

Biosafety Clearing-House (BCH)

BIOSAFETY LAW, REGULATION, GUIDELINES AND AGREEMENTS (LAW)

BCH-LAW-EU-5623-2

LAST UPDATED: 10 MAY 2010

Amendment

Is this an amendment to a law, regulation, guideline or agreement already published on the BCH?

No

General Information

Country submitting a law, regulation, guideline or agreement

[European Union](#)

Title

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

EN

Legislative details

Type of Law / Regulation

Law

Area of jurisdiction

Regional / Multilateral

Geographical or political/economic group(s)

Europe - European Union member states

Subject areas

Competent National Authorities and National Focal Points
Confidential Information
Handling, transport, packaging and identification

LMOs for direct use as feed
LMOs for direct use as food
LMOs for processing
Public awareness and participation
Risk assessment and management

Types of organisms addressed

All types of organisms

Brief description of the document including objective and scope

Regulation (EC) No 641/2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 provides further details on the applications for authorisation of GM food and feed, including the method(s) of detection, sampling and event specific identification of the transformation event, as provided for in articles 5(3) and 17(3) of Regulation (EC) No 1829/2003.

In particular Annex I of Regulation (EC) No 641/2004 on "method validation" provides detailed technical provisions on the type of information on detection methods that shall be provided by the applicant and that is needed to verify the preconditions for the fitness of the method. This includes information about the method as such and about the method testing carried out by the applicant.

Annex I of Regulation (EC) No 641/2004 also confirms that the validation process will be carried out by the CRL according to internationally accepted technical provisions. All guidance documents referred to in this Annex or produced by the Community Reference Laboratory (CRL) are to be made available by the CRL.

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Date of entry into force

07 Apr 2004

Document details

Document text

[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 \[English \]](#)

Regulatory contact information

Competent National Authority(ies) and/or Supplementary Protocol Competent Authority(ies)

- [COMPETENT NATIONAL AUTHORITY:](#) | [BCH-CNA-EU-49387-11](#)

COMPETENT NATIONAL AUTHORITY:

European Commission - Health and Food Safety Directorate General SANTE
Rue Belliard, B232

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1040, Belgium

Phone: +32 2 29 57616

Email: thomas.weber@ec.europa.eu

Website: http://ec.europa.eu/dgs/health_food-safety/index_en.htm - COMPETENT

NATIONAL AUTHORITY: | [BCH-CNA-EU-45056-4](#)

COMPETENT NATIONAL AUTHORITY:

European Commission Joint Research Centre (JRC)

Retieseweg 111

Geel

2440, Belgium

Phone: +32 14 571722

Email: hendrik.emons@ec.europa.eu Website: <http://ec.europa.eu/dgs/jrc/index.cfm>

Additional Information

EU validated detection methods for GM food/feed applications submitted under Regulation (EC) No 1829/2003 are available at <http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm>

Other relevant website addresses and/or attached documents

[European Reference Laboratory \(EURL\) for GM Food Feed](#) [*English*]

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Further Information

Questions about the Cartagena Protocol on Biosafety or the operation of the Biosafety Clearing-House may be directed to the Secretariat of the Convention on Biological Diversity.

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Convention on Biological
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