

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)

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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.

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- (27) For the performance of official controls aimed at verifying the correct application of Union agri-food chain legislation, and of the other official activities entrusted to Member State authorities by Union agri-food chain legislation, Member States should designate competent authorities which act in the public interest, are appropriately resourced and equipped, and offer guarantees of impartiality and professionalism. Competent authorities should ensure the quality, consistency and effectiveness of official controls.
- (28) The correct application and enforcement of the rules falling within the scope of this Regulation require appropriate knowledge of both those rules and the rules of this Regulation. It is therefore important that the staff performing official controls and other official activities are regularly trained on the applicable legislation, in accordance with their area of competence, as well as on the obligations resulting from this Regulation.
- (29) The competent authorities should carry out internal audits or have audits carried out on their behalf, to ascertain compliance with this Regulation. Those audits should be carried out in a transparent manner and be subject to independent scrutiny.
- (30) Operators should have the right, subject to national law, to appeal against the decisions taken by the competent authorities. The competent authorities should inform operators of that right.
- (31) The competent authorities should ensure that the staff responsible for official controls does not disclose information acquired during the performance of those controls where that information is covered by professional secrecy. Unless there is an overriding interest to justify disclosure, professional secrecy should include information which would undermine the purpose of inspections, investigations or audits, the protection of commercial interests or the protection of court proceedings and legal advice. However, professional secrecy should not prevent competent authorities from publishing factual information on the outcome of official controls regarding individual operators when the operator concerned has been allowed to comment upon it prior to the disclosure and such comments have been taken into account, or released alongside the information being disclosed by the competent authorities. The need to respect professional secrecy is also without prejudice to the obligation for competent authorities to inform the general public where there are reasonable grounds to suspect that a food or feed may present a risk for health under Article 10 of Regulation (EC) No 178/2002. The right of individuals to the protection of their personal data as provided for in Directive 95/46/EC of the European Parliament and of the Council⁽¹⁴⁾ should not be affected by this Regulation. These rules should also be without prejudice to situations where disclosure is required by Union or national legislation.
- (32) Competent authorities should perform official controls regularly, on a riskbasis and with appropriate frequency, on all the sectors and in relation to all operators, activities, animals and goods governed by Union agri-food chain legislation. The frequency of official controls should be established by the competent authorities having regard to the need to adjust the control effort to the risk and to the level of compliance expected in the different situations, including the possible violations of the Union agri-food chain legislation perpetrated through fraudulent or deceptive practices. Accordingly, the

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likelihood of non-compliance with all the areas of the Union agri-food chain legislation which fall within the scope of this Regulation should be taken into account where adjusting the control efforts. In some cases, however, and in view of the issuance of an official certificate or attestation which is a pre-requisite for the placing on the market or for the movements of animals or goods, Union agri-food chain legislation requires that official controls be performed irrespective of the level of risk or the likelihood of non-compliance. In such cases, the frequency of the official controls is dictated by the certification or attestation needs.

- (33) To preserve the effectiveness of official controls in the verification of compliance, no notice should be given prior to performing controls, unless such prior notice is absolutely necessary for the controls to be carried out (for example, in the case of those official controls performed in slaughterhouses during slaughter operations which require the continuous or regular presence of staff or representatives of the competent authorities in the operator's premises) or the nature of the official control activities requires otherwise (as is particularly the case with regard to audit activities).
- (34) Official controls should be thorough and effective and should ensure that Union legislation is applied correctly. Given that official controls may represent a burden for operators, competent authorities should organise and conduct official control activities taking their interests into account and limiting the said burden to that which is necessary for the performance of efficient and effective official controls.
- (35) Official controls should be performed by staff who are independent, that is free from any conflict of interest, and in particular who are not in a situation which, directly or indirectly, could affect their ability to carry out their professional duties in an impartial manner. Appropriate arrangements should also be in place to ensure impartiality in cases where official controls are performed on animals, goods, places or activities which belong to a public authority or body.
- (36) Official controls should be performed with the same level of care by the competent authorities of the Member State irrespective of whether the rules being enforced apply to activities which are only relevant on the territory of that Member State or to activities which will have an impact on the compliance with Union legislation on animals and goods which are to be moved or placed on the market in another Member State or exported outside the Union. In the case of exports outside the Union, competent authorities may also be required, in accordance with Union legislation, to verify the conformity of animals and goods with requirements established by the third country of destination of such animals or goods. Furthermore, as regards the establishments of models for export certificates, the relevant implementing powers provided for in this Regulation should only apply where such certification is provided for in Union law, and in particular in bilateral agreements concluded between the Union and a third country or an association of third countries.
- (37) Without prejudice to traceability requirements laid down in sectorial legislation, and to the extent strictly necessary for organising official controls, operators should be able, in exceptional circumstances, to be required by the competent authorities of a Member State to report the arrival of animals and goods from another Member State.

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- (38) To ensure that the Union agri-food chain legislation is correctly enforced, the competent authorities should have the power to perform official controls at all stages of production, processing and distribution of animals and goods concerned by that legislation. To ensure that official controls are thoroughly conducted and effective, the competent authorities should also have the power to perform official controls at all stages of production and distribution of goods, substances, materials or objects which are not governed by Union agri-food chain legislation insofar as it is necessary to fully investigate possible infringements of that legislation and to identify the cause of any such infringement. In order to perform those official controls efficiently, competent authorities should draw up and maintain a list or register of the operators to be controlled.
- (39) The competent authorities act in the interest of operators and of the general public ensuring that the high standards of protection established by Union agri-food chain legislation are consistently preserved and protected through appropriate enforcement action, and that compliance with such legislation is verified across the entire agri-food chain through official controls. The competent authorities, as well as delegated bodies and natural persons to which certain tasks have been delegated, should therefore be accountable to the operators and to the general public for the efficiency and effectiveness of the official controls they perform. They should provide access to information concerning the organisation and performance of official controls and other official activities, and regularly publish information concerning official controls and the results obtained. Competent authorities should also, subject to certain conditions, be entitled to publish or to make available information about the rating of individual operators based on the outcome of official controls. The use of rating schemes by Member States should be allowed and encouraged as a means to increase transparency along the agri-food chain, provided that appropriate guarantees of fairness, consistency, transparency and objectiveness are offered by such schemes. The competent authorities should have the necessary arrangements in place in order for the rating to reflect accurately the actual level of compliance; in particular, competent authorities should be encouraged to ensure that the rating is based on the outcome of several official controls or, when the rating is based on the outcome of one single official control and the findings are unfavourable, that subsequent official controls are carried out within a reasonable time. The transparency of rating criteria is particularly necessary so that best practices can be compared and, in time, the development of a consistent approach at Union level considered.
- (40) It is of importance that competent authorities as well as delegated bodies and natural persons to which certain tasks have been delegated, ensure and verify the effectiveness and the consistency of the official controls they perform. For that purpose they should act on the basis of written documented procedures and should provide information and instructions to staff performing official controls. They should also have appropriate documented procedures and mechanisms in place to verify continuously that their own action is effective and consistent, and take corrective action when shortcomings are identified.

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- (41) To facilitate the identification of cases of non-compliance and to streamline the taking of corrective action by the operator concerned, the outcome of official controls should be recorded in a written form and a copy should be given to the operator on request. Where official controls require the continuous or regular presence of the staff of the competent authorities to monitor the operator's activities, a written record of each individual inspection or visit to the operator would be disproportionate. In such cases, written records should be prepared with a frequency that enables the competent authorities and the operator to be informed regularly of the level of compliance and promptly notified of any identified shortcomings or non-compliance.
- (42) Operators should cooperate fully with competent authorities, delegated bodies or natural persons to which certain tasks have been delegated, to ensure the smooth performance of official controls and to enable the competent authorities to perform other official activities. Operators responsible for a consignment entering the Union should provide all available information related to that consignment. All operators should provide to the competent authorities at least the information needed to identify themselves, their activities and the operators which they supply and which supply them.
- (43) This Regulation establishes a single legislative framework for the organisation of official controls to verify compliance with Union agri-food chain legislation in all the areas that such legislation covers. In some of those areas, Union legislation lays down detailed requirements to be complied with which require special skills and specific means for the performance of official controls. To avoid diverging enforcement practices which could generate uneven protection of human, animal and plant health, animal welfare and, as regards GMOs and plant protection products, also of the environment, disrupt the functioning of the internal market for animals and goods falling within the scope of this Regulation and distort competition, the Commission should be able to supplement the rules laid down in this Regulation through the adoption of specific official control rules capable of catering for the needs of controls of those areas. In particular, such rules should lay down specific requirements for the performance of official controls and the minimum frequency for such controls, specific or additional measures to those provided for in this Regulation that competent authorities should take in relation to cases of non-compliance, specific responsibilities and tasks of the competent authorities in addition to those provided for in this Regulation and specific criteria for triggering the administrative assistance mechanism provided for in this Regulation. In other cases, such additional rules might become necessary in order to provide a more detailed framework for the performance of official controls in relation to food and feed, where new information emerges about risks to human or animal health or, in relation to GMOs and plant protection products, also to the environment, indicating that in the absence of common specifications for the performance of official controls across the Member States, the controls would fail to deliver the expected level of protection against those risks, as provided for by Union agri-food chain legislation.
- (44) To enable the efficient organisation of the official controls covered by this Regulation, Member States should have the discretion to identify the most appropriate staff to perform such controls provided that a high level of protection of human, animal and

plant health and animal welfare is ensured throughout the agri-food chain and that international standards and obligations are met. However, in certain cases, where their specific skills are necessary to ensure a sound outcome of the official controls, Member States should be required to refer to official veterinarians, plant health officers or other specifically designated persons. That should be without prejudice to the possibility for Member States to also use official veterinarians (including for official controls on poultry and lagomorphs) plant health officers or other specifically designated persons in cases where this is not required in accordance with this Regulation.

- (45) For the purpose of developing new control methods and techniques in relation to official controls on meat production, competent authorities should be allowed to adopt national measures to implement pilot projects that are limited in time and scope. Such measures should ensure that competent authorities verify that operators comply with all the fundamental provisions applicable to meat production, including the requirement that meat is safe and fit for human consumption. In order to ensure that the Commission and the Member States have the possibility to assess the impact of such national measures and express their opinion before they are adopted, and take therefore the most appropriate action, those measures should be notified to the Commission in accordance with and for the purposes of Articles 5 and 6 of Directive (EU) 2015/1535 of the European Parliament and of the Council⁽¹⁵⁾.
- (46) The competent authorities should be able to delegate some of their tasks to other bodies. Appropriate conditions should be laid down to ensure that the impartiality, quality and consistency of the official controls and of the other official activities are preserved. The delegated body should in particular be accredited according to the International Organisation for Standardisation (ISO) standard for the performance of inspections.
- (47) To ensure the reliability and consistency of official controls and other official activities across the Union, the methods used for sampling and for laboratory analyses, tests and diagnoses should meet scientific standards, satisfy the specific analytical, testing and diagnostic need of the laboratory concerned, and offer sound and reliable analytical, test and diagnostic results. Clear rules should be established for the choice of the method to be used where more than one is available from different sources, such as ISO, the European and Mediterranean Plant Protection Organization (EPPO), the International Plant Protection Convention (IPPC), the World Organization for Animal Health (OIE), European Union and national reference laboratories, or national law.
- (48) Operators whose animals or goods are subject to sampling, analysis, test or diagnosis in the context of official controls should have the right to a second expert opinion, at their own expense. Such a right should allow the operator to request a documentary review by another expert of the initial sampling, analysis, test or diagnosis, as well as a second analysis, test or diagnosis of the parts of the sampling material taken initially unless any such second analysis, test or diagnosis is technically impossible or irrelevant. Such would be the case, in particular, where the prevalence of the hazard is particularly low in the animal or good or its distribution particularly sparse or irregular for the purpose

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of assessing the presence of quarantine organisms or, as the case may be, for performing a microbiological analysis.

- (49) For the purposes of performing official controls on trade which take place through the internet or other remote means, competent authorities should be able to obtain samples through anonymously placed orders (also known as mystery shopping) which can then be analysed, tested or subject to a verification of compliance. All steps should be taken by the competent authorities to preserve the rights of the operators to a second expert opinion.
- (50) Laboratories designated by the competent authorities to carry out analyses, tests and diagnoses on samples taken in the context of official controls and other official activities should possess the expertise, equipment, infrastructure and staff to carry out such tasks to the highest standards. To ensure sound and reliable results, those laboratories should be accredited for the use of these methods according to standard EN ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories'. The accreditation should be delivered by a national accreditation body operating in accordance with Regulation (EC) No 765/2008 of the European Parliament and of the Council⁽¹⁶⁾.
- (51) While accreditation is the instrument of choice to ensure high performance by official laboratories, it is also a complex and costly process, which would result in a disproportionate burden for the laboratory in cases where the method of laboratory analysis, test or diagnosis is particularly simple to perform and does not require specialised procedures or equipment, as is the case for the detection of *Trichinella* in the context of the inspection and, under certain conditions, in cases where the laboratory only carries out analyses, tests or diagnoses in the context of other official activities and not of official controls.
- (52) In order to ensure the flexibility and proportionality of the approach, in particular for animal health or plant health laboratories, provision should be made for the adoption of derogations aimed at allowing certain laboratories not to be accredited for all the methods they use. That happens in particular where validated methods for detecting particular pests of plants are not available. Moreover, accreditation of a laboratory for all the methods that it should use as an official laboratory might not be immediately available in cases where new or recently modified methods are to be used, in cases of emerging risks or in emergency situations. Under certain conditions, official laboratories should therefore be allowed to carry out analyses, tests and diagnoses for the competent authorities before they obtain the relevant accreditation.
- (53) Official controls performed on animals and goods entering the Union from third countries are of key importance since these controls ensure compliance with legislation applicable within the Union and, in particular, with the rules established to protect human, animal and plant health, animal welfare and, as regards GMOs and plant protection products, also the environment. Such official controls should take place before the animals or goods are released for free circulation within the Union. The frequency of official controls should adequately address risks to human, animal and plant health, animal welfare and to the environment that animals and goods entering

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the Union might pose, taking into account the operator's history of compliance with the requirements provided for in Union agri-food chain legislation, the controls already performed on those animals and goods in the third country concerned, and the guarantees given by that third country that animals and goods exported to the Union meet the requirements laid down in Union legislation.

- (54) It is necessary to provide for the categories of animals and goods which should always be presented at a border control post for official controls to be performed prior to their entry into the Union. It is also necessary to provide for the possibility of requiring that other categories of goods be subject temporarily to the same requirement by virtue of specific measures to that effect, and for the possibility of requiring that certain other categories of goods, and in particular certain foodstuffs containing both products of plant origin and processed products of animal origin (composite products), always be presented for official controls at a border control post prior to their entry into the Union.
- (55) Given the risks to human, animal or plant health, animal welfare or to the environment that certain animals or goods may pose, they should be subject to specific official controls to be performed upon them on their entry into the Union. Current Union rules require the performance of official controls at Union borders to verify that human health, animal health and animal welfare standards applicable to animals, products of animal origin, germinal products and animal by-products are met and that plants and plant products comply with phytosanitary requirements. Increased controls on entry into the Union are also performed on certain other goods where emerging or known risks so warrant. The specificities of such controls, currently governed by Council Directives 97/78/EC⁽¹⁷⁾, 91/496/EEC⁽¹⁸⁾ and 2000/29/EC and Commission Regulation (EC) No 669/2009⁽¹⁹⁾ should be provided for in this Regulation.
- (56) In order to reinforce the efficiency of the Union's official control system, ensure an optimal allocation of official control resources assigned to border controls and facilitate the enforcement of Union agri-food chain legislation, a common integrated system of official controls at border control posts, replacing the current fragmented control frameworks, should be established to handle all consignments which, given the risk they may carry, should be controlled on their entry into the Union.
- (57) Official controls should be performed on consignments upon their arrival at border control posts. Those official controls should include documentary checks on all consignments, including where appropriate checks by electronic means, as well as identity checks and physical checks performed at an appropriate frequency dependent on the risk posed by each consignment of animals or goods.
- (58) The frequency of physical checks should be determined and modified on the basis of risks to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment. That approach should enable the competent authorities to allocate resources for controls where the risk is highest. The frequency of identity checks should also be subject to reduction or limited to the verification of a consignment's official seal where this is justified by a reduced risk posed by the consignments entering the Union. The risk-based approach to identity

Changes to legislation: *There are currently no known outstanding effects for the Regulation (EU) 2017/625 of the European Parliament and of the Council, Introductory Text. (See end of Document for details)*

checks and physical checks should be pursued by making use of available data sets and information, and of computerised data collection and management systems.

- (59) In certain cases, and provided that high levels of human, animal and plant health, animal welfare and, in relation to GMOs and plant protection products, also protection of the environment are ensured, official controls normally performed by competent authorities at border control posts could be performed at other control points or by other authorities.
- (60) For the purpose of organising an efficient system of official controls, consignments arriving from third countries which require controls at their entry into the Union should be accompanied by a common health entry document (CHED), to be used for the prior notification of the arrival of consignments at the border control post, and to record the outcome of official controls performed and of decisions taken by the competent authorities in relation to the consignment which they accompany. The same document should be used by the operator to obtain clearance by customs authorities once all official controls have been performed.
- (61) In some Member States, due to specific geographical constraints, such as long coasts or borders, the minimum requirements for border control posts are difficult to fulfil on a permanent basis. Imports of unprocessed logs of wood are usually done in large volumes through specialised ports or control points and with an irregular frequency which make it difficult to have permanently staffed and fully equipped border control posts. Derogations from minimum requirements for border control posts should be allowed to ensure effective official controls on specific unprocessed logs of wood.
- (62) Official controls on animals and goods entering the Union from third countries should be performed at border control posts designated by Member States in accordance with a set of minimum requirements. The designation of such posts should be withdrawn or suspended when they no longer comply with the minimum requirements or when their activities could pose a risk to human, animal or plant health, animal welfare or, in the case of GMOs and plant protection products, also to the environment. The decision whether to withdraw or suspend such a designation would need to take account of the degree of seriousness of the risk and of the principle of proportionality.
- (63) To ensure the uniform application of official control rules on consignments arriving from third countries, common rules should be established to govern the actions that the competent authorities and operators should take in the event of suspicion of non-compliance, and in relation to non-compliant consignments and of consignments which might pose a risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment.
- (64) In order to avoid inconsistencies and duplications in carrying out official controls, to allow consignments which are subject to official controls at border control posts and at other control points to be timely identified and to ensure that controls are performed in an efficient manner, cooperation and exchange of information amongst competent authorities, customs authorities and other relevant authorities dealing with consignments arriving from third countries should be ensured.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2017/625 of the European Parliament and of the Council, Introductory Text. (See end of Document for details)

- (65) Member States should ensure that adequate financial resources are always available in order to appropriately staff and equip the competent authorities performing official controls and other official activities. Although operators are primarily responsible for ensuring that their activities are carried out in compliance with Union agri-food chain legislation, the system of own controls that they put in place for that purpose should be complemented by a dedicated system of official controls maintained by each Member State to ensure effective market surveillance along the agri-food chain. Such a system is, by its very nature, complex and resource-demanding and should be provided with a stable influx of resources for official controls, and at a level appropriate to the enforcement needs at any given moment. To reduce the dependency of the official control system on public finances, competent authorities should collect fees or charges to cover the costs they incur when performing official controls on certain operators and for certain activities for which Union agri-food chain legislation requires registration or approval in accordance with Union rules on the hygiene of food and feed or rules governing plant health. Fees or charges should also be collected from operators to compensate the costs of official controls performed in view of issuing an official certificate or attestation and costs of official controls performed by the competent authorities at border control posts.
- (66) Fees or charges should cover, but not exceed, the costs, including overhead costs, incurred by the competent authorities to perform official controls. Overhead costs could include the costs of the support and organisation necessary for planning and carrying out the official controls. Such costs should be calculated on the basis of each individual official control or on the basis of all official controls performed over a given period of time. Where fees or charges are applied on the basis of the actual cost of individual official controls, operators with a good record of compliance should bear lower overall charges than non-compliant ones, as they should be subject to less frequent official controls. In order to promote compliance with Union legislation by all operators irrespective of the method (based on actual costs or on a flat rate) that each Member States has chosen for the calculation of the fees or charges, when fees or charges are calculated on the basis of overall costs incurred by the competent authorities over a given period of time, and imposed on all operators irrespective of whether they are subject to an official control during the reference period, those fees or charges should be calculated so as to reward operators with a consistent good record of compliance with Union agri-food chain legislation.
- (67) The direct or indirect refund of fees or charges collected by the competent authorities should be prohibited as it would put at a disadvantage operators not benefitting from the refund and potentially create distortions of competition.
- (68) The financing of official controls through fees or charges collected from operators should be fully transparent, so as to enable citizens and businesses to understand the method and data used to establish fees or charges.
- (69) Union agri-food chain legislation establishes the cases where the placing on the market or the movement of certain animals or goods should be accompanied by an official certificate signed by the certifying officer. It is appropriate to establish a common set

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2017/625 of the European Parliament and of the Council, Introductory Text. (See end of Document for details)

of rules laying down the obligations of the competent authorities and the certifying officers with regard to the issuance of official certificates as well as the characteristics that official certificates should have to ensure their reliability.

- (70) In other cases, the rules falling within the scope of this Regulation provide that the placing on the market or the movement of certain animals or goods are to be accompanied by an official label, official mark or other official attestation issued by the operators under the official supervision of the competent authorities or by the competent authorities themselves. Official attestations include, for example, plant passports, organic logos and identification marks, where these are required by Union legislation, and marks of protected designations of origin, protected geographical indications or traditional specialities guaranteed. It is appropriate to lay down a minimum set of rules to ensure that also the issuance of official attestations is able to be performed in accordance with appropriate guarantees of reliability.
- (71) Official controls and other official activities should be based on analytical, testing and diagnostic methods that meet state-of-the-art scientific standards and offer sound, reliable and comparable results across the Union. The methods used by official laboratories as well as the quality and uniformity of analytical, testing and diagnostic data generated by them should therefore be improved continuously. For that purpose, the Commission should be able to designate, and rely on the expert assistance of, European Union reference laboratories in all those areas of the agri-food chain where there is the need for precise and reliable analytical, testing and diagnostic results. The European Union reference laboratories should in particular ensure that national reference laboratories and official laboratories are provided with up-to-date information on available methods, organise or participate actively in inter-laboratory comparative tests and offer training courses for national reference laboratories or official laboratories.
- (72) The first paragraph of Article 32 of Regulation (EC) No 1829/2003 and the first paragraph of Article 21 of Regulation (EC) No 1831/2003 of the European Parliament and of the Council⁽²⁰⁾ confer respectively on the European Union reference laboratory for genetically modified food and feed and on the European Union reference laboratory for feed additives specific tasks as part of the authorisation procedure for genetically modified food or feed, or feed additives, relating, in particular, to the testing, evaluation and validation of the method of detection or analysis proposed by applicants. Those laboratories therefore should act as European Union reference laboratories for the purposes of this Regulation.
- (73) For the performance of official controls and other official activities which are aimed at identifying possible violations to the rules including those perpetrated through fraudulent or deceptive practices, and in the field of animal welfare, the competent authorities should have access to updated, reliable and consistent technical data, to research findings, new techniques and expertise necessary for the correct application of Union legislation applicable in those two areas. For that purpose, the Commission should be able to designate, and rely on the expert assistance of, European Union

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2017/625 of the European Parliament and of the Council, Introductory Text. (See end of Document for details)

reference centres for the authenticity and integrity of the agri-food chain and for animal welfare.

- (74) In order to pursue the objectives of this Regulation and contribute to the smooth functioning of the internal market, ensuring consumer confidence in it, cases of non-compliance with Union agri-food chain legislation requiring enforcement action in more than one Member State should be pursued efficiently and consistently. The Rapid Alert System for Food and Feed (RASFF) established pursuant to Article 50 of Regulation (EC) No 178/2002 already enables competent authorities to rapidly exchange and disseminate information on serious direct or indirect risks to human health in relation to food or feed, or serious risks to human or animal health or to the environment in relation to feed, for the purpose of enabling rapid measures to be taken to counter those serious risks. However, that instrument, while allowing for timely action across all Member States concerned to counter certain serious risks along the agri-food chain, cannot serve the purpose of enabling effective cross border assistance and cooperation between competent authorities to ensure that cases of non-compliance with Union agri-food chain legislation which have a cross-border dimension are effectively pursued not only in the Member State where the non-compliance is first detected but also in the Member State where the non-compliance originated. In particular, administrative assistance and cooperation should enable competent authorities to share information, detect, investigate and take effective and proportionate action to pursue cross-border violations of Union agri-food chain legislation also in cases where potential fraudulent or deceptive practices have or could have a cross-border dimension.
- (75) Requests for administrative assistance and all notifications should be given appropriate follow-up. In order to facilitate administrative assistance and cooperation, Member States should be required to designate one or more liaison bodies to assist and coordinate communication flows between competent authorities in different Member States. In order to ensure uniform conditions for the implementation of this Regulation and to streamline and simplify cooperation between Member States, implementing powers should be conferred on the Commission to adopt implementing acts establishing the specifications of the technical tools to be used, the procedures for communication between liaison bodies and a standard format for requests for assistance, notifications and responses.
- (76) Each Member State should be required to set up and regularly update a multi-annual national control plan (MANCP) covering all the areas governed by Union agri-food chain legislation and containing information on the structure and organisation of its system of official controls. Such MANCPs are the instrument through which each Member State should ensure that official controls are performed in a manner that is risk-based and efficient across their territory and across the entire agri-food chain, and in compliance with this Regulation. Appropriate consultation with relevant stakeholders in advance of the preparation of the plans should ensure their fitness for purpose.
- (77) In order to ensure the coherence and completeness of the MANCP each Member State should designate a single body tasked with coordinating the preparation of its MANCP and collecting, as necessary, the information on its implementation, review and update.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2017/625 of the European Parliament and of the Council, Introductory Text. (See end of Document for details)

- (78) Member States should be required to submit an annual report to the Commission with information on control activities and the implementation of the MANCPs. In order to ensure uniform conditions for the implementation of this Regulation and to facilitate the collection and transmission of comparable data, the subsequent compilation of such data into Union-wide statistics and the preparation of reports by the Commission on the operation of official controls across the Union, implementing powers should be conferred on the Commission to adopt implementing acts in respect of establishing standard model forms for annual reports.
- (79) Commission experts should be able to perform controls, including audits, in Member States to verify the application of the relevant Union legislation and the functioning of national control systems and competent authorities. Commission controls should also serve to investigate and collect information on enforcement practices or problems, emergencies and new developments in Member States. At the request of the Member States concerned, Commission experts should also be able to participate in controls performed by the competent authorities of third countries on the territory of that Member State; such controls should be organised in close cooperation between the Member States concerned and the Commission.
- (80) Animals and goods from third countries should comply with the same requirements which apply to Union animals and goods, or with requirements which are recognised to be at least equivalent in relation to the objectives pursued by Union agri-food chain legislation. This principle is enshrined in Article 11 of Regulation (EC) No 178/2002, which requires that food and feed imported into the Union comply with the relevant requirements of the Union's food law or with requirements considered to be at least equivalent thereto. Specific requirements to apply that principle are provided for in Union rules on protective measures against pests of plants, which prohibit the introduction into the Union of certain pests which are not present (or only present to a limited extent) in the Union, in Union rules laying down animal health requirements, which allow the entry of animals and of certain products of animal origin into the Union only from third countries which are included in a list set up for that purpose, and in Union rules for the organisation of official controls on products of animal origin intended for human consumption, which also provide for the establishment of a list of third countries from which those products can enter the Union.
- (81) In order to ensure that animals and goods entering the Union from third countries comply with all the requirements laid down in Union agri-food chain legislation or with requirements considered equivalent, in addition to the requirements established by Union rules on protective measures against pests of plants, Union rules laying down animal health requirements and Union rules laying down specific hygiene rules for food of animal origin to ensure that the requirements laid down in Union agri-food chain legislation in relation to phytosanitary and veterinary concerns are met, the Commission should be allowed to establish conditions for the entry of animals and goods into the Union to the extent necessary to ensure that those animals and goods comply with all relevant requirements of Union agri-food chain legislation or equivalent requirements.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2017/625 of the European Parliament and of the Council, Introductory Text. (See end of Document for details)

Such conditions should apply to animals or goods or categories of animals or goods from all third countries or from certain third countries or regions thereof.

- (82) Where, in specific cases, there is evidence that certain animals or goods originating from a third country, a group of third countries, or regions thereof, give rise to risks to human, animal or plant health or, as regards GMOs and plant protection products, also to the environment or where there is evidence that widespread serious non-compliance with Union agri-food chain legislation might be taking place, the Commission should be able to adopt measures to contain such risks.
- (83) The performance of effective and efficient official controls and other official activities, and ultimately the safety and health of humans, animals and plants, and the protection of the environment, also depends on the availability to the control authorities of well trained staff possessing an appropriate knowledge of all the matters relevant for the correct application of Union legislation. Appropriate and dedicated training should be provided by the Commission to promote a uniform approach to official controls and other official activities by the competent authorities. To promote the knowledge of Union agri-food chain legislation and requirements in third countries, such training should also be addressed to staff of the competent authorities in third countries. In the latter case, the training activities should be designed to take into account the specific needs of developing countries, to support their controls and enforcement actions so that they can meet the requirements applicable to import of animals and goods into the Union.
- (84) To promote the sharing of experience and best practices among competent authorities, the Commission should also be able to organise, in cooperation with the Member States, programmes for the exchange between Member States of staff tasked with official controls or other official activities.
- (85) It is important for the performance of effective official controls and other official activities that the competent authorities in the Member States, the Commission and, where relevant, operators be able to exchange data and information related to official controls or results therefrom rapidly and efficiently. Several information systems are established by Union legislation and managed by the Commission to allow such data and information to be handled and managed through Union-wide computerised and internet-based tools. A system dedicated to recording and tracing official control results is the Trade Control and Expert System (Traces system), established by Commission Decisions 2003/24/EC⁽²¹⁾ and 2004/292/EC⁽²²⁾ in accordance with Council Directive 90/425/EEC⁽²³⁾ and currently used for the management of data and information on animals and products of animal origin and official controls thereon. This Regulation should allow that system to be maintained and upgraded so as to allow its use for all goods for which Union agri-food chain legislation establishes specific requirements or practical arrangements for official controls. Dedicated computerised systems also exist for the rapid exchange of information between Member States and with the Commission on risks which might arise in the agri-food chain or for animal and plant health. Article 50 of Regulation (EC) No 178/2002 establishes the RASFF which is a system for notifying direct or indirect risk to human health deriving from

Changes to legislation: *There are currently no known outstanding effects for the Regulation (EU) 2017/625 of the European Parliament and of the Council, Introductory Text. (See end of Document for details)*

food or feed, Article 20 of Regulation (EU) 2016/429 of the European Parliament and of the Council⁽²⁴⁾ a system for the notification and reporting on the measures on listed diseases, and Article 103 of Regulation (EU) 2016/2031 of the European Parliament and of the Council⁽²⁵⁾ a system for the notification and reporting of the presence of pests and the notification of cases of non-compliance. All such systems should work in a harmonious and consistent manner that makes use of synergies between the different systems, avoids duplications, simplifies their operation and makes them more efficient.

- (86) To support a more efficient management of official controls, a computerised information system integrating and upgrading as necessary all relevant existing information systems should be set up by the Commission, allowing for the use of advanced communication and certification tools, and for the most efficient use of the data and information related to official controls. In view of avoiding unnecessary duplications of information requirements, the design of such computerised system should take into account the need to ensure, wherever appropriate, the compatibility and inter-operability of such a computerised system with other information systems operated by public authorities and through which relevant data is automatically exchanged or made available. Moreover, the possibility to use electronic signatures within the meaning of Directive 1999/93/EC of the European Parliament and the Council⁽²⁶⁾ should be provided for, in line with the Digital Agenda for Europe. The European Data Protection Supervisor should be consulted during the development stage of any new functionality of such computerised system, as well as during the development of relevant implementing measures which might affect the processing of personal data and privacy.
- (87) In order to ensure uniform conditions for the implementation of this Regulation regarding the proper functioning of the computerised information system, its technical specifications, as well as the duties and prerogatives of the various actors and users involved, taking into account in particular the need to minimise administrative burdens by using, as appropriate, internationally standardised language, message structure and exchange protocols, implementing powers should be conferred on the Commission.
- (88) The competent authorities should investigate cases where there is a suspicion of non-compliance with Union agri-food chain legislation and, where non-compliance is established, determine its origin and extent as well as the operators' responsibilities. The competent authorities should also take appropriate measures to ensure that the operators concerned remedy the situation and to prevent further non-compliance. The organisation and performance of investigations and enforcement actions by the competent authorities should duly take into account potential risks and the likelihood of fraudulent or deceptive practices along the agri-food chain.
- (89) The verification of compliance with Union agri-food chain legislation through official controls is of fundamental importance to ensure that, across the Union, the objectives of that legislation are effectively achieved. Disruptions in a Member State's control systems can in certain cases substantially hinder the achievement of those objectives and lead to the emergence of risks to human, animal and plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment, independently

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2017/625 of the European Parliament and of the Council, Introductory Text. (See end of Document for details)

of the involvement or responsibility of operators or other actors, or lead to situations of widespread serious non-compliance with Union agri-food chain legislation. In order to ensure uniform conditions for the implementation of this Regulation, the Commission should be able, in the event of serious disruptions in a Member State's control system, to react by adopting measures aimed at containing or eliminating those risks from the agri-food chain, pending the necessary action to be taken by the Member State concerned to remedy the disruption in the control system. Implementing powers should therefore be conferred on the Commission.

- (90) Infringements of the rules of the Union agri-food chain legislation and of this Regulation should be subject to effective, dissuasive and proportionate penalties at national level throughout the Union, the severity of which takes account, inter alia, of the potential damage to human health that may result from infringements, including in cases where operators fail to cooperate during an official control and in cases where false or misleading official certificates or attestations are produced or used. For financial penalties applicable to violations of the rules perpetrated through fraudulent or deceptive practices to be sufficiently deterrent, they should be set at a level which seeks to exceed the undue advantage for the perpetrator resulting from those practices.
- (91) Any person should be able to bring new information to the attention of competent authorities which assists them in detecting, and imposing penalties in cases of, infringements of this Regulation and of the rules referred to in Article 1(2). However, whistleblowing could be deterred by the lack of clear procedures or for fear of retaliation. Reporting of infringements of this Regulation is a useful tool to ensure that a competent authority is able to detect and impose penalties for infringements. This Regulation should therefore ensure that adequate arrangements are in place to enable any person to alert the competent authorities to possible infringements of this Regulation and to protect that person from retaliation.
- (92) This Regulation covers areas that are already covered in certain acts currently in force. To avoid duplications and to establish a coherent legislative framework, the following acts should be repealed and replaced by this Regulation: Regulation (EC) No 882/2004 and Regulation (EC) No 854/2004 of the European Parliament and of the Council⁽²⁷⁾, Council Directives 89/608/EEC⁽²⁸⁾, 89/662/EEC⁽²⁹⁾, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC⁽³⁰⁾ and 97/78/EC and Council Decision 92/438/EEC⁽³¹⁾.
- (93) In order to ensure consistency, the following acts should be amended: Regulation (EC) No 999/2001 of the European Parliament and of the Council⁽³²⁾, Council Regulation (EC) No 1/2005⁽³³⁾, Regulation (EC) No 396/2005 of the European Parliament and of the Council⁽³⁴⁾, Regulation (EC) No 1069/2009, Council Regulation (EC) No 1099/2009⁽³⁵⁾, Regulation (EC) No 1107/2009 of the European Parliament and of the Council⁽³⁶⁾, Regulation (EU) No 1151/2012 of the European Parliament and of the Council⁽³⁷⁾, and Council Directives 98/58/EC⁽³⁸⁾, 1999/74/EC⁽³⁹⁾, 2007/43/EC⁽⁴⁰⁾, 2008/119/EC⁽⁴¹⁾ and 2008/120/EC⁽⁴²⁾.
- (94) Regulation (EU) No 652/2014 of the European Parliament and of the Council⁽⁴³⁾ provides a framework for the Union's financing of actions and measures across the agri-food chain in those areas under the multi-annual financial framework 2014-2020. Some

Changes to legislation: *There are currently no known outstanding effects for the Regulation (EU) 2017/625 of the European Parliament and of the Council, Introductory Text. (See end of Document for details)*

of those acts and measures aim to improve the performance of official controls and other official activities across the Union. Regulation (EU) No 652/2014 should be amended to take account of the repeal of Regulation (EC) No 882/2004 by this Regulation.

- (95) Considering the specific situation as regards the plant sector, which has so far not been subject to the same level of controls as other goods under this Regulation, it is essential that the introduction of the new system be as smooth and seamless as possible. For that reason, it is necessary to introduce specific provisions regarding the timing of the adoption of relevant delegated acts. It is also clear that it is justified to have an exemption from the obligation of documentary checks to be carried out at border control posts for the plant sector in the case of plants, plant products and other objects posing a low level of risk and to permit documentary checks at a distance from border control posts for plants, plant products and other objects where such checks at a distance are able to provide an equal level of assurance.
- (96) In order to amend the references to European standards, and Annexes II and III to this Regulation to take into account of legislative and technical and scientific developments, and to supplement this Regulation with specific rules governing official controls and other official activities in the areas it covers, including rules on the qualification and training of staff, on additional responsibilities and tasks of the competent authorities, on the cases where the accreditation of laboratories is not required, on certain exemptions from official controls at the borders, on the criteria to be used to determine the frequency of identity checks and physical checks, on the establishment of conditions to be fulfilled by certain animals or goods entering the Union from third countries, on additional requirements and tasks of European Union reference laboratories and centres and on additional requirements for national reference laboratories, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making⁽⁴⁴⁾. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.
- (97) In order to ensure uniform conditions for the implementation of this Regulation regarding the designation of European Union reference laboratories and of the European Union reference centres for the authenticity and integrity of the agri-food chain and for animal welfare, the adoption of the programme of the Commission controls in the Member States, and the performance of increased official controls in the event of infringements of Union agri-food chain legislation which require coordinated assistance and follow-up by the Commission, implementing powers should be conferred on the Commission.
- (98) In order to ensure uniform conditions for the implementation of this Regulation, including rules and practical arrangements in respect of audits, the format of certificates

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2017/625 of the European Parliament and of the Council, Introductory Text. (See end of Document for details)

and other documents, the establishment of computerised information management systems, the cooperation between operators and competent authorities and amongst competent authorities, customs authorities and other authorities, the methods of sampling and of laboratory analysis, test and diagnosis as well as their validation and interpretation, traceability, the listing of animals or goods subject to controls as well the listing of countries or regions that can export certain animals and goods to the Union, prior notification of consignments, exchanges of information, border control posts, isolation and quarantine, approval of pre-export controls performed by third countries, measures to contain a risk or put an end to a widespread serious non-compliance relating to certain animals or goods originating from a third country or a region thereof, the recognition of third countries or regions that offer equivalent guarantees to those applied in the Union and its repeal, training activities and exchange programmes of staff amongst Member States and on the contingency plans for food and feed for the application of the general plan for crisis management provided for in Article 55(1) of Regulation (EC) No 178/2002, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council⁽⁴⁵⁾.

- (99) Since the objective of this Regulation, namely to ensure a harmonised approach with regard to official controls and other official activities performed in view of ensuring the application of Union agri-food chain legislation, cannot be sufficiently achieved by the Member States but can rather, by reason of its effect, complexity, trans-border and international character, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. 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,

HAVE ADOPTED THIS REGULATION:

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2017/625 of the European Parliament and of the Council, Introductory Text. (See end of Document for details)

- (1) [OJ C 67, 6.3.2014, p. 166.](#)
- (2) [OJ C 114, 15.4.2014, p. 96.](#)
- (3) Position of the European Parliament of 15 April 2014 (not yet published in the Official Journal) and position of the Council at first reading of 19 December 2016 (not yet published in the Official Journal). Position of the European Parliament of 15 March 2017 (not yet published in the Official Journal).
- (4) 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 setting out procedures in matters of food safety ([OJ L 31, 1.2.2002, p. 1.](#))
- (5) 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 ([OJ L 106, 17.4.2001, p. 1.](#))
- (6) Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([OJ L 268, 18.10.2003, p. 1.](#))
- (7) 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 food and feed law, animal health and animal welfare rules ([OJ L 165, 30.4.2004, p. 1.](#))
- (8) Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) ([OJ L 300, 14.11.2009, p. 1.](#))
- (9) 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 ([OJ L 169, 10.7.2000, p. 1.](#))
- (10) Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC ([OJ L 125, 23.5.1996, p. 10.](#))
- (11) Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides ([OJ L 309, 24.11.2009, p. 71.](#))
- (12) Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ([OJ L 347, 20.12.2013, p. 671.](#))
- (13) Regulation (EU) No 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008 ([OJ L 347 20.12.2013, p. 549.](#))
- (14) Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data ([OJ L 281, 23.11.1995, p. 31.](#))
- (15) Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services ([OJ L 241, 17.9.2015, p. 1.](#))
- (16) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 ([OJ L 218, 13.8.2008, p. 30.](#))
- (17) 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.](#))
- (18) 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 and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC ([OJ L 268, 24.9.1991, p. 56.](#))

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2017/625 of the European Parliament and of the Council, Introductory Text. (See end of Document for details)

- (19) Commission Regulation (EC) No 669/2009 of 24 July 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and the Council as regards the increased level of official controls on imports of certain food and feed of non-animal origin and amending Decision 2006/504/EC (OJ L 194, 25.7.2009, p. 11).
- (20) Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29).
- (21) Commission Decision 2003/24/EC of 30 December 2002 concerning the development of an integrated computerised veterinary system (OJ L 8, 14.1.2003, p. 44).
- (22) Commission Decision 2004/292/EC of 30 March 2004 on the introduction of the Traces system and amending Decision 92/486/EEC (OJ L 94, 31.3.2004, p. 63).
- (23) Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market (OJ L 224, 18.8.1990, p. 29).
- (24) Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (OJ L 84, 31.3.2016, p. 1).
- (25) Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (OJ L 317, 23.11.2016, p. 4).
- (26) Directive 1999/93/EC of the European Parliament and the Council of 13 December 1999 on a Community framework for electronic signatures (OJ L 13, 19.1.2000, p. 12).
- (27) 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).
- (28) Council Directive 89/608/EEC of 21 November 1989 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of legislation on veterinary and zootechnical matters (OJ L 351, 2.12.1989, p. 34).
- (29) Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market (OJ L 395, 30.12.1989, p. 13).
- (30) Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products (OJ L 13, 16.1.1997, p. 28).
- (31) Council Decision 92/438/EEC of 13 July 1992 on computerization of veterinary import procedures (Shift project), amending Directives 90/675/EEC, 91/496/EEC, 91/628/EEC and Decision 90/424/EEC, and repealing Decision 88/192/EEC (OJ L 243, 25.8.1992, p. 27).
- (32) 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).
- (33) Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97 (OJ L 3, 5.1.2005, p. 1).
- (34) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum levels of pesticides in or on food and feed of plant of animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).
- (35) Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing (OJ L 303, 18.11.2009, p. 1).
- (36) Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).
- (37) Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs (OJ L 343, 14.12.2012, p. 1).

Changes to legislation: *There are currently no known outstanding effects for the Regulation (EU) 2017/625 of the European Parliament and of the Council, Introductory Text. (See end of Document for details)*

- (38) Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes ([OJ L 221, 8.8.1998, p. 23](#)).
- (39) Council Directive 1999/74/EC of 19 July 1999 laying down minimum standards for the protection of laying hens ([OJ L 203, 3.8.1999, p. 53](#)).
- (40) Council Directive 2007/43/EC of 28 June 2007 laying down minimum rules for the protection of chickens kept for meat production ([OJ L 182, 12.7.2007, p. 19](#)).
- (41) Council Directive 2008/119/EC of 18 December 2008 laying down minimum standards for the protection of calves ([OJ L 10, 15.1.2009, p. 7](#)).
- (42) Council Directive 2008/120/EC of 18 December 2008 laying down minimum standards for the protection of pigs ([OJ L 47, 18.2.2009, p. 5](#)).
- (43) Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/EC and 2008/90/EC, Regulations (EC) No 178/2002, (EC) No 882/2004 and (EC) No 396/2005 of the European Parliament and of the Council, Directive 2009/128/EC of the European Parliament and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC ([OJ L 189, 27.6.2014, p. 1](#)).
- (44) [OJ L 123, 12.5.2016, p. 1](#).
- (45) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers ([OJ L 55, 28.2.2011, p. 13](#)).

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