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[(1)], 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.

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*

(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[(2)] 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:

***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*

CHAPTER I

Applications for authorisation

[F1 Article 1

This chapter provides detailed rules concerning applications for authorisation submitted in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 except for those applications covered by Commission Implementing Regulation (EU) No 503/2013[3].**]**

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006 (Text with EEA relevance).

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 17(3) and (5) of Regulation (EC) No 1829/2003, and taking into account the guidance of the European Food Safety Authority (the Authority) provided for in Articles 5(8) and 17(8) of that Regulation, applications for authorisation submitted in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 (the applications) shall comply with the requirements of paragraphs 1 to 4 of this Article and with Articles 3 and 4 of this Regulation.

2 In supplying the information required under Article 5(3)(b) and Article 17(3)(b) of Regulation (EC) No 1829/2003, the application shall clearly identify the products covered by it in accordance with Articles 3(1) and 15(1) of that Regulation. Where the application is limited to either food or feed use, it shall contain a verifiable justification explaining why the authorisation should not cover both uses in accordance with Article 27 of Regulation (EC) No 1829/2003.

3 The application shall clearly state which parts of the application are considered to be confidential, together with a verifiable justification in accordance with Article 30 of Regulation (EC) No 1829/2003. Confidential parts shall be submitted in separate documents.

4 The application shall specify, in supplying the information required under Article 5(3)(c) and Article 17(3)(c) of Regulation (EC) No 1829/2003, whether the information included in the application may be notified as such to the biosafety clearing house under the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (the Cartagena Protocol) approved by Council Decision 2002/628/EC[4].

If the application may not be notified as such, it shall include the information which complies with Annex II to the Cartagena Protocol and which may be notified to the biosafety clearing house by the Commission as provided in Article 44 of Regulation (EC) No 1829/2003 in a separate and clearly identified document.

5 Paragraph 4 shall not apply to applications concerning only food and feed produced from genetically modified organisms (GMOs) or containing ingredients produced from GMOs.

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*

Article 3

1 The application shall include the following:

a the monitoring plan referred to in Article 5(5)(b) and Article 17(5)(b) of Regulation (EC) No 1829/2003, taking into account Council Decision 2002/811/EC[(5)];

b in supplying the information required under Article 5(5)(a) and Article 17(5)(a) of Regulation (EC) No 1829/2003, a proposal for labelling complying with the requirements of Annex IV to Directive 2001/18/EC of the European Parliament and of the Council[(6)];

c in supplying the information required under Article 5(5)(a) and Article 17(5)(a) of Regulation (EC) No 1829/2003, a proposal for a unique identifier for the GMO in question, developed in accordance with Commission Regulation (EC) No 65/2004[(7)];

d a proposal for labelling in all official Community languages, where a proposal for specific labelling is needed in accordance with Article 5(3)(f) and Article (g) and 17(3)(f) and (g) of Regulation (EC) No 1829/2003;

e a description of a method(s) of detection, sampling and event specific identification of the transformation event, as provided for in Article 5(3)(i) and Article 17(3)(i) of Regulation (EC) No 1829/2003, in accordance with Annex I to this Regulation;

f a proposal for post-market monitoring regarding the use of the food for human consumption or the feed for animal consumption, as provided for in Article 5(3)(k) and Article 17(3)(k) of Regulation (EC) No 1829/2003, and according to the characteristics of the products concerned, or a verifiable justification to the effect that a post-market monitoring is not necessary.

2 Points (a), (b) and (c) of paragraph 1 shall not apply to applications concerning only food and feed produced from GMOs or containing ingredients produced from GMOs.

Article 4

1 Samples of the food and feed and their control samples which are to be submitted in accordance with Article 5(3)(j) and Article 17(3)(j) of Regulation (EC) No 1829/2003 shall be in accordance with the requirements set out in Annexes I and II to this Regulation.

The application shall be accompanied by information concerning the place where the reference material developed in accordance with Annex II may be found.

2 The summary to be provided in accordance with Article 5(3)(l) and Article 17(3)(l) of Regulation (EC) No 1829/2003 shall:

a be presented in an easily comprehensible and legible form;

b not contain parts which are considered to be confidential.

F2SECTION 2

[F2Transformation of requests and notifications into applications in accordance with Regulation (EC) No 1829/2003

F2Article 5

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F2Article 6

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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*

[F2]Article 7

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Textual Amendments

F2 Deleted by Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006 (Text with EEA relevance).

[F2]SECTION 3

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

[F2]Article 8

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[F2]CHAPTER II

Notification of existing products

[F2]Article 9

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[F2]SECTION 1

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

[F2]Article 10

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[F2]SECTION 2

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

[F2]Article 11

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[F2]Article 12

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