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)

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)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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), 11(5), 17(7) and 23(5) thereof,

After consulting the European Food Safety Authority,

Whereas:

(1) Regulation (EC) No 1829/2003 lays down Union procedures for the authorisation and supervision of genetically modified food and feed, including rules for the labelling of such food and feed. That Regulation provides for a scientific evaluation to be carried out on the risks that the genetically modified food or feed may present for human and animal health and, as the case may be, for the environment. It also provides that a genetically modified food or feed must not mislead the consumer or the user and must not differ from the food or feed which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for humans or animals.

(2) Regulation (EC) No 1829/2003 provides, in particular, that applications for authorisation are to adequately and sufficiently demonstrate that the genetically modified food and feed satisfy the requirements laid down in that Regulation, in respect of their proposed uses.

(3) In the interest of consistency of Union legislation, certain definitions laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[(2)] should also apply to this Regulation.

(4) Commission Regulation (EC) No 641/2004[(3)] on detailed rules for the implementation of Regulation (EC) No 1829/2003 provides for certain detailed rules concerning

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applications for authorisation submitted in accordance with Regulation (EC) No 1829/2003. To facilitate the preparation of applications and ensure that they contain all the information needed for their assessment, it is necessary to provide for more comprehensive and systematic rules concerning applications for authorisation, which should also be specific to each type of genetically modified organisms (GMO), namely plants, animals and micro-organisms.

(5) The rules laid down in this Regulation should only cover applications concerning genetically modified plants for food or feed uses, food or feed containing or consisting of genetically modified plants and food or feed produced from such plants. Genetically modified plants, for which sufficient experience is available to date, constitute the vast majority of current applications.

(6) The rules laid down in this Regulation should specify the general requirements for the presentation and preparation of applications, namely requirements to provide general and scientific information, including methods for detection, and identification, as well as reference material so as to ensure that applications comply with the conditions laid down in Articles 5, 17 and 30 of Regulation (EC) No 1829/2003.

(7) The applicant should also take into consideration the scientific information to be provided in the application as regards the environmental risk assessment of GMOs or food and feed containing or consisting of GMOs, as set out in the principles for the environmental risk assessment in Annex II to Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC[(4)], as well as the applicable guidance published by the European Food Safety Authority (EFSA) in this regard.

(8) In addition to the general requirements for the presentation and preparation of applications, it is appropriate to provide for specific rules to ensure that the scientific information required in the application adequately and sufficiently demonstrates that the genetically modified food or feed satisfy the requirements laid down in Regulation (EC) No 1829/2003, in respect of their proposed uses.

(9) These rules should therefore provide for a set of studies that should be included in all applications, as well as the test methods to be followed to perform such studies, whilst taking into account relevant international standards, such as the guideline of the Codex Alimentarius for the conduct of safety assessment of foods derived from the recombinant-DNA plant[(5)].

(10) In accordance with the applicable guidance of the EFSA[(6)], the safety assessment of the genetically modified food or feed should include studies related to new components resulting from the genetic modification, the molecular characterisation of the genetically modified plant, the comparative analysis of the composition and the phenotype of the genetically modified plant compared to its conventional counterpart. Depending on the characteristics of the genetically modified plant and on the outcome of that first set of studies, the EFSA guidance indicates that it may be necessary to perform additional studies. In that respect, the EFSA considers that notwithstanding its limitations, a 90-day feeding study in rodents with whole food or feed is, when

justified, the primary additional study to address uncertainties identified in the course of the safety assessment.

(11) It has, however, not been proved possible to define with the necessary precision the level of uncertainties which would require the submission of 90-day feeding studies. In addition, some food and feed assessment bodies of Member States are of the opinion that such study should be performed in all applications for genetically modified plants containing single transformation events. Considering these diverging views, as well as to improve consumer confidence, such studies should be, for the time being, requested in all applications related to genetically modified plants with single transformation events and, where appropriate, on genetically modified plants containing stacked transformation events.

(12) Studies to demonstrate that a genetically modified food or feed fulfils the requirements of Regulation (EC) No 1829/2003 involving the use of laboratory animals should be carried out in accordance with Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 regarding the protection of the animals used for scientific purposes[7], and should be kept to a minimum while ensuring an adequate demonstration of the safety of the genetically modified food or feed. The current uncertainties in relation to the need and design of 90-day feeding trials will be addressed by a large research project under the 2012 work programme of Theme 2 'Food, Agriculture and Fisheries, and Biotechnologies' of the seventh Framework Programme for Research (FP7). The requirements regarding animal feeding trials in the context of GMO risk assessments should be reviewed in the light of the outcome of this project expected to be available by the end of 2015 at the latest. Other credible scientific knowledge which might be available at that time should also be taken into account.

(13) While the rules laid down in this Regulation should be valid for all applications for genetically modified plants, the type and necessity of the studies to evaluate the characteristics and safety of genetically modified food or feed subject to an application may vary, depending on the nature of the genetic modification or of the product. For example, genetic modifications which have negligible impact on the composition of a genetically modified food or feed or highly refined products that may be proven to be identical to products produced from the conventional counterpart require different studies than a product resulting from complex genetic modification aiming to modify its nutritional characteristics.

(14) The requirements laid down in this Regulation regarding the studies which have to be included in an application for authorisation under Regulation (EC) No 1829/2003 should not prevent the EFSA to request, where appropriate, the applicant to supplement the particulars accompanying the application in accordance with Articles 6(2) and 18(2) of Regulation (EC) No 1829/2003.

(15) In order to ensure that studies are of high quality and documented in a transparent way, it is essential that they are performed under appropriate quality assurance systems and raw data should be provided in all cases and be in a suitable electronic format. Toxicological studies should be performed in accordance with the quality assurance principles laid down by Directive 2004/10/EC of the European Parliament and of

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the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances[8]. If such studies are carried out outside the Union, they should follow the state-of-the-art OECD Principles on Good Laboratory Practice (GLP). With regard to studies other than toxicological studies, they should be conducted under ISO or GLP standards.

(16) It is also necessary to define the requirements regarding the submission of additional information related to the safety of the GMO and scientific peer-reviewed literature related to the potential effects on health and on the environment of the products covered by the application.

(17) During the process of the genetic modification of plants and other organisms, marker genes are often used to facilitate the selection and identification of genetically modified cells, containing the gene of interest inserted into the genome of the host organism, among the vast majority of untransformed cells. Such marker genes should be carefully selected. In addition, it is now possible to develop GMOs without the use of antibiotic resistance marker genes. Against this background and in accordance with Article 4(2) of Directive 2001/18/EC, the applicant should therefore aim to develop GMOs without the use of antibiotic resistance marker genes.

(18) The harvest of segregating genetically modified plants (segregating crops) containing stacked transformation events contains various subcombinations of transformation events. In addition, current control procedures do not allow identifying the origin of combinations of transformation events. Therefore, in order to ensure that authorisations are coherent with the products of which the placing on the market is unavoidable and for the feasibility of controls, the applications for genetically modified food and feed from segregating crops should include all subcombinations independently of their origin and not yet authorised.

(19) Regulation (EC) No 1829/2003 provides that a proposal for post-market monitoring of the use of the genetically modified food or feed shall only be submitted by the applicant where it is appropriate. It is therefore necessary to set out the conditions under which such a proposal should, according to the outcome of the risk assessment, accompany the application. Post-market monitoring should only be considered in cases where, notwithstanding the fact that the safety of genetically modified food and feed has been demonstrated, it is appropriate to confirm the expected consumption, the application of conditions of uses or identified effects. This is for example the case when the genetically modified food or feed has altered nutritional composition or when that its nutritional value differs from the conventional food or feed that it would replace or when there is a likelihood of increased allergenicity due to the genetic modification.

(20) This Regulation should take account of the international trade commitments of the Union and of the requirements of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (the Cartagena Protocol), approved by Council Decision 2002/628/EC of 25 June 2002 concerning the conclusion, on behalf of the European Community, of the Cartagena Protocol on Biosafety[9] as well as the provisions of

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Regulation (EC) No 1946/2003 of 15 July 2003 of the European Parliament and of the Council on transboundary movements of genetically modified organisms[(10)].

(21) In order to ensure that test methods included in the application are adequate to demonstrate that the food or feed complies with the requirements for authorisation set out in Regulation (EC) No 1829/2003, they should be carried out in accordance with the present Regulation, or internationally agreed guidelines such as those described by the OECD, when available. To ensure that applications for renewal meet the same standards as regards tests methods, it is appropriate that these requirements also apply to application for renewal of authorisation of GM food and feed.

(22) In order to provide an accurate designation of the GM food or feed subject to an application under Regulation (EC) No 1829/2003, applications should include proposals for a unique identifier for each GMO concerned in accordance with Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms[(11)].

(23) This Regulation replaces certain provisions of Regulation (EC) No 641/2004 as regards genetically modified plants for food or feed uses, food or feed containing or consisting of genetically modified plants and food or feed produced from genetically modified plants. However, Regulation (EC) No 641/2004 should continue to apply as regards other types of genetically modified products, namely genetically modified animals and genetically modified micro-organisms. Moreover, certain provisions of that Regulation are obsolete. Regulation (EC) No 641/2004 should therefore be amended accordingly.

(24) Commission Regulation (EC) No 1981/2006 of 22 December 2006 on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the Community reference laboratory for genetically modified organisms[(12)] should be amended to include references to this Regulation.

(25) Regulation (EC) No 1829/2003 provides that the Commission is to consult the EFSA before establishing implementing rules with regard to the applications for authorisation under that Regulation. The EFSA has been consulted on those rules accordingly.

(26) This Regulation has been drawn up on the basis of current scientific and technical knowledge. Therefore, the Commission should monitor any developments in this field and the publication of new or additional guidance by the EFSA.

(27) This Regulation applies to applications submitted after its entry into force. It is necessary to provide for transitional measures in order to enable the applicants to comply with those rules and for the current applications or the applications close to being submitted to proceed without unnecessary delays.

(28) 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: