

Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (repealed)

[^{X1}REGULATION (EC) No 882/2004 OF THE
EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 29 April 2004

on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules] (repealed)

[^{X1}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 152(4)(b) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee⁽¹⁾,

Having regard to the opinion of the Committee of the Regions⁽²⁾,

Acting in accordance with the procedure laid down in Article 251 of the Treaty⁽³⁾,

Whereas:

- (1) Feed and food should be safe and wholesome. Community legislation comprises a set of rules to ensure that this objective is attained. These rules extend to the production and the placing on the market of both feed and food.
- (2) The basic rules with regard to feed and food law are 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⁽⁴⁾.
- (3) In addition to those basic rules, more specific feed and food law covers different areas such as animal nutrition including medicated feedingstuffs, feed and food hygiene, zoonoses, animal by-products, residues and contaminants, control and eradication of animal diseases with a public health impact, feed and food labelling, pesticides, feed and food additives, vitamins, mineral salts, trace elements and other additives, materials in contact with food, quality and compositional requirements, drinking water, ionisation, novel foods and genetically modified organisms (GMOs).
- (4) Community feed and food law is based on the principle that feed and food business operators at all stages of production, processing and distribution within the businesses under their control are responsible for ensuring that feed and food satisfy the requirements of feed and food law which are relevant to their activities.
- (5) Animal health and animal welfare are important factors that contribute to the quality and safety of food, to the prevention of the spreading of animal diseases and to a humane

Status: Point in time view as at 01/01/2012.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 882/2004 of the European Parliament and of the Council (repealed), Introductory Text. (See end of Document for details)

treatment of animals. The rules covering these matters are laid down in several acts. These acts specify the obligations of natural and legal persons with regard to animal health and animal welfare as well as the duties of the competent authorities.

- (6) The Member States should enforce feed and food law, animal health and animal welfare rules and monitor and verify that the relevant requirements thereof are fulfilled by business operators at all stages of production, processing and distribution. Official controls should be organised for that purpose.
- (7) It is therefore appropriate to establish at Community level a harmonised framework of general rules for the organisation of such controls. It is appropriate to assess in the light of experience whether such a general framework functions properly, in particular in the area of animal health and welfare. It is therefore appropriate for the Commission to present a report together with any necessary proposal.
- (8) As a general rule this Community framework should not include official controls with regard to organisms harmful to plants and plant products since these controls are already adequately covered by Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community⁽⁵⁾. Certain aspects of this Regulation should however also apply to the plant health sector and in particular those concerning the establishment of multiannual national control plans and Community inspections within the Member States and in third countries. It is therefore appropriate to amend Directive 2000/29/EC accordingly.
- (9) Council Regulations (EEC) No 2092/91 of 24 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs⁽⁶⁾, (EEC) No 2081/92 of 14 July 1992 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs⁽⁷⁾, and (EEC) No 2082/92 of 14 July 1992 on certificates of specific character for agricultural products and foodstuffs⁽⁸⁾ contain specific measures for the verification of compliance with the requirements contained therein. The requirements of this Regulation should be flexible enough so as to take account of the specificity of these areas.
- (10) For the verification of compliance with the rules on the common organisation of the markets of agricultural products (arable crops, wine, olive oil, fruit and vegetables, hops, milk and milk products, beef and veal, sheepmeat and goatmeat and honey) a well established and specific control system is already in place. This Regulation should therefore not apply to these areas, all the more since the objectives of this Regulation differ from the objectives pursued by the control mechanisms for the common organisation of the markets of agricultural products.
- (11) The competent authorities for performing official controls should meet a number of operational criteria so as to ensure their impartiality and effectiveness. They should have a sufficient number of suitably qualified and experienced staff and possess adequate facilities and equipment to carry out their duties properly.
- (12) The official controls should be carried out using appropriate techniques developed for that purpose, including routine surveillance checks and more intensive controls

Status: Point in time view as at 01/01/2012.

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such as inspections, verifications, audits, sampling and the testing of samples. The correct implementation of those techniques requires appropriate training of the staff performing official controls. Training is also required in order to ensure that the competent authorities take decisions in a uniform way, in particular with regard to the implementation of the hazard analysis and critical control points (HACCP) principles.

- (13) The frequency of official controls should be regular and proportionate to the risk, taking into account the results of the checks carried out by feed and food business operators under HACCP based control programmes or quality assurance programmes, where such programmes are designed to meet requirements of feed and food law, animal health and animal welfare rules. Ad hoc controls should be carried out in case of suspicion of non-compliance. Additionally ad hoc controls could be carried out at any time, even where there is no suspicion of non-compliance.
- (14) Official controls should take place on the basis of documented procedures so as to ensure that these controls are carried out uniformly and are of a consistently high quality.
- (15) The competent authorities should ensure that where different control units are involved in carrying out official controls, appropriate coordination procedures are in place and effectively implemented.
- (16) The competent authorities should also ensure that, where the competence to carry out official controls has been delegated from the central level to a regional or local level, there is effective and efficient coordination between the central level and that regional or local level.
- (17) Laboratories involved in the analysis of official samples should work in accordance with internationally approved procedures or criteria-based performance standards and use methods of analysis that have, as far as possible, been validated. Such laboratories should in particular have equipment that enables the correct determination of standards such as maximum residue levels fixed by Community law.
- (18) The designation of Community and national reference laboratories should contribute to a high quality and uniformity of analytical results. This objective can be achieved by activities such as the application of validated analytical methods, ensuring that reference materials are available, the organisation of comparative testing and the training of staff from laboratories.
- (19) The activities of reference laboratories should cover all the areas of feed and food law and animal health, in particular those areas where there is a need for precise analytical and diagnostic results.
- (20) For a number of activities related to official controls, the European Committee for Standardisation (CEN) has developed European standards (EN standards) appropriate for the purpose of this Regulation. These EN standards relate in particular to the operation and assessment of testing laboratories and to the operation and accreditation of control bodies. International standards have also been drawn up by the International Organisation for Standardisation (ISO) and the International Union of Pure and Applied Chemistry (IUPAC). These standards might, in certain well defined cases, be appropriate for the purposes of this Regulation, taking into account that performance

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criteria are laid down in feed and food law in order to ensure flexibility and cost effectiveness.

- (21) Provision should be made for delegating competence for performing specific control tasks from the competent authority to a control body, and for the conditions under which such delegation can take place.
- (22) Appropriate procedures should be available for the cooperation of the competent authorities in and between the Member States, in particular when official controls reveal that feed and food problems extend to more than one Member State. In order to facilitate such cooperation, Member States should designate one or more liaison bodies with the role of coordinating the transmission and reception of requests for assistance.
- (23) In accordance with Article 50 of Regulation (EC) No 178/2002, the Member States shall inform the Commission where information relating to the existence of a serious direct or indirect risk to human health deriving from food or feed is available.
- (24) It is important to create uniform procedures for the control of feed and food from third countries introduced into the territory of the Community, taking into account that harmonised import procedures have already been established for food of animal origin by virtue of Council Directive 97/78/EC⁽⁹⁾, and for live animals by virtue of Council Directive 91/496/EEC⁽¹⁰⁾.
These existing procedures function properly and should be maintained.
- (25) The checks on feed and food from third countries referred to in Directive 97/78/EC are limited to veterinary aspects. It is necessary to supplement these checks with official controls on aspects that are not covered by veterinary checks, such as those on additives, labelling, traceability, irradiation of food and materials in contact with food.
- (26) Community legislation also provides for procedures for the control of imported feed by virtue of Council Directive 95/53/EC of 25 October 1995 fixing the principles governing the organisation of official inspections in the field of animal nutrition⁽¹¹⁾. That Directive contains principles and procedures that must be applied by the Member States when releasing imported feed for free circulation.
- (27) It is appropriate to establish Community rules in order to ensure that feed and food from third countries is submitted to official controls before release for free circulation in the Community. Special attention should be paid to import controls of feed and food for which there may be an increased risk of contamination.
- (28) Provision should also be made for the organisation of official controls of feed and food that is introduced into the territory of the Community under customs procedures other than free circulation, and in particular those introduced under the customs procedures referred to in points (b) to (f) of Article 4(16) of Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code⁽¹²⁾, as well as their entry into a free zone or free warehouse. This includes the introduction of feed and food from third countries by passengers of international means of transport and through parcels sent by mail.

Status: Point in time view as at 01/01/2012.

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- (29) For the purpose of official controls on feed and food, it is necessary to define the territory of the Community in which the rules apply in order to ensure that feed and food that is introduced into this territory is submitted to the controls laid down by this Regulation. This territory is not necessarily the same as provided for in Article 299 of the Treaty, or as defined in Article 3 of Regulation (EEC) No 2913/92.
- (30) In order to ensure a more efficient organisation of the official controls on feed and food from third countries and in order to facilitate commercial flows, it may be necessary to designate specific points of entry for feed and food from third countries into the territory of the Community. Likewise, it may be necessary to require prior notification of the arrival of goods at the territory of the Community. It should be ensured that each designated point of entry has access to the appropriate facilities to operate controls within reasonable time limits.
- (31) In establishing rules on the official controls of feed and food from third countries, it should be ensured that the competent authorities and the customs services work together, taking into account the fact that rules to that effect already exist in Council Regulation (EEC) No 339/93 of 8 February 1993 on checks for conformity with the rules on product safety in the case of products imported from third countries⁽¹³⁾.
- (32) Adequate financial resources should be available for organising official controls. Hence, the competent authorities of the Member States should be able to levy the fees or charges to cover the costs incurred through official controls. In the process, the competent authorities of the Member States will be at liberty to establish the fees and charges as flat-rate amounts based on the costs incurred and taking the specific situation of the establishments into account. Where fees are imposed on operators, common principles should apply. It is appropriate therefore to lay down the criteria for setting the level of inspection fees. With regard to fees applicable for import controls, it is appropriate to establish directly the rates for main import items with a view to ensuring their uniform application and to avoiding trade distortions.
- (33) Community feed and food law provides for the registration or approval of certain feed and food businesses by the competent authority. This is particularly the case in Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs⁽¹⁴⁾, Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin⁽¹⁴⁾, Council Directive 95/69/EC of 22 December 1995 laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector⁽¹⁵⁾ and the future regulation on feed hygiene.
Procedures should be put in place in order to ensure that registration and approval of feed and food businesses are carried out in an effective and transparent way.
- (34) In order to have a global and uniform approach with regard to official controls, Member States should establish and implement multiannual national control plans in accordance with broad guidelines drawn up at Community level. These guidelines should promote coherent national strategies, and identify risk-based priorities and the most effective control procedures. A Community strategy should take a comprehensive, integrated

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approach to the operation of controls. In view of the non-binding character of certain technical guidelines to be established it is appropriate to establish them by means of a consultative Committee procedure.

- (35) The multiannual national control plans should cover feed and food law, and the legislation on animal health and animal welfare.
- (36) The multiannual national control plans should establish a solid basis for the Commission inspection services to carry out controls in the Member States. The control plans should enable the Commission inspection services to verify whether the official controls in the Member States are organised in accordance with the criteria laid down in this Regulation. Where appropriate and, in particular, where the audit of the Member States against the multiannual national control plans shows weaknesses or failures, detailed inspections and audits should be carried out.
- (37) Member States should be required to present an annual report to the Commission with information on the implementation of the multiannual national control plans. This report should provide the results of the official controls and audits carried out during the previous year and, where necessary, an update of the initial control plan in response to these results.
- (38) Community controls in the Member States should allow the Commission control services to verify whether feed and food law and the legislation on animal health and animal welfare are implemented in a uniform and correct way throughout the Community.
- (39) Community controls in third countries are required in order to verify compliance or equivalence with Community feed and food law as well as with the legislation on animal health and, where appropriate, welfare. Third countries may also be requested to provide information on their control systems. This information, which should be established on the basis of Community guidelines, should form the basis for subsequent Commission controls, which should be carried out within a multidisciplinary framework covering the main sectors exporting to the Community. This evolution should allow a simplification of the current regime, enhance effective control cooperation, and consequently facilitate trade flows.
- (40) In order to ensure that imported goods comply with or are equivalent to Community feed and food law, it is necessary to establish procedures that allow the definition of import conditions and certification requirements as appropriate.
- (41) Breaches of feed and food law and of animal health and animal welfare rules may constitute a threat to human health, animal health, and animal welfare. Such breaches should therefore be subject to effective, dissuasive and proportionate measures at national level throughout the Community.
- (42) Such measures should include administrative action by the competent authorities in the Member States who should have procedures in place for that purpose. The advantage of such procedures is that quick action can be undertaken in order to restore the situation.

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- (43) Operators should have a right to appeal against the decisions taken by the competent authority as a result of the official controls, and be informed of such a right.
- (44) It is appropriate to take account of the special needs of developing countries, and in particular of the least-developed countries, and to introduce measures to that effect. The Commission should be committed to support developing countries with regard to feed and food safety, which is an important element of human health and trade development. Such support should be organised in the context of the Community's development cooperation policy.
- (45) The rules contained in this Regulation underpin the integrated and horizontal approach necessary to implement a coherent control policy on feed and food safety, animal health and animal welfare. There should be room however to develop specific control rules where required, for example with regard to the setting of maximum residue levels for certain contaminants at Community level. Likewise, more specific rules existing in the area of feed and food and animal health and animal welfare controls should be kept in place.
- These include in particular the following acts: Directive 96/22/EC Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in⁽¹⁶⁾, Directive 96/23/EC⁽¹⁷⁾, Regulation (EC) No 854/2004⁽¹⁸⁾, Regulation (EC) No 999/2001⁽¹⁹⁾, Regulation (EC) No 2160/2003⁽²⁰⁾, Directive 86/362/EEC⁽²¹⁾, Directive 90/642/EEC⁽²²⁾ and the implementing rules resulting therefrom, Directive 92/1/EEC⁽²³⁾, Directive 92/2/EEC⁽²⁴⁾, and acts on the control of animal diseases such as foot-and-mouth disease, swine fever etc., as well as requirements on the official controls on the welfare of animals.
- (46) This Regulation covers areas that are already covered in certain acts in force at present. It is appropriate therefore to repeal in particular the following acts on feed and food controls and to replace them by the rules of this Regulation: Directive 70/373/EEC⁽²⁵⁾; Directive 85/591/EEC⁽²⁶⁾; Directive 89/397/EEC⁽²⁷⁾; Directive 93/99/EEC⁽²⁸⁾; Decision 93/383/EEC⁽²⁹⁾; Directive 95/53/EC; Directive 96/43/EC⁽³⁰⁾; Decision 98/728/EC⁽³¹⁾; and Decision 1999/313/EC⁽³²⁾.
- (47) In the light of this Regulation, Directives 96/23/EC, 97/78/EC and 2000/29/EC should be amended.
- (48) Since the objective of this Regulation, namely to ensure a harmonised approach with regard to official controls, cannot be sufficiently achieved by the Member States and can therefore, by reason of its complexity, its trans-border character and, with regard to feed and food imports, its international character, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.
- (49) 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⁽³³⁾,

HAVE ADOPTED THIS REGULATION:]

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- (1) ^[^{XI}][OJ C 234, 30.9.2003, p. 25.](#)
- (2) [OJ C 23, 27.1.2004, p. 14.](#)
- (3) Opinion of the European Parliament of 9 March 2004 (not yet published in the Official Journal) and Council Decision of 26 April 2004.
- (4) [OJ L 31, 1.2.2002, p. 1.](#) Regulation as last amended by Regulation (EC) No 1642/2003 ([OJ L 245, 29.9.2003, p. 4.](#)).
- (5) [OJ L 169, 10.7.2000, p. 1.](#) Directive as last amended by Commission Directive 2004/31/EC ([OJ L 85, 23.3.2004, p. 18.](#)).
- (6) [OJ L 198, 22.7.1991, p. 1.](#) Regulation as last amended by Regulation (EC) No 392/2004 ([OJ L 65, 3.3.2004, p. 1.](#)).
- (7) [OJ L 208, 24.7.1992, p. 1.](#) Regulation as last amended by Regulation (EC) No 806/2003 ([OJ L 122, 16.5.2003, p. 1.](#)).
- (8) [OJ L 208, 24.7.1992, p. 9.](#) Regulation as last amended by Regulation (EC) No 806/2003.
- (9) Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries ([OJ L 24, 30.1.1998, p. 9.](#)).
- (10) Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organisation of veterinary checks on animals entering the Community from third countries ([OJ L 268, 24.9.1991, p. 56.](#)). Directive as last amended by Directive 96/43/EC ([OJ L 162, 1.7.1996, p. 1.](#)).
- (11) [OJ L 265, 8.11.1995, p. 17.](#) Directive as last amended by Directive 2001/46/EC of the European Parliament and of the Council ([OJ L 234, 1.9.2001, p. 55.](#)).
- (12) [OJ L 302, 19.10.1992, p. 1.](#) Regulation as last amended by Regulation (EC) No 2700/2000 of the European Parliament and of the Council ([OJ L 311, 12.12.2000, p. 17.](#)).
- (13) [OJ L 40, 17.2.1993, p. 1.](#) Regulation as last amended by Regulation (EC) No 806/2003.
- (14) [OJ L 139, 30.4.2004, p. 55.](#)
- (15) [OJ L 332, 30.12.1995, p. 15.](#) Directive as last amended by Regulation (EC) No 806/2003.
- (16) stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, ([OJ L 125, 23.5.1996, p. 3.](#)). Directive as last amended by Directive 2003/74/EC of the European Parliament and of the Council ([OJ L 262, 14.10.2003, p. 17.](#)).
- (17) Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products ([OJ L 125, 23.5.1996, p. 10.](#)). Directive as last amended by Regulation (EC) No 806/2003.
- (18) Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption ([OJ L 139, 30.4.2004, p. 206.](#)).
- (19) Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies ([OJ L 147, 31.5.2001, p. 1.](#)). Regulation as last amended by Commission Regulation (EC) No 2245/2003 ([OJ L 333, 20.12.2003, p. 28.](#)).
- (20) Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other food-borne zoonotic agents ([OJ L 325, 12.12.2003, p. 1.](#)).
- (21) Council Directive 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals ([OJ L 221, 7.8.1986, p. 37.](#)). Directive as last amended by Commission Directive 2004/2/EC ([OJ L 14, 21.1.2004, p. 10.](#)).
- (22) Council Directive 90/642/EEC of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables ([OJ L 350, 14.12.1990, p. 71.](#)). Directive as last amended by Commission Directive 2004/2/EC.

Status: Point in time view as at 01/01/2012.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 882/2004 of the European Parliament and of the Council (repealed), Introductory Text. (See end of Document for details)

- (23) Commission Directive 92/1/EEC of 13 January 1992 on the monitoring of temperatures in the means of transport, warehousing and storage of quick-frozen foodstuffs intended for human consumption ([OJ L 34, 11.2.1992, p. 28](#)).
- (24) Commission Directive 92/2/EEC of 13 January 1992 laying down the sampling procedure and the Community method of analysis for the official control of the temperatures of quick-frozen foods intended for human consumption ([OJ L 34, 11.2.1992, p. 30](#)).
- (25) Council Directive 70/373/EEC of 20 July 1970 on the introduction of Community methods of sampling and analysis for the official control of feedingstuffs ([OJ L 170, 3.8.1970, p. 2](#)). Directive as last amended by Regulation (EC) No 807/2003 ([OJ L 122, 16.5.2003, p. 36](#)).
- (26) Council Directive 85/591/EEC of 20 December 1985 concerning the introduction of Community methods of sampling and analysis for the monitoring of foodstuffs intended for human consumption ([OJ L 372, 31.12.1985, p. 50](#)). Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council ([OJ L 284, 31.10.2003, p. 1](#)).
- (27) Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs ([OJ L 186, 30.6.1989, p. 23](#)).
- (28) Council Directive 93/99/EEC of 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs ([OJ L 290, 24.11.1993, p. 14](#)). Directive as amended by Regulation (EC) No 1882/2003.
- (29) Council Decision 93/383/EEC of 14 June 1993 of reference laboratories for the monitoring of marine biotoxins ([OJ L 166, 8.7.1993, p. 31](#)). Decision as amended by Decision 1999/312/EC ([OJ L 120, 8.5.1999, p. 37](#)).
- (30) Council Directive 96/43/EC of 26 June 1996 amending and consolidating Directive 85/73/EEC in order to ensure financing of veterinary inspections and controls on live animals and certain animal products ([OJ L 162, 1.7.1996, p. 1](#)).
- (31) Council Decision 98/728/EC of 14 December 1998 concerning a Community system for fees in the animal feed sector ([OJ L 346, 22.12.1998, p. 51](#)).
- (32) Council Decision 1999/313/EC of 29 April 1999 on reference laboratories for monitoring bacteriological and viral contamination of bivalve molluscs ([OJ L 120, 8.5.1999, p. 40](#)).
- (33) [OJ L 184, 17.7.1999, p. 23](#).]

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