 5, as applicable	
Essen	Essential Requirement 3: Hygiene, health and environment				
3	Air permeability	Permitted	2.4.3	assessment or declared value	
4	Water permeability	Permitted	2.4.4	assessment or declared value	
5	Release of dangerous substances	Permitted	2.4.5	Indication of dangerous substances or "No dangerous substances" *1)	

Esse	ntial Requirement 4: Safety in use	9			
6	Mechanical resistance and stability	Permitted	2.4.6	Declared values, levels etc., as appropriate	
7	Resistance to impact/movement	Permitted	2.4.7	Declared values, levels etc., as appropriate	
8	Adhesion *2)	Permitted	2.4.8	Declared values, levels etc., as appropriate	
Esse	ntial Requirement 5: Protection a	gainst noise			
9	Airborne sound insulation	Permitted	2.4.9	Single number rating	
10	Impact sound insulation	Permitted	2.4.10	Single number rating	
Esse	Essential Requirement 6: Energy economy and heat retention				
11	Thermal properties	Permitted	2.4.11	Declared values, levels etc., as appropriate	
12	Water vapour permeability *3)	Permitted	2.4.12	Declared values, levels etc., as appropriate	
Gene	eral aspects relating to fitness for u	ıse * <sup>4)</sup>	,		
13	Durability and serviceability	Not permitted	2.4.13	Specific requirements and assessments are described in the other parts of this ETA Guideline	
*1)		For the meaning of the option "No performance determined" regarding ER 3, see EOTA TR 034			
*2)		This characteristic is placed under ER 4 for convenience, but also relates to other Essential Requirements, particularly ER 2. For specific products also the bond strength on a substrate could be meant.			
*3)	This characteristic also relates to ER 3				
*4)	Aspects of durability and economy of the works which are not considered under the Essential Requirements 1 to 6. Such aspects are also referred to as "serviceability".				

## 2.4 Product characteristics which are relevant for the fitness for use

## 2.4.1 Reaction to fire

#### 2.4.1.1 Method of verification

## Case 1: Normal case

The fire stopping and/or fire sealing product shall be tested, using the test method(s) relevant for the corresponding reaction to fire class, in order to be classified according to EN 13501-1.

Mountings and fixing provisions that are considered to be appropriate for the testing of the fire stopping and fire sealing product and that are representative for the fire stopping or fire sealing' intended use application are specified in the specific parts of this ETA Guideline, where relevant.

## Case 2: Products satisfying the requirements for the reaction to fire class A1, without the need for testing

The fire stopping and/or fire sealing product is considered to satisfy the requirements for performance class A1 of the characteristic reaction to fire, in accordance with the provisions of EC decision 96/603/EC (as amended) without the need for testing on the basis of its listing in that decision.

## Case 3: Products classified without the need for further testing (CWFT)

The fire stopping and/or fire sealing product is considered to satisfy the requirements for the required performance class of the characteristic reaction to fire in accordance to the appropriate EC CWFT decision without the need for further testing on the basis of its conformity with the specification of the product detailed in that decision and its intended end use application being covered by that decision.

Detailed information is given in the relevant specific part of this ETA Guideline.

## 2.4.1.2 Method of assessing and judging

The product shall be classified according to EN 13501-1.

#### 2.4.2 Resistance to fire

#### 2.4.2.1 Method of verification

The part of the works or assembled system in which the fire stopping and/or fire sealing product is intended to be incorporated, installed or applied shall be tested, using the test method relevant for the corresponding fire resistance class, in order to be classified according to the appropriate part of EN 13501.

Detailed information is given in the relevant specific part of this ETAG.

#### 2.4.2.2 Method of assessing and judging

The part of the works or assembled system in which the fire stopping and/or fire sealing product is intended to be incorporated, installed or applied shall be classified according to the appropriate part of EN 13501, Part 2, 3, 4 or 5, as applicable.

## 2.4.3 Air permeability

#### 2.4.3.1 Method of verification

Air permeability of the Fire Sealing and Fire Stopping Product shall be assessed by comparing the ETA-applicant's design solutions with standard construction details and good engineering practice.

If the air permeability cannot be assessed by the use of existing knowledge, e.g. because of unfamiliar or innovative solutions for the relevant construction details, tests shall be carried out under the responsibility of the Approval Body.

Detailed test methods, if appropriate, are given in the relevant specific part of this ETAG.

## 2.4.3.2 Method of assessing

The air permeability of the product shall be given in qualitative or quantitative terms depending on the type of assessment.

For some products, the value will be valid for the assembled system, as subjected to testing, and this information will be provided in the ETA.

## 2.4.4 Water permeability

## 2.4.4.1 Method of verification

Water permeability (liquid water penetration) of the Fire Sealing and Fire Stopping Product intended to be used externally or internally shall be assessed by comparing the ETA-applicant's design solutions with standard construction details and good engineering practice.

If the water permeability cannot be assessed by the use of existing knowledge, e.g. because of unfamiliar or innovative solutions for the relevant construction details, tests shall be carried out under the responsibility of the Approval Body.

Because there is no general test available, detailed test methods, if necessary, are given in the relevant specific part of this ETAG.

#### 2.4.4.2 Method of assessing

The water permeability of the product shall be given in qualitative or quantitative terms depending on the type of assessment.

For some products, the value will be valid for the assembled system, as subjected to testing, and this information will be provided in the ETA.

## 2.4.5 Content and/or Release of dangerous substances

## 2.4.5.1 **General**

The applicant shall

- submit the chemical constitution and composition of the product and/or constituents of the product to the Approval Body which will observe strict rules of confidentiality; or
- submit a written declaration to the Approval Body stating whether or not and in which concentration the product and/or constituents of the product contains substances which have to be classified as dangerous according to Directive 67/548/EEC and Regulation (EC) No 1272/2008 and listed in the "Indicative list on dangerous substances" of the EGDS taking into account the installation conditions of the construction product and the release scenarios resulting from there.

The use of recycled materials shall always be indicated, because this could lead to the implementation of further assessment and verification methods.

The information concerning the presence of dangerous substances listed in Council Directive 67/548/EEC and Regulation (EC) No 1272/2008 regulated at European level and listed in the "Indicative list on dangerous substances" of the EGDS and/or of other dangerous substances, shall be circulated as part of the evaluation report by the issuing Approval Body to the other Approval Bodies, under strict conditions of confidentiality.

#### 2.4.5.2 Method of verification

The product and/or constituents of the product listed in the EOTA TR 034: "General Checklist for ETAGs/CUAPs/ETAs -Content and/or release of dangerous substances in products/kits", which have to be considered will be verified by the given methods taking into account the installation conditions of the construction product and the release scenarios resulting from there. Regulations related to placing the product on the market may also need to be taken into account.

Regarding the release scenarios referred to in the EOTA TR 034, the following use categories have to be considered:

Category IA1: Product with direct contact to indoor air

Category IA2: Product with no direct contact to (e.g. covered products) but possible impact on indoor air

Category IA3: Product with no contact to and no impact on indoor air

Category S/W1: Product with direct contact to soil-, ground- and surface water

Category S/W2: Product with no direct contact to but possible impact on soil-, ground- and surface water

Category S/W3: Product with no contact to and no impact on soil-, ground- and surface water

Categories IA1 and S/W1 are applicable for products which are in contact with indoor air, soil or water in a way that dangerous substances could be released directly out of the product.

Category IA2 is applicable for products which are covered with other products but nevertheless could release dangerous substances to indoor air (e.g. products covered with porous/unsealed coverings incapable of avoiding migration).

Category S/W2 is applicable for products which can be leached by rain and could release dangerous substances which can have impact on soil and water.

Categories IA3 and S/W3 are applicable for products which are completely covered with tight products capable of avoiding any kind of migration of dangerous substances to indoor air, soil or water.

Note that all restrictions in content have to be considered in all cases.

#### 2.4.5.3 Method of assessing and judging

The product and/or constituents of the product listed in the EOTA TR 034 and the related dangerous substances which have to be considered, will be assessed by the given methods taking into account the installation conditions of the construction product and the release scenarios resulting from there.

NOTE (to be implemented in the ETA): For dangerous substances there might be the necessity for an additional assessment, if

- no assessment and verification methods are given (or cannot be found in TR 034) or
- "no performance determined" is declared or
- the chosen verification and assessment method does not comply with the regulatory requirements of a particular Member State.

## 2.4.6 Mechanical resistance and stability

## 2.4.6.1 Method of verification

For specific fire stopping and/or fire sealing products mechanical resistance and stability shall be verified in accordance with the test methods as specified in the relevant part of this ETAG.

#### 2.4.6.2 Method of assessing and judging

The criteria and the way of expressing the results of the verification methods are specified in the relevant part of this ETAG.

## 2.4.7 Resistance to impact/movement

## 2.4.7.1 Method of verification

For specific fire stopping or fire sealing products, impact resistance shall be verified in accordance with the test methods as specified in the relevant part of this ETAG.

Existing EOTA technical reports could be applied, as well as appropriate European test standards. Specific test methods and deviations from existing standard test methods shall be described.

## 2.4.7.2 Method of assessing and judging

The criteria and the way of expressing the results of the verification methods are specified in the relevant part of this ETAG.

#### 2.4.8 Adhesion

#### 2.4.8.1 Method of verification

For specific fire stopping and fire sealing products adhesion shall be verified in accordance with the test methods as specified in the relevant part of this ETAG.

#### 2.4.8.2 Method of assessing and judging

The criteria and the way of expressing the results of the verification methods are specified in the relevant part of this ETAG.

#### 2.4.9 Airborne sound insulation

#### 2.4.9.1 Method of verification

Airborne sound insulation shall be verified in accordance with EN 10140-2, if no specific test method is given in the specific part.

## 2.4.9.2 Method of assessing and judging

The measured airborne sound insulation is expressed as a single number rating,  $R_w$ , or  $D_{n,w}$ , in accordance with EN ISO 717-1.

#### 2.4.10 Impact sound insulation

#### 2.4.10.1 Method of verification

Impact sound insulation shall be verified in accordance with EN 10140-3, if no specific test method is given in the specific part.

## 2.4.10.2 Method of assessing and judging

The measured impact sound insulation is expressed as a single number rating, in accordance with EN ISO 717-2.

#### 2.4.11 Thermal insulation

## 2.4.11.1 Method of verification

The thermal conductivity shall be determined based on declared values as quoted in European harmonised product standards or European technical approvals.

Where the applicant declares specific thermal conductivity values, these shall be tested in accordance with EN 12664, EN 12667 or EN 12939.

Alternatively, the thermal resistance and thermal transmittance (U-value) may be verified by testing according to EN ISO 8990.

If necessary, the thermal resistance shall be calculated on the basis of EN ISO 6946.

In principle, thermal bridges shall be prevented. However, if such bridges do occur, their effect on the overall thermal performance shall be incorporated in the above mentioned thermal resistance calculations, taking into account results of thermal bridges calculation methods as described in EN ISO 14683 or EN ISO 10211.

NOTE: EN ISO 10456 can be used, as far as applicable for the product concerned.

#### 2.4.11.2 Method of assessing and judging

On the basis of the verification method used, the corresponding tabulated or measured  $\lambda$ -value (in W/mK), the thermal resistance value R (in m² K/W), or the thermal transmittance coefficient, U (in W/m²K), calculated, where relevant, in accordance with EN ISO 6946, shall be declared. The source of the declared values or the standard used to determine the values shall be quoted.

#### 2.4.12 Water vapour permeability

## 2.4.12.1 Method of verification

Where relevant, the water vapour transmission coefficient shall be determined on the basis of tabulated values as declared in – European harmonised product standards or European technical approvals; or

declared values following EN ISO 10456.

Where the applicant declares specific water vapour transmission coefficient values, these shall be tested in accordance with EN ISO 12572 or EN 12086 or similar European standards.

NOTE: EN ISO 10456 can be used, as far as applicable for the product concerned.

#### 2.4.12.2 Method of assessing and judging

The tabulated or measured value of the water vapour transmission coefficient ( $\mu$ -value) shall be declared. The source of the values or the standard used to determine the values shall be quoted.

#### 2.4.13 Durability and Serviceability

#### 2.4.13.1 Method of verification

#### 2.4.13.1.1 General

Fire stopping and fire sealing products shall be assessed, taking into account the following agents:

- physical agents
- chemical agents

The test methods – if relevant with respect to the use categories, described in chapter 2.2 - are described in the relevant specific part of this ETA Guideline.

## 2.4.13.1.2 Biological attack

Fire stopping and fire sealing products may be influenced by biological effects, i.e. mould growth and/or subject to deterioration due to attack by insects or mammals, e.g. rodents. This ETAG foresees no assessment to cover this eventuality. In general, it is an assumption that design provisions will prevent deterioration from occurring (see clause 4.7). Where the Approval Body expects biological attack to be of particular importance for specific products, additional, case-by-case assessment shall take place, taking into account the nature of the biological agent (the type of mould or mammal).

## 2.4.13.2 Method of assessing and judging

The Approval Body shall assess the possible effects on the performance of the assembled system due to the declared limits, which could be e.g.

- declared physical
- declared chemical
- declared biological

The ETA shall contain the results, expressed in quantitative or qualitative terms, of the verification methods used to verify the durability and serviceability aspects of the product, related to one or more essential requirements.

## 3 EVALUATION AND ATTESTATION OF CONFORMITY AND CE MARKING

## 3.1 System of attestation of conformity

According to the decision 1999/454/EC of the European Commission<sup>5</sup> as amended, the system of attestation of conformity given in Table 2a applies.

Table 2a - System of attestation of conformity applicable to fire stopping or fire sealing products

Product(s)	Intended use(s)	Level(s) or class(es) (Resistance to fire)	Attestation of conformity system
Fire Stopping and Fire Sealing Products	for fire compartmentation and/or fire protection or fire performance	any	1

In addition, according to the decision 1999/454/EC of the European Commission<sup>5</sup>, as amended, the systems of attestation of conformity given in Table 2b apply to fire stopping and fire sealing products with regard to reaction to fire.

Table 2b Choice of the system of attestation of conformity applicable fire stopping and fire sealing products with respect to reaction to fire

Product(s)	Intended use(s)	Level(s) or class(es) (reaction to fire)	Attestation of conformity system(s)
Fire Stopping and Fire	for uses subject to	A1*, A2*, B*, C*	1
Sealing Products	regulations on reaction to fire	A1**, A2**, B**, C**, D,	3
		E, (A1 to E) *** , F	4

System 1: See Directive 89/106/EEC Annex III.2.(i), without audit-testing of samples

System 3: See Directive 89/106/EEC Annex III.2.(ii), Second possibility

System 4: See Directive 89/106/EEC Annex III.2.(ii), third possibility

- \* Products/materials for which a clearly identifiable stage in the production process results in an improvement of the reaction to fire classification (e.g. an addition of fire retardants or a limiting of organic material)
- \*\* Products/materials not covered by footnote (\*)
- Products/materials that do not require to be tested for reaction to fire (e.g. products/materials of class A1 according to Commission Decision 96/603/EC, as amended)

Because all products according to this ETAG have to be assessed for resistance to fire, all products fall under AoC System 1. The systems shown in table 2b only indicate who is responsible for testing reaction to fire.

The systems of attestation of conformity referred to above are defined as follows:

System 1: Certification of the conformity of the product by a Notified Product Certification Body on the basis of:

- (a) Tasks for the manufacturer:
  - (1) factory production control;
  - (2) further testing of samples taken at the factory by the manufacturer in accordance with a prescribed test plan;
- (b) Tasks for the Notified Product Certification Body:
  - (3) initial type-testing of the product;
  - (4) initial inspection of factory and of factory production control;
  - (5) continue surveillance, assessment and approval of factory production control.

System 3: Declaration of conformity of the product by the manufacturer on the basis of:

- (a) Tasks for the manufacturer:
  - (1) factory production control;
- (b) Tasks for the notified testing laboratory:
  - (2) Initial type-testing of the product.

<sup>&</sup>lt;sup>5</sup> Official Journal of the European Communities L178/52 of 14/7/1999

System 4: Declaration of conformity of the product by the manufacturer: Tasks for the manufacturer:

- (1) Initial type-testing of the product;
- (2) Factory production control.

For all products, the manufacturer has to make a declaration of conformity.

## 3.2 Tasks and responsibilities for the manufacturer and Notified Bodies

#### 3.2.1 Tasks for the manufacturer

The "corner stones" of the actions to be undertaken by the manufacturer of the Fire Stopping and/or Fire Sealing Product in the procedure of attestation of conformity are laid down in Table 3 and 3.2.1.1 to 3.2.1.6.

Table 3 - Control plan for the manufacturer;

Nr	Subject/type of control	Test or control method	Criteria, if any	Minimum number of specimens <sup>6</sup>	Minimum frequency of control <sup>6</sup>
Facto	ory production control (FPC)				
1	Quality management (system)	clauses 3.2.1.1 to 3.2.1.6			
2	Characteristics of the product	see the relevant other parts of this ETAG			

#### 3.2.1.1 General

The manufacturer shall exercise permanent internal control of production. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic manner in the form of written policies and procedures, including records of results performed in accordance with the test plan. This production control system shall ensure that the product is in conformity with the European Technical Approval (ETA).

Manufacturers having a quality management system which complies with EN ISO 9001 <u>and</u> which includes all relevant requirements of the ETA are recognised to satisfy the FPC requirements of the Directive.

## 3.2.1.2 Personnel and equipment

The personnel involved in the production process shall be identified, sufficiently qualified and trained to operate and maintain the production equipment. Machinery and equipment shall be regularly maintained and this shall be documented. All processes and procedures of production shall be recorded at regular intervals.

## 3.2.1.3 Traceability of processes

The manufacturer shall maintain a traceable documentation of the production process from purchasing or delivery of raw or basic raw materials up to the storage and delivery of finished products.

## 3.2.1.4 Non-conforming products

Products that do not comply with requirements as specified in the ETA shall be separated from the conforming products and marked as such. The manufacturer shall register non-compliant production and action(s) taken to prevent further non-conformities. External complaints shall also be documented, as well as actions taken.

## 3.2.1.5 Materials/components in products/kits

Where the manufacturer buys in products as a component of a product or kit he shall ensure that the characteristics of materials/components comply with the specification.

#### 3.2.1.6 Control of monitoring and measuring devices

Where necessary, measuring equipment shall be:

- calibrated or verified at specific intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no standards exists, the basis used for calibration shall be recorded;
- be adjusted or re-adjusted as necessary;
- be identified to enable the calibration standard to be determined;

<sup>&</sup>lt;sup>6</sup> For details see the relevant specific part of this ETAG

When the equipment is found not to conform to requirements, the validity of previous measuring results shall be assessed and recorded. Appropriate action shall be taken on the equipment and any product affected.

#### 3.2.2 Tasks for Notified Body

The corner stones of the actions to be undertaken by the Notified Product Certification Body in the procedure of attestation of conformity for fire stopping and fire sealing products are laid down in table 4.

Table 4 - Control plan for the Notified Product Certification Body

Nr	Subject/type control	of Test or control method	Criteria, if any	Minimum number of specimens	Minimum frequency of control
	Initial type-testing of the product (ITT)				
	See 3.2.2.1, 3.2.2.2 and the relevant other parts of this ETAG				
	Initial inspection of factory and factory production control (FPC)				C)
	See 3.2.2.1, 3.2.2.2, Table 3 and Annex A				
	Continuing surveillance, judgment and assessment of factory production control (FPC)				
	See 3.2.2.1, 3.2.2.2, Table 3 and Annex A				

#### 3.2.2.1 Tasks concerning initial type testing for all products

For the initial type testing of the product the tasks for the Notified Product Certification Body will be limited to the following characteristics, where relevant:

- Resistance to fire
- Mechanical resistance and stability
- Adhesion
- Resistance to impact/movement
- Release of dangerous substances

Approval tests will have been conducted by the Approval Body or under its responsibility (which may include a proportion conducted by an indicated laboratory or by the manufacturer, witnessed by the Approval Body) in accordance with section 2.4 of this ETAG, unless the ETA-holder has opted to make use of the possibility not to declare the product's performance (NPD)<sup>7</sup>. The Approval Body will have assessed the results of these tests in accordance with section 2.4 of this ETAG, as part of the ETA issuing procedure.

These tests should be used for the purposes of Initial Type Testing.

#### System 1:

This work shall be validated by the Notified Product Certification Body for certificate of conformity purposes.

For the initial inspection of the factory and of the factory production control, and for the continuing surveillance, judgement and assessment of the factory production control, parameters related to the following characteristics shall be of interest to the Notified Product Certification Body, where relevant:

- Resistance to fire
- Mechanical resistance and stability
- Adhesion
- Resistance to impact/movement

It is recommended to conduct surveillance inspections at least twice per year.

## 3.2.2.2 Tasks concerning uses subject to reaction to fire regulations

For fire stopping and fire sealing products under systems 1 and 3, regarding the initial type testing of the product, the task for the Notified Body will be limited to the assessment of the reaction to fire class, as indicated in the Commission Decision 2000/147/EC.

For fire stopping and fire sealing products under system 1, for the initial inspection of the factory and of the factory production control, and for the continuing surveillance, assessment and approval of the factory production control, parameters related to the reaction to fire class, as indicated in the Commission Decision 2000/147/EC shall be of the interest of the Notified Product Certification Body.

It is recommended to conduct surveillance inspections at least twice per year.

ETAG 026-1

<sup>&</sup>lt;sup>7</sup> NPD is not permitted for the performance of resistance to fire

## 3.2.3 Special methods of control and testing used for the evaluation

See the relevant other parts of this ETAG.

## 3.3 CE marking and accompanying information

According to Council Directive 93/68/EEC<sup>8</sup> the CE marking consists of the letters "CE" in the form laid down in the Directive, followed by the identification number of the Notified Product Certification Body.

The CE marking of fire stopping and fire sealing products shall be accompanied by the following information:

- the name and address of the producer or the authorised representative established in the EEA,
- the last two digits of the year in which the CE marking was affixed,
- the number of the EC certificate of conformity for the product,
- the number of the European technical approval (see NOTES 1 and 2 below),
- number and part of the ETAG used
- Intended use, use category as relevant

NOTE 1: Since the ETA provides all the information regarding the performance characteristics, then reference to the ETA is sufficient.

NOTE 2: If the ETA covers more than one type of a Fire Stopping and Fire Sealing Product, and the type designation provides all the information regarding the performance characteristics, then reference to the ETA and the relevant type is sufficient.

#### Example of CE marking and accompanying information:

((

1234

Any Company Street 1, City, Country

04

1234-CPD-0321

ETA-12/1234

ETAG 026, Part 1 and ...

YYY see ETA-12/1234 for relevant characteristics "CE" marking

Identification number of Notified Product Certification Body

Name and address of the producer or its authorised representative established in the EEA

Two last digits of year of affixing CE marking

Number of EC certificate of conformity

ETA number

ETAG number (ETAG 026 - 1) and specific part number

Product name,

Reference to the specific ETA for relevant characteristics

<sup>&</sup>lt;sup>8</sup> Official Journal of the European Communities L 220 of 30.8.1993

# 4 ASSUMPTIONS UNDER WHICH THE FITNESS FOR THE INTENDED USE IS ASSESSED

## 4.1 Manufacture of the product

No specific provisions

## 4.2 Packaging, transport, storage of the product

The Approval Body shall check that the manufacturer takes suitable precautions to limit the risk of damage or deterioration during transport and storage.

Specific requirements are given in the relevant other parts of this ETA Guideline.

## 4.3 Installation of the product in the works

Installation of the Fire Stopping and Fire Sealing Product shall be practicable under normal site conditions and is assumed to be performed by adequately trained installers.

The Fire Stopping and Fire Sealing Product shall be assessed on the assumption that the element to which it is attached or the assembly into which it is inserted in the works allows for correct fixing and does not apply excessive stress, in a manner for which the product was not designed. Such stress could arise, for example, due to thermal movement or structural settlement. The specific parts of this ETAG will give guidance where possible but, ultimately, it is for the user to ensure that the product characteristics set out in the ETA can be realised in particular installations.

Specific aspects for various products are given in the relevant other parts of this ETA Guideline.

## 4.4 Use, maintenance, repair

The assessment of the fitness for use is based on the assumption that damage, for example that caused by impact, is repaired. It is further assumed that replacement of components in the Fire Stopping and Fire Sealing Product during maintenance will be undertaken using materials covered by the ETA.

Specific requirements are given in the relevant other parts of this ETA Guideline.

## 4.5 Components in products

With an interchange of a component of a Fire Stopping and Fire Sealing Product, it shall be ensured that the new component does not have a negative influence on the performance level and/or the Working life of that product.

## 4.6 Auxiliary components

In many cases it is necessary to include auxiliary components, like fixings or adhesives in an assembled system, for the purpose of testing a particular manufacturer's Fire Stopping and Fire Sealing Product. This is particularly relevant in tests to determine resistance to fire, where most products cannot be tested in isolation.

The results of such tests will only be valid for the product in service, if it is used with auxiliary components having the same performance characteristics. It is therefore crucial that the auxiliary components are clearly specified as such in the ETA.

This can be achieved in two ways: by a specific or generic reference.

A 'specific' reference means a reference to a particular manufacturer's product by name, type number etc.

A 'generic' reference means a reference to a standard or other specification that completely defines that product. The manufacturer may determine which procedure is to be used in order to ensure that correct auxiliary components can be fully described; the Approval Body shall determine whether the procedure allows such components to be fully identified. It is then the responsibility of the user/installer to ensure that the correct auxiliary components are obtained and used in the Works.

The inclusion, in an ETA, of a reference to auxiliary components, is not to be taken as any guarantee or assurance of the component's durability or ongoing consistency of production.

## 4.7 Biological attack

In rare cases, deterioration of the fire stopping and fire sealing products may occur due to biological attack, i.e. mould growth on the products and/or the products being subject to deterioration due to insects or mammals infestation. This ETA-Guideline does not foresee product assessment for resistance to biological attack. Where the Approval Body expects biological attack to be of particular importance for specific products, additional, case-by-case assessment shall take place (see clause 2.4.13.1.2).

Moulds and other fungi that may damage products require warm (10°C to 35°C), humid conditions (> 70% RH), and a suitable food source. Mould growth is encouraged by dark conditions and lack of air movement. Design solutions should prevent the possibility of mould growth by ensuring that areas where these products are used can be ventilated sufficiently. Users should use the ventilation possibilities offered.

Proper water tightness of the building envelope, using appropriate design principles and details, are essential. During the exposed and partially enclosed phases of construction, to minimize the potential for mould growth, it is important to minimize the risk of water damage and wet surfaces due to external factors such as rain, snow, flooding, and high relative humidity. During construction, the following should be considered to minimize the potential for mould growth: minimizing the exposure of interior building products to exterior conditions; protecting stored materials from moisture; minimizing moisture accumulation within the building; preventing spillage of water within the building; maintaining the integrity of the building envelope components through ongoing monitoring and inspections; achieving balance control of thermal comfort and relative humidity in the building; checking all material deliveries to validate that components are dry and clean; rejecting wet or mouldy materials, and monitoring installations to ensure they remain clean and dry (including the HVAC systems).

In addition, where animals (insects, mammals) might attack these products, design solutions should prevent animal access to places where the products have been used and habitable voids that might harbour animals should be either avoided or sealed.

#### 5 IDENTIFICATION OF THE CONSTRUCTION PRODUCT

#### 5.1 Means of identification

#### 5.1.1 General

The product which is the subject of the technical approval shall be identified by (either individually or in combination):

- Testing of product characteristics as laid down in the relevant other parts of this ETA Guideline.
- Fingerprinting,
- Formulation,
- Manufacturing process parameters,
- Calculations, detailing, drawings.

#### 5.1.2 Components in kits

For products supplied as kits, the ETA-holder has the following options regarding the specification of components and these options will have been taken into account by the Approval Body issuing the ETA:

The incorporation of **specific components**; that is, components from a particular supplier that have been accepted by the Approval Body on the basis of their performance in the application.

The incorporation of **generic components**; that is, components that have been accepted by the Approval Body on the basis of conformity to a relevant standard that fully covers the product in the application.

A kit could include specific **and/or** generic types of specifications for components. Furthermore, it is likely that during the lifetime of an ETA, the holder will wish to change the specifications and/or supplier of some components.

The European Technical Approval is issued for the kit on the basis of agreed data and information, deposited with the issuing Approval Body, which identifies the kit and its components which shall have been assessed and iudged.

Changes in composition or production process shall be notified to the Approval Body which issued the ETA before the changes are introduced to avoid that the deposited data/information is incorrect. The Approval Body which issued the ETA will decide whether or not such changes may affect the ETA and consequently the validity of the CE marking on the basis of the ETA and if so whether further assessment/alterations to the ETA, shall be necessary.

Where a component has been defined in terms of a specific manufacturer's product or where a generic specification does not fully cover the fitness of a component for use in a Fire Stopping and Fire Sealing Product, any change can only be accepted by the Approval Body issuing the ETA, on completion of additional verification as is deemed necessary.

Generally, in such cases, issuing a modified ETA will be necessary, with the consequent amendment of the instructions to the notified body.

Where a component of a Fire Stopping and Fire Sealing Product is specified generically, e.g. by reference to a standard, and the Approval Body has confirmed, in the ETA the full adequacy of that specification to prove the

fitness for use of the component in the product, then a change of supplier will be acceptable.

The notified body checks the documentation as deemed necessary by the Approval Body issuing the ETA. In case of doubt reference shall be made to the Approval Body.

With an interchange of a component of Fire Stopping and Fire Sealing Product, it shall be ensured that the new component does not have a negative influence on the performance level or the life of that product.

## 5.2 Product characteristics which are relevant for identification checking

See the relevant other parts of this ETA Guideline.

## 6 FORMAT OF ETAS ISSUED ON THE BASIS OF THE ETAG

The manufacturer shall provide an Installation Guide for his product. Attention shall be drawn, in the ETA, to any particular precautions necessary when installing the product, taking account of the degree of training of installers.

European technical approvals issued on the basis of this ETAG shall be in accordance with the ETA format given in the Addendum to the specific parts of this ETAG.

## 7 REFERENCE DOCUMENTS

## 7.1 General

This ETA-Guideline incorporates, by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed below. For dated references subsequent amendments to, or revisions of these publications, apply to this ETAG only when incorporated in it by amendment or revision. For undated references the latest dated revision of the publication referred to, applies.

**EOTA Technical Reports** go into detail in some aspects and as such are not part of the ETAG but express the common understanding of existing knowledge and experience of the EOTA-bodies at that moment. When knowledge and experience is developing, especially through approval work, these reports can be amended and supplemented.

#### 7.2 EC Documents

Commission Decision 96/603/EC of 4 October 1996 establishing the list of products belonging to Classes A 'No contribution to fire' provided for in Decision 94/611/EC implementing Article 20 of Council Directive 89/106/EEC on construction products, OJ L 267, 19/10/1996, p. 23

Commission Decision 1999/454/EC of 22 June 1999 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards fire stopping, fire sealing and fire protective products, OJ L 78, 14/07/1999, p. 52

Commission Decision 2000/147/EC of 8 February 2000 implementing Council Directive 89/106/EEC as regards the classification of reaction to fire performance of construction products; OJ L 50, 23/02/2000, p. 14

Commission Decision 2000/605/EC of 26 September 2000 amending Commission Decision 96/603/EC establishing the list of products belonging to Classes A 'No contribution to fire' provided for in Decision 94/611/EC implementing Article 20 of Council Directive 89/106/EEC on construction products, OJ L 258, 12/10/2000, p. 36

Commission Decision 2001/596/EC of 8 January 2001 amending Commission Decisions 95/467/EC, 96/578/EC, 96/580/EC, 97/176,EC, 97/462/EC, 97/556/EC, 97/740/EC, 97/808/EC, 98/213/EC, 98/214/EC, 98/279/EC, 98/436/EC, 98/437/EC, 98/599/EC, 98/600/EC, 98/601/EC, 1999/89/EC, 1999/90/EC, 1999/91/EC, 1999/454/EC, 1999/469/EC, 1999/470/EC, 1999/471/EC, 1999/472/EC, 2000/245/EC, 2000/273/EC and 2000/447/EC on the procedure for attesting the conformity of certain construction products pursuant to Article 20 of Council Directive 89/106/EECCommission Decision 2003/424/EC of 6 June 2003 amending Decision 96/603/ECestablishing the list of products belonging to Classes A 'No contribution to fire' provided for in Decision94/611/EC implementing Article 20 of Council Directive 89/106/EEC on construction products, OJ L 209, 02/08/2001, p. 33

## 7.3 Test methods and classification standards

EN 12086	Thermal insulating products for building application - Determination of water vapour transmission properties
EN 12664	Thermal performance of building materials and products – Determination of thermal resistance by means of hot plate and heat flow meter methods – Dry and moist products with medium and low thermal resistance
EN 12667	Thermal performance of building materials and products – Determination of thermal resistance by means of hot plate and heat flow meter methods – Dry and moist products with high and medium thermal resistance
EN 12939	Thermal performance of building materials and products - Determination of thermal resistance by means of hot plate and heat flow meter methods - Thick products of high and medium thermal resistance
EN 13501	Fire classification of construction products and building elements,
	Part 1: Classification using test data from reaction to fire tests
	Part 2: Classification using data from fire resistance tests, excluding ventilation services
	Part 3: Classification using data from fire resistance tests on products and elements used in building service installations: fire resisting ducts and fire dampers (incl. Amendment A1:2009)
	Part 4: Classification using data from fire resistance tests on components of smoke control systems (incl. Amendment A1:2009)
	Part 5: Classification using data from external fire exposure to roof tests (incl. Amendment A1:2009)
EN 10140	Acoustics – Laboratory measurement of sound insulation of building elements Part 1: Application rules for specific products
	Part 2: Measurement of airborne sound insulation
	Part 3: Measurement of impact sound insulation
	Part 4: Measurement procedures and requirements
	Part 5: Requirements for test facilities and equipment
EN ISO 717	Acoustics - Rating of sound insulation of buildings and of building elements Part 1: Airborne sound insulation Part 2: Impact sound insulation
EN ISO 6946	Building components and building elements – Thermal resistance and thermal transmittance – Calculation method
EN ISO 8990	Thermal insulation - Determination of steady-state thermal transmission properties - Calibrated and guarded hot box
EN ISO 10211	Thermal bridges in building construction – Heat flows and surface temperatures Part 1: General calculation methods Part 2: Linear thermal bridges
EN ISO 10456	Building materials and products – Hygrothermal properties – Tabulated design values and procedures for determining declared and designed values
EN ISO 12572	Hygrothermal performance of building materials and products – Determination of water vapour transmission properties
EN ISO 14683	Thermal bridges in building construction - Linear thermal transmittance - Simplified methods and default values
7.4 Others	
EN ISO 9001	Quality management systems – Requirements (incl. corrigendum 1:2008-12 to EN ISO 9001)
EOTA TR 034	General Checklist for ETAGs/CUAPs/ETAs - Content and/or release of dangerous substances in products/kits

## ANNEX A

# Recommended Checklist for Initial Inspection of Factory, Factory Production Control and the Continuing Surveillance of Factory Production Control

#### A.1 General

The purpose of this checklist is primarily to assist those involved in the implementation of the technical specification. The checklist is a recommendation for use by the Notified Product Certification Bodies and not legally binding. It complies with the provisions of the CPD and of Guidance Papers 'B' and 'K'. The checklist is intended for initial inspection and the continuing surveillance only.

## A.2 Initial inspection of the factory and factory production control (FPC)

The initial inspection of the factory provides for the identification and documentation of the kind and manner of the manufacturing process and factory production control of the products. This is to enable the Notified Product Certification Body to assess the compliance with the provisions of the technical specification on the one hand and to provide a baseline to identify possible changes that may occur during surveillance on the other hand.

## A.3 Surveillance of factory production control (FPC)

The surveillance of the manufacturing process includes checking the documentation of the factory production control to ensure continuous compliance with the provisions of the technical specification, and the identification of changes by comparing data obtained during the initial inspection or during the latest inspection.

## A.4 Examples for questions to be considered

01	Does the ETA-holder apply a quality management system related to the technical specification and if so, is that proved by a valid certificate and by whom? Does the factory production control for the products to be certified form part of the quality management system?
02	Does the ETA-holder have direct control of the appropriate machinery for the production of the products to be certified, or are key elements of the production with respect to the essential characteristics subcontracted to others on or off the site?
03	Is the maintenance of machinery and measuring equipment carried out properly, regularly, and is this documented and is the documentation up to date?
04	Are the personnel involved in the production sufficiently qualified and trained to operate and maintain the production equipment? Have the personnel involved in the production been identified?
05	Are all processes and procedures of the production recorded at regular intervals or continuously (automatically)? How is the documentation organised?
06	Has traceability of kit components and constituents been ensured? Is an inspection of the incoming material carried out, and if yes, how and at what intervals?
07	Are the manner, extent and frequency of factory production control in accordance with the provisions of the ETA and the documented system? What are the test methods and equipment used? Have any changes been made concerning test methods and/or testing equipment? If so, have appropriate comparable measurements been performed and documented?
	Is the testing equipment correctly maintained and calibrated on a continuous basis to ensure consistent accuracy of the tests performed during factory production control and its surveillance?