

▼B*ANNEX II***Minimum requirements regarding a technical file to be included in the application for a new textile fibre name**

(referred to in Article 6)

A technical file to be attached to an application for the inclusion of a new textile fibre name in the list set out in Annex I, as provided for in Article 6, shall contain at least the following information:

- (1) Proposed name of the textile fibre:

The name proposed shall be related to the chemical composition and shall provide information about the characteristics of the fibre, if appropriate. The name proposed shall be free of any intellectual property rights and shall not be linked to the manufacturer.

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- (2) Proposed definition of the textile fibre:

The definition proposed shall describe the fibre composition. The characteristics mentioned in the definition of the new textile fibre, such as elasticity, shall be verifiable via standard test methods to be provided with the technical file along with the experimental results of analyses.

- (3) Identification of the textile fibre: chemical formula, differences from existing textile fibres, FTIR spectrum together with, where relevant, detailed data such as melting point, density, refractive index and burning behaviour.

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- (4) Proposed agreed allowance to be used in the calculation of fibre composition.

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- (5) Proposed identification and quantification methods, including experimental data:

The applicant shall evaluate the possibility to use the methods listed in Annex VIII or the harmonised standards to be introduced in that Annex to analyse the most expected commercial mixtures of the new textile fibre with other textile fibres and shall propose at least one of those methods. For those methods or harmonised standards where the textile fibre can be considered as an insoluble component, the applicant shall indicate the 'd' factors, which correspond to the mass correction factors to be applied for the calculations (to account for the loss in mass, known to occur during the analysis) of the new textile fibre.

If methods listed in this Regulation are not suitable, the applicant shall provide adequate reasoning and propose one or more new methods. The proposed new method or methods shall describe the field of application (including fibre mixtures), the principle (notably chemical process and steps), the apparatus and reagent or reagents, the test procedure, the calculation and expression of results (including the value of 'd' factors), and the precision (confidence limits of results).

The application shall contain all the experimental data, in particular regarding fibre characteristics, identification and quantification methods proposed. Data on the accuracy, robustness and repeatability of the methods shall be provided with the file.

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- (6) Available scientific information concerning possible allergic reactions or other adverse effects of the new textile fibre on human health, including results of tests conducted to that effect in compliance with relevant Union legislation.

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- (7) Additional information on production process and consumer relevance to support the application:

The technical file shall, at least, contain information on the number of producers, the location of production facilities and the expected market availability of the new fibre or of products manufactured from that fibre.

- (8) Availability of samples:

The manufacturer or any person acting on the manufacturer's behalf shall provide representative samples of the new pure textile fibre and the relevant textile fibre mixtures necessary for verifying the accuracy, robustness and repeatability of the proposed identification and quantification methods. The Commission may request additional samples of relevant fibre mixtures from the manufacturer or the person acting on the manufacturer's behalf.

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The manufacturer or any person acting on the manufacturer's behalf shall provide representative samples of the new pure textile fibre and the relevant textile fibre mixtures necessary to conduct the validation of the proposed identification and quantification methods. The Commission may request additional samples of relevant fibre mixtures from the manufacturer or the person acting on the manufacturer's behalf.