

Guideline

9/11

CLAP

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Directive 97/23/EC

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Particular material appraisal

PMA

Material recognised as being safe

Material

Directive references:

Annex I, 4.2b third indent - 97/23 EC

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Subject: ESR on materials – particular appraisal for materials recognized as being safe to use

Question: When performing a particular appraisal for materials recognized as being safe to use before 29.11.1999, shall the existing data for these materials be taken into account when assessing the suitability of this material?

Answer: Yes, and if this data as referred to in CLAP 105 - Guideline 9/2 is sufficient for the proof of conformity, in principle no additional testing should be performed .

The manufacturer (and the Notified Body) shall take into account the material properties of the actual deliveries when claiming the history of safe use for a particular material, if its specification has significantly wider limits.

Reasons:

1. Even though the PED does not specify the content of a particular material appraisal, the concept of safe history applies similarly as for EAM.
2. It would be incorrect to assume that every batch supplied to the wider specification has equally good properties.

For example, in many steel specifications, sulphur may be permitted up to 0,030%, but modern steelmaking techniques produce lower sulphur levels consistently less than 0,010%. The good impact toughness associated with the low sulphur content will not be obtained if another batch of steel is supplied at or near 0,030% sulphur.

Note: Where such commonly used materials are not covered by harmonised standards or EAM, particular material appraisal is the only other route that remains.

Modifications compared to the previous adopted version: Editorial correction on 2004-09-16.