Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (Text with EEA relevance)

REGULATION (EU) 2017/625 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 15 March 2017

on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43(2), Article 114 and Article 168(4)(b) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

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 ordinary legislative procedure[(3)],

Whereas:

(1) The Treaty on the Functioning of the European Union (TFEU) requires a high level of protection of human and animal health and of the environment to be ensured in the

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definition and implementation of Union policies and activities. The achievement of that objective should, inter alia, be pursued via measures in the veterinary and phytosanitary fields which have as their final objective the protection of human health.

(2) The TFEU also provides that the Union is to contribute to the attainment of a high level of consumer protection by the measures it adopts in the context of the completion of the internal market.

(3) Union legislation provides for a set of harmonised rules to ensure that food and feed are safe and wholesome, and that activities which might have an impact on the safety of the agri-food chain or on the protection of consumers' interests in relation to food and food information are performed in accordance with specific requirements. Union rules exist also to ensure a high level of human, animal and plant health as well as animal welfare along the agri-food chain and in all those areas of activity where a key objective is the fight against the possible spread of animal diseases, in some cases transmissible to humans, or of pests injurious to plants or plant products, and to ensure the protection of the environment from risks that might arise from genetically modified organisms (GMOs) or plant protection products. The correct application of those rules, hereinafter collectively referred to as 'Union agri-food chain legislation', contributes to the functioning of the internal market.

(4) The basic Union rules with regard to food and feed law are laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council[(4)]. In addition to those basic rules, more specific food and feed law covers different areas such as animal nutrition, including medicated feedingstuffs, food and feed hygiene, zoonoses, animal by-products, residues of veterinary medicinal products, contaminants, control and eradication of animal diseases with a human health impact, food and feed labelling, plant protection products, food and feed additives, vitamins, mineral salts, trace elements and other additives, food contact materials, quality and compositional requirements, drinking water, ionisation, novel foods and GMOs.

(5) Union legislation on animal health aims to ensure high standards of human and animal health in the Union, the rational development of the agriculture and aquaculture sectors, and to increase productivity. That legislation is necessary to contribute to the completion of the internal market for animals and animal products and to avoid the spread of infectious diseases of Union concern. It covers areas that include intra-Union trade, entry into the Union, disease eradication, veterinary controls and notification of diseases, and also contributes to the safety of food and feed.

(6) Transmissible animal diseases, including by micro-organisms that have developed resistance to antimicrobials, may have a significant impact on public health, food and feed safety, and animal health and welfare. In order to ensure high standards of animal and public health in the Union, rules on animal health measures and on feed and food safety are laid down at Union level. Compliance with those rules, including the rules that are intended to tackle the problem of antimicrobial resistance, should be subjected to the official controls provided for in this Regulation. Additionally, Union legislation provides for rules on the placing on the market and use of veterinary medicinal products which contribute to coherent action at Union level directed at enforcing the prudent

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use of antimicrobials at farm level and at minimising the development of antimicrobial resistance in animals and its transmission through food of animal origin. Actions number 2 and 3 advocated by the Communication of 15 November 2011 from the Commission to the European Parliament and to the Council entitled 'Action plan against the rising threats from Antimicrobial Resistance' emphasise the essential role played by the specific Union rules in the area of veterinary medicinal products. Compliance with those specific rules should be subjected to the controls provided for in that Union legislation and, therefore, does not fall within the scope of this Regulation.

(7) Article 13 TFEU recognises that animals are sentient beings. Union legislation on animal welfare requires animal owners, animal keepers and competent authorities to respect welfare requirements of animals to ensure their humane treatment and avoid causing them unnecessary pain and suffering. Those rules are based on scientific evidence and may improve the quality and safety of food of animal origin.

(8) Union legislation on plant health regulates the entry, establishment and spread of pests of plants that do not exist, or are not widely present, in the Union. Its objective is to protect the health of Union crops and of public and private green space and forests while simultaneously safeguarding the Union's biodiversity and environment, and ensure the quality of plants and plant products and safety of food and feed made from plants.

(9) Union legislation on plant protection products regulates the authorisation, placing on the market, use and control of plant protection products and of any active substances, safeners, synergists, co-formulants and adjuvants, which they might contain or of which they might consist. The objective of those rules is to ensure a high level of protection of both human and animal health and of the environment through evaluation of the risks posed by plant protection products, while improving the functioning of the Union market through harmonisation of the rules for their placing on the market and while also improving agricultural production.

(10) Directive 2001/18/EC of the European Parliament and of the Council[(5)] and Regulation (EC) No 1829/2003 of the European Parliament and of the Council[(6)] provide for the prior authorisation, traceability and labelling of GMOs and genetically modified food and feed. GMOs which are not for the purpose of direct consumption, such as seeds used as source material for the production of food and feed, are able to be authorised under Directive 2001/18/EC or under Regulation (EC) No 1829/2003. Irrespective of the legal basis under which GMOs could be authorised, the same rules on official controls should apply.

(11) Union legislation on organic production and labelling of organic products provides a basis for the sustainable development of organic production and aims to contribute to the protection of natural resources, biodiversity and animal welfare, and the development of rural areas.

(12) Union legislation on agricultural quality schemes for agricultural products and foodstuffs identifies products and foodstuffs farmed and produced to exact specifications whilst encouraging diverse agricultural production, protecting product names and informing consumers about the specific character of agricultural products and foodstuffs.

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(13) Union agri-food chain legislation is based on the principle that operators at all the stages of production, processing and distribution which are under their control are responsible for ensuring compliance with the requirements relevant to their activities established by Union agri-food chain legislation.

(14) Union rules on marketing standards for fishery and aquaculture products ensure sustainable products and the realisation of the full potential of the internal market; they facilitate marketing activities based on fair competition, thereby helping to improve the profitability of production. These rules ensure compliance with the same requirement both for imports and products originating from within the Union. Union rules on marketing standards for agricultural products contribute to improving the economic conditions for the production and marketing and the quality of such products.

(15) The responsibility to enforce Union agri-food chain legislation lies with Member States, whose competent authorities monitor and verify, through the organisation of official controls, that relevant Union requirements are effectively complied with and enforced.

(16) Regulation (EC) No 882/2004 of the European Parliament and of the Council[(7)] has established a single legislative framework for the organisation of official controls. That framework has significantly improved the efficiency of official controls, the enforcement of Union agri-food chain legislation and the level of protection against risks to human, animal and plant health and animal welfare in the Union and the level of protection of the environment from risks that might arise from GMOs and plant protection products. It has also provided a consolidated legal framework to support an integrated approach towards the performance of official controls along the agri-food chain.

(17) There are a number of provisions in Union agri-food chain legislation, the enforcement of which has not, or has only partially, been governed by Regulation (EC) No 882/2004. In particular, specific official control rules were kept in place in Regulation (EC) No 1069/2009 of the European Parliament and of the Council[(8)]. Plant health also largely falls outside the scope of Regulation (EC) No 882/2004 with certain rules on official controls being laid down in Council Directive 2000/29/EC[(9)].

(18) Council Directive 96/23/EC[(10)] also provides a very detailed set of rules that establish inter alia the minimum frequency of official controls and specific enforcement measures to be adopted in cases of non-compliance.

(19) In order to rationalise and simplify the overall legislative framework, whilst simultaneously pursuing the objective of better regulation, the rules applicable to official controls in specific areas should be integrated into a single legislative framework for official controls. For that purpose, Regulation (EC) No 882/2004 and other Union acts currently governing official controls in specific areas should be repealed and replaced by this Regulation.

(20) This Regulation should seek to establish a harmonised Union framework for the organisation of official controls, and official activities other than official controls, along the entire agri-food chain, taking into account the rules on official controls laid down in

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Regulation (EC) No 882/2004 and in relevant sectoral legislation, and the experience gained from the application of those rules.

(21) The rules which set out the requirements for the sustainable use of plant protection products laid down in Directive 2009/128/EC of the European Parliament and of the Council[(11)] include, in Article 8 thereof, provisions on the inspection of application equipment, which will continue to apply while the rules on official controls of this Regulation do not apply to those inspection activities.

(22) 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 the verification of compliance with Regulation (EU) No 1308/2013 of the European Parliament and of the Council[(12)] governing the common organisations of the markets in agricultural products, except where the controls carried out in relation to marketing standards under Regulation (EU) No 1306/2013 of the European Parliament and of the Council[(13)] indicate possible cases of fraudulent or deceptive practices.

(23) Certain definitions currently set out in Regulation (EC) No 882/2004 should be adapted to take account of the broader scope of this Regulation, to align them with those set out in other Union acts, and to clarify or, where appropriate, replace terminology having different meanings in different sectors.

(24) Where Union agri-food chain legislation requires the competent authorities to verify that the operators comply with the relevant Union rules and that the animals or goods meet specific requirements for the purpose of issuing official certificates or attestations, such verification of compliance should be considered as an official control.

(25) Union agri-food chain legislation entrusts additionally the competent authorities of the Member States with specialised tasks to be carried out for the protection of animal health, plant health and animal welfare and for the protection of the environment in relation to GMOs and plant protection products. Those tasks are the public interest activities which the competent authorities of the Member States are required to carry out for the purpose of eliminating, containing or reducing any hazard which may arise for human, animal or plant health, animal welfare or also for the environment. Those other official activities, which include the granting of authorisations or approvals, the epidemiological surveillance and monitoring, eradication and containment of diseases or pests, as well as the issuance of official certificates or attestations, are governed by the same sectoral rules which are enforced through the official controls and therefore by this Regulation.

(26) Competent authorities should be designated by the Member States for all the areas that fall within the scope of this Regulation. While Member States are best placed to identify and decide which are the competent authority or authorities to designate for each area or part thereof, they should also be required to designate a single authority that for each area or part of area ensures appropriately coordinated communication with other Member States' competent authorities and with the Commission.