GUIDANCE DOCUMENT

The provision of data for assessments leading to ETA

Guidance Document 004

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EUROPEAN ORGANISATION FOR TECHNICAL APPROVALS

This EOTA Guidance Document has been endorsed at the 34th meeting of the EOTA ExCom in December 1999.

This paper provides guidance to Approval bodies in order to assist them in moving to a common approach to data utilisation.

It is presumed that the product is not new and has been used for the defined purpose or similar purpose for several years and sometimes in more than one country. Some of the concepts may however be applied to products, which have just come onto the market, or just about to.

This paper does not attempt to set amounts of data that can be accepted from each source; to do so would be artificial. Instead it offers a number of techniques, which enables existing data to be used which might otherwise be rejected.

Existing data that could be used for the assessment of products requiring ETA exists in a number of different forms, the following is a methodology to deal with it.

Before considering the questions below it is important to establish responsibility.

An Approval body is responsible for ensuring that the samples that have been tested are representative of existing production. An Approval body also takes responsibility as to the quality of the laboratory that provides the data.

An Approval body shall evaluate if the test method is the same (identical) as in the ETAG/CUAP, HOWEVER if the method is not the same in all respects, the use of the data from that method must be subject to EOTA consensus. Hence `method equivalence decisions' rest with the TB. Also, during the commenting period for draft ETAs all of the methods used and data obtained will be in the technical file for examination by relevant TB members. It will also be necessary to ensure that the test methods and data will be acceptable to an approved body where the system of A/C demands their involvement.

The questions to be addressed are:

1 why should it be considered?

2 what could be available?

3 are the samples that were tested representative of the product being assessed for ETA?

4 how closely do the data and the test method and/or calculation procedure match the ETAG/CUAP?

5 how should old data be considered?

6 what is the degree of risk?

7 how can the data be utilised?

8 what are the advantages/disadvantages of using the data?

The following pages attempt to offer answers.

1 Why consider other Data

The amount of work required to undertake a full test programme, starting from nothing to enable an assessment against an ETAG can be rather large (ie Anchors & SSGS) and cannot be avoided in some cases). Hence the cost to a customer (manufacturer or agent) can be excessive.

Given that most already have national approval, often in several member states; they also have the strongly held opinion that to start again is ridiculous.

Arguments about whether or not the old products are the same as those currently produced are rejected, often again being supported by reference to long-standing national approvals.

The view held by the product supplier can be summarised as `if I have proof that my product is fit for purpose and has been for many years why are you telling me now that I have to undergo a tortuous re-examination.'

In addition many of the products have been on the market for many years, usually demonstrating satisfactory performance in real use.

Notwithstanding this view, there will however be cases where testing will have to be undertaken where the data is to be used directly for regulatory purposes in EEA member states.

EOTA member bodies have to reconcile this argument.

2 Available Data

It exists in several forms. The laboratory from which the data is obtained should have the necessary competence and impartiality and is therefore fit to be an indicated laboratory (ETAG Format clause 8.2.2.1).

Test data can be from:

a) laboratories that are accredited/approved nationally and/or are notified in any EEA member state for the relevant tests specified in the ETAG or CUAP. They can be independent, a university or manufacturer linked.
b) independent laboratories inside or outside the EEA.
c) EOTA approval bodies.
d) manufacturer laboratories, or universities and colleges not accredited nor notified for the relevant testing.

In addition, manufacturer production control records could be useful.

Good long-term records of performance in use could be essential for durability and working life predictions (eg site inspections).

The approach that has to be taken is to judge the data available against each and every one of the test and assessment and design value requirements, set out in the ETAG or CUAP. A weighting has to be given as to the source.

Clearly data from sources a) and/or c) is acceptable.

Data from source b) can be accepted provided the approval body can establish competence of the laboratory.

Data from laboratories d) can be accepted provided the approval body has checked/examined the competence of the laboratory and confirmatory test data is available from sources a) and/or c) for some of the `range'. Range means that data may be related eg if there are a number of sizes of a given product some data at the beginning, middle and end of the range from a) and/or c) can be used to confirm data covering the complete range from other sources eg the manufacturer.

Sometimes a manufacturer has the only piece of suitable test equipment. In this case witness testing is the only possibility, therefore their data obtained unwitnessed should be confirmed by a suitable number of additional witnessed tests, to confirm the data obtained from the unwitnessed testing. The witness should be from a) or c).

Data from universities or colleges tends to be the most difficult to judge. Whilst some can provide first class data by being accredited or demonstrate high standards of laboratory technique eg well maintained equipment, regularly calibrated with traceability to national standards, many view such demands as an annoying inconvenience. However the `science' is often needed with novel products. In these cases it is essential to have confirmatory testing, for instance, at a source such as a) or c). Witnessed tests may provide an alternative approach.

3 Representative Samples

Tests conducted by the manufacturer have sometimes been performed at a stage where series production had not yet started. Tests may concern prototypes that had been the subject of a peculiar care. The ETA body must make sure that the samples tested by the manufacturer were representative of the products to which the ETA will eventually apply. Naturally this recommendation is also valid for the samples tested under the responsibility of the Approval body. This point is particularly important if the attestation of conformity of the product will not require a product certification by third party.

4 Matching of Data

If the source of the data is satisfactory, the next step is to examine the equivalence of the test method to that in the ETAG/CUAP. If the method is the same, the data can be accepted provided other requirements as set out below are satisfied.

If there are differences in the method, a judgement of them can initially be made as to the effect on the data. However the Approval body must seek consensus from EOTA before using it for an ETA. A judgement will be made as to whether the result is method dependent or has little effect on the data. Where there may be, or is a problem, further confirmatory testing is needed.

5 Old Data

The judgement of acceptability is the responsibility of the Approval body and is normally applied to testing of `as new material or product'. However where continuity of production can be confirmed, data made available which applies to earlier production, can be examined.

6 Risk Assessment

Often test methods do not match precisely, or there is a degree of doubt in relation to the other criteria above. An approach to overcoming concerns is to consider the relevance of the data to the fitness for purpose of the product. For instance, the measurement of tensile strength of a membrane may be called for but an error in result of say ± 30% is of little significance to the assessment in a particular case. On the other hand the same may not be true for a product such as the sealant for SSGS.

A risk assessment is therefore a useful tool that can sometimes be used to convert unacceptable data into usable information. Again if this procedure is proposed its use should be confirmed with the other EOTA members.

7 Utilisation of the Data

This has to be a process of assessment and judgement, and take into account the points made above. Of primary importance is the need to not only satisfy the assessor but also those who will judge the technical file in support of the draft ETA. Where inconsistency exists, the assessor must fully document the procedure whereby the data is accepted.

8 Advantages and Disadvantages of this Approach

For:

* good data is not wasted

* amount of test work could be reduced significantly

* cost to the manufacturer or agent could be greatly reduced

* draft ETA or ETA could be available sooner

* manufacturer or agent could have a more positive opinion of the ETA route.

Against:

* assessment of the data is more complicated and difficult

* opportunity to dispute the draft ETA is greater

* risk of an inadequate assessment could be increased.

Definitions of terms used in the paper

Confirmatory testing	-	a few tests undertaken by a suitable laboratory to validate data from a large number of tests carried out by a laboratory whose reliability cannot be confirmed
Prototype testing	-	all testing for which there is no clear relationship with fpc data
Witness testing	-	testing accepted by the Approval body which is carried out by, or on behalf of the manufacturer or Approval body and supervised by a person recognised by the Approval body as qualified in the relevant testing.