Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (Text with EEA relevance)

REGULATION (EC) No 1829/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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on genetically modified food and feed

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THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 37, 95 and Article 152(4)(b) thereof,

Having regard to the proposal from the Commission[(1)],

Having regard to the opinion of the European Economic and Social Committee[(2)],

Having regard to the opinion of the Committee of the Regions[(3)],

Acting in accordance with the procedure referred to in Article 251 of the Treaty[(4)],

Whereas:

(1) The free movement of safe and wholesome food and feed is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.

(2) A high level of protection of human life and health should be ensured in the pursuit of Community policies.

(3) In order to protect human and animal health, food and feed consisting of, containing or produced from genetically modified organisms (hereinafter referred to as genetically modified food and feed) should undergo a safety assessment through a Community procedure before being placed on the market within the Community.

(4) Differences between national laws, regulations and administrative provisions concerning the assessment and authorisation of genetically modified food and feed may hinder their free movement, creating conditions of unequal and unfair competition.

(5) An authorisation procedure involving Member States and the Commission has been established for genetically modified foods in Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients[(5)]. This procedure should be streamlined and made more transparent.

(6) Regulation (EC) No 258/97 also provides for a notification procedure for novel foods which are substantially equivalent to existing foods. Whilst substantial equivalence is a key step in the procedure for assessment of the safety of genetically modified foods,

it is not a safety assessment in itself. In order to ensure clarity, transparency and a harmonised framework for authorisation of genetically modified food, this notification procedure should be abandoned in respect of genetically modified foods.

(7) Feed consisting of or containing genetically modified organisms (GMOs) has so far been authorised, subject to the authorisation procedure provided by Council Directive 90/220/EEC of 23 April 1990[(6)] and 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[(7)]; no authorisation procedure exists for feed produced from GMOs; a single, efficient and transparent Community authorisation procedure for feed consisting of, containing or produced from GMOs should be established.

(8) The provisions of this Regulation should also apply to feed intended for animals which are not destined for food production.

(9) The new authorisation procedures for genetically modified food and feed should include the new principles introduced in Directive 2001/18/EC. They should also make use of the new framework for risk assessment in matters of food safety set up by 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[(8)]. Thus, genetically modified food and feed should only be authorised for placing on the Community market after a scientific evaluation of the highest possible standard, to be undertaken under the responsibility of the European Food Safety Authority (Authority), of any risks which they present for human and animal health and, as the case may be, for the environment. This scientific evaluation should be followed by a risk management decision by the Community, under a regulatory procedure ensuring close cooperation between the Commission and the Member States.

(10) Experience has shown that authorisation should not be granted for a single use, when a product is likely to be used both for food and feed purposes; therefore such products should only be authorised when fulfilling authorisation criteria for both food and feed.

(11) Under this Regulation, authorisation may be granted either to a GMO to be used as a source material for production of food or feed and products for food and/or feed use which contain, consist of or are produced from it, or to foods or feed produced from a GMO. Thus, where a GMO used in the production of food and/or feed has been authorised under this Regulation, foods and/or feed containing, consisting of or produced from that GMO will not need an authorisation under this Regulation, but will be subject to the requirements referred to in the authorisation granted in respect of the GMO. Furthermore, foods covered by an authorisation granted under this Regulation will be exempted from the requirements of Regulation (EC) No 258/97 concerning novel foods and novel food ingredients, except where they fall under one or more of the categories referred to in Article 1(2)(a) of Regulation (EC) No 258/97 in respect of a characteristic which has not been considered for the purpose of the authorisation granted under this Regulation.

(12) Council Directive 89/107/EEC of 21 December 1988 on the approximation of laws of the Member States concerning food additives authorised for use in foodstuffs intended

for human consumption[9] provides for authorisation of additives used in foodstuffs. In addition to this authorisation procedure, food additives containing, consisting of or produced from GMOs should fall also within the scope of this Regulation for the safety assessment of the genetic modification, while the final authorisation should be granted under the procedure referred to in Directive 89/107/EEC.

(13) Flavourings falling within the scope of Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production[10] which contain, consist of or are produced from GMOs should also fall within the scope of this Regulation for the safety assessment of the genetic modification.

(14) Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition[11] provides for an approval procedure for feed materials produced using different technologies that may pose risk to human or animal health and the environment. These feed materials containing, consisting of or produced from GMOs should fall instead within the scope of this Regulation.

(15) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs[12], provides for an authorisation procedure for placing on the market additives used in feedingstuffs. In addition to this authorisation procedure, feed additives containing, consisting of or produced from GMOs should also fall within the scope of this Regulation.

(16) This Regulation should cover food and feed produced ‘from’ a GMO but not food and feed ‘with’ a GMO. The determining criterion is whether or not material derived from the genetically modified source material is present in the food or in the feed. Processing aids which are only used during the food or feed production process are not covered by the definition of food or feed and, therefore, are not included in the scope of this Regulation. Nor are food and feed which are manufactured with the help of a genetically modified processing aid included in the scope of this Regulation. Thus, products obtained from animals fed with genetically modified feed or treated with genetically modified medicinal products will be subject neither to the authorisation requirements nor to the labelling requirements referred to in this Regulation.

(17) In accordance with Article 153 of the Treaty, the Community is to contribute to promoting the right of consumers to information. In addition to other types of information to the public provided for in this Regulation, the labelling of products enables the consumer to make an informed choice and facilitates fairness of transactions between seller and purchaser.

(18) Article 2 of Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs[13] provides that labelling must not mislead the purchaser as to the characteristics of the foodstuff and among other things, in particular, as to its nature, identity, properties, composition, method of production and manufacturing.

(19) Additional requirements for the labelling of genetically modified foods are laid down in Regulation (EC) No 258/97, in Council Regulation (EC) No 1139/98 of 26 May 1998 concerning the compulsory indication, on the labelling of certain foodstuffs produced from genetically modified organisms, of particulars other than those provided for in Directive 79/112/EEC[(14)] and in Commission Regulation (EC) No 50/2000 of 10 January 2000 on the labelling of foodstuffs and food ingredients containing additives and flavourings that have been genetically modified or have been produced from genetically modified organisms[(15)].

(20) Harmonised labelling requirements should be laid down for genetically modified feed to provide final users, in particular livestock farmers, with accurate information on the composition and properties of feed, thereby enabling the user to make an informed choice.

(21) The labelling should include objective information to the effect that a food or feed consists of, contains or is produced from GMOs. Clear labelling, irrespective of the detectability of DNA or protein resulting from the genetic modification in the final product, meets the demands expressed in numerous surveys by a large majority of consumers, facilitates informed choice and precludes potential misleading of consumers as regards methods of manufacture or production.

(22) In addition, the labelling should give information about any characteristic or property which renders a food or feed different from its conventional counterpart with respect to composition, nutritional value or nutritional effects, intended use of the food or feed and health implications for certain sections of the population, as well as any characteristic or property which gives rise to ethical or religious concerns.

(23) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC[(16)] ensures that relevant information concerning any genetic modification is available at each stage of the placing on the market of GMOs and food and feed produced therefrom and should thereby facilitate accurate labelling.

(24) Despite the fact that some operators avoid using genetically modified food and feed, such material may be present in minute traces in conventional food and feed as a result of adventitious or technically unavoidable presence during seed production, cultivation, harvest, transport or processing. In such cases, this food or feed should not be subject to the labelling requirements of this Regulation. In order to achieve this objective, a threshold should be established for the adventitious or technically unavoidable presence of genetically modified material in foods or feed, both when the marketing of such material is authorised in the Community and when this presence is tolerated by virtue of this Regulation.

(25) It is appropriate to provide that, when the combined level of adventitious or technically unavoidable presence of genetically modified materials in a food or feed or in one of its components is higher than the set threshold, such presence should be indicated in

accordance with this Regulation and that detailed provisions should be adopted for its implementation. The possibility of establishing lower thresholds, in particular for foods and feed containing or consisting of GMOs or in order to take into account advances in science and technology, should be provided for.

(26) It is indispensable that operators strive to avoid any accidental presence of genetically modified material not authorised under Community legislation in food or feed. However, in order to ensure the practicability and feasibility of this Regulation, a specific threshold, with the possibility of establishing lower levels in particular for GMOs sold directly to the final consumer, should be established as a transitional measure for minute traces in food or feed of this genetically modified material, where the presence of such material is adventitious or technically unavoidable and provided that all specific conditions set in this Regulation are met. Directive 2001/18/EC should be amended accordingly. The application of this measure should be reviewed in the context of the general review of the implementation of this Regulation.

(27) In order to establish that the presence of this material is adventitious or technically unavoidable, operators must be in a position to demonstrate to the competent authorities that they have taken appropriate steps to avoid the presence of the genetically modified food or feed.

(28) Operators should avoid the unintended presence of GMOs in other products. The Commission should gather information and develop on this basis guidelines on the coexistence of genetically modified, conventional and organic crops. Moreover, the Commission is invited to bring forward, as soon as possible, any further necessary proposal.

(29) The traceability and labelling of GMOs at all stages of placing on the market, including the possibility of establishing thresholds, is ensured by Directive 2001/18/EC and Regulation (EC) No 1830/2003.

(30) It is necessary to establish harmonised procedures for risk assessment and authorisation that are efficient, time-limited and transparent, and criteria for evaluation of the potential risks arising from genetically modified foods and feed.

(31) In order to ensure a harmonised scientific assessment of genetically modified foods and feed, such assessments should be carried out by the Authority. However, as specific acts or omissions on the part of the Authority under this Regulation could produce direct legal effects on applicants, it is appropriate to provide for the possibility of an administrative review of such acts or omissions.

(32) It is recognised that, in some cases, scientific risk assessment alone cannot provide all the information on which a risk management decision should be based, and that other legitimate factors relevant to the matter under consideration may be taken into account.

(33) Where the application concerns products containing or consisting of a genetically modified organism, the applicant should have the choice of either supplying an authorisation for the deliberate release into the environment already obtained under part C of Directive 2001/18/EC, without prejudice to the conditions set by that authorisation, or of applying for the environmental risk assessment to be carried out at the same

time as the safety assessment under this Regulation. In the latter case, it is necessary for the evaluation of the environmental risk to comply with the requirements referred to in Directive 2001/18/EC and for the national competent authorities designated by Member States for this purpose to be consulted by the Authority. In addition, it is appropriate to give the Authority the possibility of asking one of these competent authorities to carry out the environmental risk assessment. It is also appropriate, in accordance with Article 12(4) of Directive 2001/18/EC, for the national competent authorities designated under the said Directive in all cases concerning GMOs and food and/or feed containing or consisting of a GMO to be consulted by the Authority before it finalises the environmental risk assessment.

(34) In the case of GMOs to be used as seeds or other plant-propagating materials falling within the scope of this Regulation, the Authority should be under an obligation to delegate the environmental risk assessment to a national competent authority. Nonetheless, authorisations under this Regulation should be without prejudice to the provisions of Directives 68/193/EEC[(17)], 2002/53/EC[(18)] and 2002/55/EC[(19)], which provide in particular for the rules and the criteria for the acceptance of varieties and their official acceptance for inclusion in common catalogues; nor should they affect the provisions of Directives 66/401/EEC[(20)], 66/402/EEC[(21)], 68/193/EEC, 92/33/EEC[(22)], 92/34/EEC[(23)], 2002/54/EC[(24)], 2002/55/EC, 2002/56/EC[(25)] or 2002/57/EC[(26)] which regulate in particular the certification and the marketing of seeds and other plant-propagating materials.

(35) It is necessary to introduce, where appropriate and on the basis of the conclusions of the risk assessment, post-market monitoring requirements for the use of genetically modified foods for human consumption and for the use of genetically modified feed for animal consumption. In the case of GMOs, a monitoring plan concerning environmental effects is compulsory under Directive 2001/18/EC.

(36) To facilitate controls on genetically modified food and feed, applicants for authorisation should propose appropriate methods for sampling, identification and detection, and deposit samples of the genetically modified food and feed with the Authority; methods of sampling and detection should be validated, where appropriate, by the Community reference laboratory.

(37) Technological progress and scientific developments should be taken into account when implementing this Regulation.

(38) Food and feed falling within the scope of this Regulation which have been lawfully placed on the Community market before the date of application of this Regulation should continue to be allowed on the market, subject to the transmission to the Commission by the operators of information concerning the risk assessment, methods for sampling, identification and detection as appropriate, including the transmission of samples of the food and feed and their control samples within six months after the date of application of this Regulation.

(39) A register of genetically modified food and feed authorised under this Regulation should be established, including product specific information, studies which demonstrate the safety of the product, including, where available, references to independent and peer-

reviewed studies, and to methods for sampling, identification and detection. Non-confidential data should be made available to the public.

(40) In order to stimulate research and development into GMOs for food and/or feed use, it is appropriate to protect the investment made by innovators in gathering the information and data supporting an application under this Regulation. This protection should however be limited in time in order to avoid the unnecessary repetition of studies and trials which would be against the public interest.

(41) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[(27)].

(42) Provision should be made for consultation of the European Group on Ethics in Science and New Technologies established by Commission Decision of 16 December 1997, or any other appropriate body established by the Commission, with a view to obtaining advice on ethical issues regarding the placing on the market of genetically modified food or feed. Such consultations should be without prejudice to the competence of Member States as regards ethical issues.

(43) In order to provide a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, requirements arising from this Regulation should apply in a non-discriminatory manner to products originating in the Community and imported from third countries, in accordance with the general principles referred to in Regulation (EC) No 178/2002. The content of this Regulation takes account of the international trade commitments of the European Communities and of the requirements of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity as regards importer obligations and notification.

(44) Certain instruments of Community law should be repealed and others amended as a result of this Regulation.

(45) The implementation of this Regulation should be reviewed in the light of experience gained in the short term, and the impact of the application of this Regulation on human and animal health, consumer protection, consumer information and the functioning of the internal market should be monitored by the Commission,

HAVE ADOPTED THIS REGULATION:

(**1**) OJ C 304 E, 30.10.2001, p. 221.

(**2**) OJ C 221, 17.9.2002, p. 114.

(**3**) OJ C 278, 14.11.2002, p. 31.

(**4**) Opinion of the European Parliament of 3 July 2002 (not yet published in the Official Journal), Council Common Position of 17 March 2003 (OJ C 113 E, 13.5.2003, p. 31), Decision of the European Parliament of 2 July 2003 (not yet published in the Official Journal) and Council Decision of 22 July 2003.

(**5**) OJ L 43, 14.2.1997, p. 1.

(**6**) OJ L 117, 8.5.1990, p. 15. Directive repealed by Directive 2001/18/EC.

(**7**) OJ L 106, 17.4.2001, p. 1. Directive as last amended by Council Decision 2002/811/EC (OJ L 280, 18.10.2002, p. 27).

(**8**) OJ L 31, 1.2.2002, p. 1.

(**9**) OJ L 40, 11.2.1989, p. 27. Directive as amended by Directive 94/34/EC of the European Parliament and of the Council (OJ L 237, 10.9.1994, p. 1).

(**10**) OJ L 184, 15.7.1988, p. 61. Directive as amended by Commission Directive 91/71/EEC (OJ L 42, 15.2.1991, p. 25).

(**11**) OJ L 213, 21.7.1982, p. 8. Directive as last amended by Directive 1999/20/EC (OJ L 80, 25.3.1999, p. 20).

(**12**) 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).

(**13**) OJ L 109, 6.5.2000, p. 29. Directive as amended by Commission Directive 2001/101/EC (OJ L 310, 28.11.2001, p. 19).

(**14**) OJ L 159, 3.6.1998, p. 4. Regulation as amended by Commission Regulation (EC) No 49/2000 (OJ L 6, 11.1.2000, p. 13).

(**15**) OJ L 6, 11.1.2000, p. 15.

(**16**) See page 24 of this Official Journal.

(**17**) OJ L 93, 17.4.1968, p. 15. Directive as last amended by Directive 2002/11/EC (OJ L 53, 23.2.2002, p. 20).

(**18**) OJ L 193, 20.7.2002, p. 1.

(**19**) OJ L 193, 20.7.2002, p. 33.

(**20**) OJ 125, 11.7.1966, p. 2298/66. Directive as last amended by Directive 2001/64/EC (OJ L 234, 1.9.2001, p. 60).

(**21**) OJ 125, 11.7.1966, p. 2309/66. Directive as last amended by Directive 2001/64/EC.

(**22**) OJ L 157, 10.6.1992, p. 1. Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

(**23**) OJ L 157, 10.6.1992, p. 10. Directive as last amended by Regulation (EC) No 806/2003.

(**24**) OJ L 193, 20.7.2002, p. 12.

(**25**) OJ L 193, 20.7.2002, p. 60. Directive amended by Commission Decision 2003/66/EC (OJ L 25, 30.1.2003, p. 42).

(**26**) OJ L 193, 20.7.2002, p. 74. Directive amended by Commission Directive 2003/45/EC (OJ L 138, 5.6.2003, p. 40).

(**27**) OJ L 184, 17.7.1999, p. 23.

Changes to legislation:
There are outstanding changes not yet made to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

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

- Art. 5para. 3 Point (m) addition by EUR 2019/1381 Regulation (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Art. 5para. 3 Text replacement by EUR 2019/1381 Regulation (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Art. 5para. 3 Point (l) replacement by EUR 2019/1381 Regulation (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Art. 6para. 7 replacement by EUR 2019/1381 Regulation (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Art. 10para. 1 replacement by EUR 2019/1381 Regulation (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Art. 11para. 2 Text replacement by EUR 2019/1381 Regulation (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Art. 17para. 3 Point (m) addition by EUR 2019/1381 Regulation (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Art. 17para. 3 Point (l) replacement by EUR 2019/1381 Regulation (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Art. 17para. 3 Text replacement by EUR 2019/1381 Regulation (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Art. 18para. 7 replacement by EUR 2019/1381 Regulation (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Art. 22para. 1 replacement by EUR 2019/1381 Regulation (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Art. 23para. 2 Text replacement by EUR 2019/1381 Regulation (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Art. 29para. 2 replacement by EUR 2019/1381 Regulation (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Art. 29para. 1 replacement by EUR 2019/1381 Regulation (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Art. 35(4)(d) words substituted by S.I. 2019/1013 reg. 30 (This amendment not applied to legislation.gov.uk. S.I. 2019/1013 revoked immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 21(e))