

Guideline

7/3

CLAP

FORM N°80

Version : 2

Directive 97/23/EC

Keywords : European approval of materials

Notified body

EAM

Directive references: Article 11 § 2 - 97/23 EC

Adopted by WPG: 29/01/1999

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Subject: ESR on materials – Delays for European approval for materials

Question: A notified body is in the process of giving a European approval for materials. In Article 11.2 an information process with delays is given. Having sent out the information the notified body must wait for comments. How long must the body wait?

Answer: The approval can be given three months after the mailing date of the information, with one exception: if a Member State or the Commission refers the matter to the Standing Committee set up by Article 5 of Directive 98/34/EC (ex 83/189/EEC), it must inform the notified body which must wait for a letter from the Commission giving the conclusions of the Committee.

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