

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)

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)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed<sup>(1)</sup>, and in particular Articles 5(7), 8(8), 17(7), 20(8) and 47(4) thereof,

After consulting the European Food Safety Authority in accordance with Articles 5(7) and 17(7) of Regulation (EC) No 1829/2003,

Whereas:

- (1) Regulation (EC) No 1829/2003 lays down Community procedures for the authorisation and supervision of genetically modified food and feed and for the labelling of such food and feed.
- (2) It is necessary to provide detailed rules concerning applications for authorisations submitted in accordance with Regulation (EC) No 1829/2003.
- (3) In addition, Regulation (EC) No 1829/2003 provides that the European Food Safety Authority (the Authority) is to publish detailed guidance to assist the applicant in the preparation and the presentation of the application, concerning notably the information and data to be provided in order to demonstrate that the product complies with the criteria referred to in Articles 4(1) and 16(1) of that Regulation.
- (4) In order to ensure a smooth transition to the regime provided by Regulation (EC) No 1829/2003 transitional measures laid down in that Regulation as regards requests and notifications of products falling within the scope of other Community legislation, should be subject to implementing rules.

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*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](#)

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- (5) It is also necessary to provide detailed rules on the preparation and presentation of notifications of existing products submitted to the Commission under Regulation (EC) No 1829/2003 as regards products placed on the market in the Community before 18 April 2004.
- (6) Such rules should facilitate the task of operators, in preparing applications for authorisations and in the preparation of notifications of existing products, and the Authority in evaluating such applications and verifying such notifications.
- (7) The scope of Regulation (EC) No 1829/2003 includes food which consists of, contains or is produced from genetically modified organisms (GMOs) such as genetically modified plants and micro-organisms. Therefore, in the interests of consistency of Community legislation, the scope of the present Regulation should also cover existing food consisting of, containing or produced from genetically modified plants and micro-organisms.
- (8) The scope of Regulation (EC) No 1829/2003 covers feed, including feed additives as defined in Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding-stuffs<sup>(2)</sup> consisting of, containing or produced from GMOs such as genetically modified plants and micro-organisms. Therefore, the scope of the present Regulation should also cover existing feed, including feed additives consisting of, containing or produced from genetically modified plants and micro-organisms.
- (9) The scope of Regulation (EC) No 1829/2003 does not cover processing aids, including enzymes used as processing aids. Therefore, the scope of the present Regulation similarly should not cover existing processing aids.
- (10) Regulation (EC) No 1829/2003 provides that detailed rules are to be adopted for implementing the transitional measures for the adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation. In the interests of consistency of Community legislation those rules should in particular clarify which genetically modified material is covered by such transitional measures and how the 0,5 % threshold is to be applied.
- (11) It is necessary for this Regulation to apply as a matter of urgency as Regulation (EC) No 1829/2003 applies from 18 April 2004.
- (12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

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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.](#))

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**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\(b\)](#)