

Commission Regulation (EC) No 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation (Text with EEA relevance)

CHAPTER I

Applications for authorisation

Article 1 This chapter provides detailed rules concerning applications for authorisation submitted...

SECTION 1

Requirements for applications for authorisation of genetically modified food and feed

Article 2 (1) Without prejudice to Article 5(3) and (5) and Article...
Article 3 (1) The application shall include the following:
Article 4 (1) Samples of the food and feed and their control...

SECTION 2

Transformation of requests and notifications into applications
in accordance with Regulation (EC) No 1829/2003

Article 5
Article 6
Article 7

SECTION 3

Supplementation of requests under Directive 70/524/EEC
by an application under Regulation (EC) No 1829/2003

Article 8

CHAPTER II

Notification of existing products

Article 9

Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EC) No 641/2004. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

SECTION 1

General requirements for notifications of certain products placed on the market before 18 April 2004

Article 10

SECTION 2

Additional requirements for notifications of certain products placed on the market before 18 April 2004

Article 11
 Article 12
 Article 13
 Article 14
 Article 15
 Article 16
 Article 17

CHAPTER III

Transitional measures for adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation

Article 18
 Article 19

CHAPTER IV

Final provision

Article 20 This Regulation shall enter into force on the day of...
 Signature

ANNEX I

METHOD VALIDATION

1. INTRODUCTION
 - A. For the purpose of implementing Articles 5(3)(i) and 17(3)(i) of...
 - B. The method acceptance criteria and method performance requirements have been...
 - C. The CRL, established under Regulation (EC) No 1829/2003 and assisted...
 - D. If the information provided about the method is considered adequate...
 - E. The validation process will be carried out by the CRL...
 - F. The CRL, together with ENGL, shall provide further information about...
 - G. The CRL, assisted by ENGL, shall evaluate the results obtained...
2. INFORMATION ABOUT THE METHOD

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- A. The method shall refer to all the methodological steps needed...
 - B. As described in the document referred to under 1(B), ENGL...
 - C. The applicant shall demonstrate that the method fulfils the following...
 - D. For the purpose of implementing Articles 5(3)(i) and 17(3)(i) of...
 - E. The applicant shall provide a complete and detailed description of...
3. INFORMATION ABOUT THE METHOD TESTING CARRIED OUT BY THE APPLICANT...
- A. The applicant shall provide all the available and relevant data...
 - B. The information provided shall demonstrate the robustness of the method...
 - C. Information required about the method development and the method optimisation:...
 - D. Testing report. Besides the values obtained for the performance indices,...
4. SAMPLES OF THE FOOD AND FEED AND THEIR CONTROL SAMPLES...

ANNEX II REFERENCE MATERIAL

The reference material as referred to in Articles 5(3)(j) and...
For verification and value assignment, a method that has been...

- A. Terminology:
- B. GM RM containers:
- C. Homogeneity testing:
- D. Stability testing:
- E. Batch characterisation:
- F. Final storage:
- G. Establishment of a certificate for CRMs:

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- (1) [OJ L 268, 18.10.2003, p. 1.](#)
- (2) [OJ L 270, 14.12.1970, p. 1.](#) Directive as last amended by Regulation (EC) No 1756/2002 ([OJ L 265, 3.10.2002, p. 1.](#)).

Changes to legislation:

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Changes and effects yet to be applied to :

- Annex 1 point 1.A word omitted by [S.I. 2019/705 reg. 46\(a\)](#)
- Annex 1 point 2.B word substituted by [S.I. 2019/705 reg. 46\(f\)](#)
- Annex 1 point 3.A word substituted by [S.I. 2019/705 reg. 46\(g\)\(i\)](#)
- Annex 1 word substituted by [S.I. 2019/705 reg. 46\(h\)](#)
- Annex 1 point 1.C words omitted by [S.I. 2019/705 reg. 46\(c\)](#)
- Annex 1 point 1.F words omitted by [S.I. 2019/705 reg. 46\(d\)](#)
- Annex 1 point 1.G words omitted by [S.I. 2019/705 reg. 46\(e\)](#)
- Annex 1 point 3.A words omitted by [S.I. 2019/705 reg. 46\(g\)\(ii\)](#)
- Annex 1 point 1.B words substituted by [S.I. 2019/705 reg. 46\(b\)](#)
- Art. 2(1) words substituted by [S.I. 2019/705 reg. 43\(a\)](#)
- Art. 2(4) words substituted by [S.I. 2019/705 reg. 43\(b\)](#)

Changes and effects yet to be applied to the whole legislation item and associated provisions

- Signature words omitted by [S.I. 2019/705 reg. 45](#)
- Art. 3(1)(a) words omitted by [S.I. 2019/705 reg. 44\(a\)](#)
- Art. 3(1)(d) words omitted by [S.I. 2019/705 reg. 44\(b\)](#)