

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)

TITLE VI

UNION ACTIVITIES

CHAPTER I

Commission controls

Article 116

Commission controls in Member States

- 1 Commission experts shall perform controls, including audits, in each Member State to:
 - a verify the application of the rules referred to in Article 1(2) and those provided for in this Regulation;
 - b verify the functioning of national control systems in the areas governed by the rules referred to in Article 1(2) and those provided for in this Regulation, and of the competent authorities which operate them;
 - c investigate and collect information:
 - (i) on official controls and enforcement practices in the areas governed by the rules referred to in Article 1(2) and those provided for in this Regulation;
 - (ii) on important or recurring problems with the application or enforcement of the rules referred to in Article 1(2);
 - (iii) in relation to emergency situations, emerging problems or new developments in the Member States in the areas governed by the rules referred to in Article 1(2) and those provided for in this Regulation.
- 2 The controls provided for in paragraph 1 shall be organised in cooperation with the competent authorities of the Member States and shall be performed on a regular basis.

3 The controls provided for in paragraph 1 may include on-the-spot verifications. The Commission experts may accompany the staff of the competent authorities performing official controls.

4 Experts from the Member States may assist the Commission experts. National experts accompanying Commission experts shall be given the same rights of access as the Commission experts.

Article 117

Reports by the Commission on controls in Member States

The Commission shall:

- (a) prepare a draft report on the findings and on recommendations addressing the shortcomings identified by its experts during controls performed in accordance with Article 116(1);
- (b) send to the Member State where those controls have been performed a copy of the draft report provided for in point (a) for its comments;
- (c) take the comments of the Member State referred to in point (b) into account in preparing the final report on the findings of the controls performed by its experts in the Member States as provided for in Article 116(1); and
- (d) make publicly available the final report referred to in point (c) and the comments of the Member State referred to in point (b).

Article 118

Programme of the Commission controls in Member States

- 1 The Commission shall, by means of implementing acts:
 - a establish an annual or multiannual control programme for the controls to be performed by its experts in the Member States as provided for in Article 116(1); and
 - b by the end of each year, communicate to the Member States the annual control programme or any update to the multiannual control programme for the following year.
- 2 The Commission may, by means of implementing acts, amend its control programme to take account of developments in the areas governed by the rules referred to in Article 1(2). Any such amendment shall be communicated without delay to the Member States.

Article 119

Obligations of the Member States as regards Commission controls

Member States shall:

- (a) take appropriate follow-up measures to remedy any specific or systemic shortcomings identified through the controls performed by the Commission experts in accordance with Article 116(1);
- (b) give the necessary technical assistance and provide the available documentation, including the results of the audits referred to in Article 6, upon justified request, and

- other technical support that Commission experts request to enable them to perform controls efficiently and effectively; and
- (c) give the necessary assistance to ensure that the Commission experts have access to all premises or parts of premises, animals and goods, and to information, including computing systems, relevant for the execution of their duties.

Article 120

Commission controls in third countries

- 1 Commission experts may perform controls in third countries in order to:
- a verify the compliance or equivalence of third-country legislation and systems, including official certification and the issuance of official certificates, official labels, official marks and other official attestations, with the requirements laid down in the rules referred to in Article 1(2);
 - b verify the capacity of the third country control system to ensure that consignments of animals and goods exported to the Union comply with relevant requirements established by the rules referred to in Article 1(2) or with requirements recognised to be at least equivalent thereto;
 - c collect information and data to elucidate the causes of recurring or emerging problems in relation to exports of animals and goods from a third country.
- 2 The controls provided for in paragraph 1 shall have particular regard to:
- a the legislation of the third country;
 - b the organisation of the third country's competent authorities, their powers and independence, the supervision to which they are subject and the authority they have to enforce the applicable legislation effectively;
 - c the training of staff of the competent authority of the third country in the performance of official controls;
 - d the resources including analytical, testing and diagnostic facilities available to competent authorities;
 - e the existence and operation of documented control procedures and control systems based on priorities;
 - f where applicable, the situation regarding animal health, animal welfare, zoonoses and plant health, and procedures for notifying the Commission and relevant international bodies of outbreaks of animal diseases and pests of plants;
 - g the extent and operation of controls performed by the competent authority of the third country on animals, plants and their products arriving from other third countries; and
 - h the assurances which the third country can give regarding compliance with, or equivalence to, the requirements laid down in the rules referred to in Article 1(2).
- 3 In order to facilitate the efficiency and effectiveness of the controls provided for in paragraph 1, the Commission may, prior to performing such controls, request that the third country concerned provide:
- a the necessary information referred to in Article 125(1); and
 - b where appropriate and necessary, the written records on the controls its competent authorities perform.
- 4 The Commission may appoint experts from Member States to assist its own experts during the controls provided for in paragraph 1.

Article 121

Frequency of Commission controls in third countries

The frequency of Commission controls in third countries referred to in Article 120 shall be determined on the basis of the following criteria:

- (a) a risk assessment of the animals and goods exported to the Union from the third country concerned;
- (b) the rules referred to in Article 1(2);
- (c) the volume and nature of animals and goods entering the Union from the third country concerned;
- (d) the outcome of controls already performed by the Commission experts or by other inspection bodies;
- (e) the outcome of official controls on animals and goods entering the Union from the third country concerned and of any other official controls that competent authorities of Member States have performed;
- (f) information received from the EFSA or similar bodies;
- (g) information received from internationally recognised bodies such as:
 - (i) the World Health Organization;
 - (ii) the Codex Alimentarius Commission;
 - (iii) the World Organization for Animal Health (OIE);
 - (iv) European and Mediterranean Plant Protection Organization and any other regional plant protection organisations established under the International Plant Protection Convention (IPPC);
 - (v) the secretariat of the IPPC;
 - (vi) Organisation for Economic Co-operation and Development;
 - (vii) United Nations Economic Commission for Europe;
 - (viii) the secretariat of the Cartagena Protocol on Biosafety to the Convention on Biological Biodiversity;
- (h) evidence of emerging disease situations or other circumstances that might result in animals and goods entering the Union from a third country presenting health or environmental risks or a risk of fraudulent or deceptive practices;
- (i) the need to investigate or respond to emergency situations in individual third countries.

Article 122

Reports by the Commission on controls in third countries

The Commission shall report on the findings of each control performed in accordance with Articles 120 and 121. Its report shall, where appropriate, contain recommendations.

The Commission shall make its reports publicly available.

Article 123

Programme of the Commission controls in third countries

The Commission shall communicate its programme of controls in third countries to Member States in advance and shall report on the results. The Commission may amend that programme to take account of developments in the areas governed by the rules referred to in Article 1(2). Any such amendment shall be communicated to the Member States in advance.

Article 124

Third-country controls in Member States

1 Member States shall inform the Commission of planned controls in the areas governed by the rules referred to in Article 1(2) on their territory, by the competent authorities of third countries.

2 Commission experts may participate in the controls referred to in paragraph 1, at the request of the competent authorities of Member States where those controls are being performed.

3 The participation by Commission experts in the controls referred to in paragraph 1 shall serve in particular to:

- a provide advice on the rules referred to in Article 1(2);
- b provide information and data available at Union level that may be useful for the control performed by the competent authorities of the third country;
- c facilitate consistency and uniformity with regard to controls performed by the competent authorities of third countries in different Member States.

CHAPTER II

Conditions for the entry into the Union of animals and goods

Article 125

Information on third countries' control systems

1 The Commission shall request third countries which intend to export animals and goods to the Union to provide the following accurate and up-to-date information on the general organisation and management of sanitary and phytosanitary control systems in their territory:

- a any sanitary or phytosanitary rules adopted or proposed within their territory;
- b risk-assessment procedures and factors taken into consideration for the assessment of risks and for the determination of the appropriate level of sanitary or phytosanitary protection;
- c any control and inspection procedures and mechanisms, including, where relevant, on animals or goods arriving from other third countries;
- d official certification mechanisms;
- e where appropriate, any measures taken following recommendations provided for in the first paragraph of Article 122;
- f where relevant, results of controls performed on animals and goods intended to be exported to the Union; and
- g where relevant, information on changes made to the structure and functioning of control systems adopted to meet Union sanitary or phytosanitary requirements or recommendations provided for in the first paragraph of Article 122.

2 The request for information referred to in paragraph 1 shall be proportionate, taking account of the nature of the animals and goods to be exported to the Union and of the specific situation in, and structure of, the third country.

Article 126

Establishment of additional conditions for entry into the Union of animals and goods

1 The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning the conditions to be respected by animals and goods entering the Union from third countries which are necessary to ensure that the animals and goods comply with the relevant requirements established by the rules referred to in Article 1(2), with the exception of points (d), (e), (g) and (h) of Article 1(2), or with requirements recognised to be at least equivalent thereto.

2 The conditions laid down in the delegated acts referred to in paragraph 1 shall identify animals and goods by referring to their codes from the Combined Nomenclature and may include:

- a the requirement that certain animals and goods shall only enter the Union from a third country or region of a third country which appears on a list drawn up by the Commission for that purpose;
- b the requirement that consignments of certain animals and goods from third countries be dispatched from, and obtained or prepared in, establishments which comply with the relevant requirements referred to in paragraph 1 or with requirements recognised to be at least equivalent thereto;
- c the requirement that consignments of certain animals and goods be accompanied by an official certificate, an official attestation, or by any other evidence that the consignments comply with the relevant requirements referred to in paragraph 1 or with requirements recognised to be at least equivalent thereto, including the results of the analysis performed by an accredited laboratory;
- d the obligation to provide the evidence referred to in point (c) in accordance with a specific format;
- e any other requirement necessary to ensure that certain animals and goods offer a level of protection of health and, as regards GMOs, also of the environment, equivalent to that ensured by the requirements referred to in paragraph 1.

3 The Commission may, by means of implementing acts, lay down rules on the format and type of official certificates, official attestations, or evidence required in accordance with the rules provided for in point (c) of paragraph 2 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

Article 127

Inclusion in the list of third countries referred to in point (a) of Article 126(2)

1 The inclusion of a third country or region thereof in the list referred to in point (a) of Article 126(2) shall be made in accordance with paragraphs 2 and 3 of this Article.

2 The Commission shall approve, by means of implementing acts, the request transmitted to it for the purpose referred to in paragraph 1 of this Article by the third country concerned, accompanied by appropriate evidence and guarantees that the animals and goods concerned from that third country comply with the relevant requirements referred to in Article 126(1) or with requirements equivalent thereto. Those implementing acts shall be adopted and updated in accordance with the examination procedure referred to in Article 145(2).

3 The Commission shall decide on the request referred to in paragraph 2 taking into account, as appropriate:

- a the third country's legislation in the sector concerned;
- b the structure and organisation of the competent authorities of the third country and its control services, the powers available to them, the guarantees that can be provided with regard to the application and enforcement of the legislation of the third country applicable to the sector concerned, and the reliability of the official certification procedures;
- c the performance by the competent authorities of the third country of adequate official controls and other activities to assess the presence of hazards for human, animal or plant health, for animal welfare or, in relation to GMOs and plant protection products, also for the environment;
- d the regularity and rapidity of information supplied by the third country on the presence of hazards for human, animal or plant health, for animal welfare or, in relation to GMOs and plant protection products, also for the environment;
- e the guarantees given by the third country that:
 - (i) conditions applied to the establishments from which animals or goods are exported to the Union comply with requirements that are equivalent to those referred to in Article 126(1);
 - (ii) a list of the establishments referred to in point (i) is drawn up and kept up to date;
 - (iii) the list of establishments referred to in point (i) and updates thereof are communicated to the Commission without delay;
 - (iv) the establishments referred to in point (i) are the subject of regular and effective controls by the competent authorities of the third country;
- f the findings of controls performed by the Commission in the third country in accordance with Article 120(1);
- g any other information or data on the capability of the third country to ensure that only animals or goods which provide the same or an equivalent level of protection as that afforded by the relevant requirements referred to in Article 126(1) enter the Union.

4 The Commission shall delete the reference to a third country or a region of a third country from the list referred to in point (a) of Article 126(2) where the conditions for inclusion on the list cease to be met. The procedure referred to in paragraph 2 of this Article shall apply.

Article 128

Special measures regarding the entry into the Union of certain animals and goods

1 Where, in cases other than those referred to in Article 53 of Regulation (EC) No 178/2002 and Article 249 of Regulation (EU) 2016/429, there is evidence that the entry into the Union of certain animals or goods originating from a third country, a region thereof or a group of third countries, pose a risk to human, animal or plant health or, as regards GMOs, also to the environment, or where there is evidence that widespread serious non-compliance with the rules referred to in Article 1(2) of this Regulation is taking place, the Commission shall adopt, by means of implementing acts, the measures necessary to contain such risk or put an end to the identified non-compliance. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2) of this Regulation.

2 The measures referred to in paragraph 1 shall identify animals and goods by referring to their codes from the Combined Nomenclature, and may include:

- a the prohibition of entry into the Union of the animals and goods referred to in paragraph 1 originating in or dispatched from the third countries concerned or regions thereof;
- b the requirement that the animals and goods referred to in paragraph 1 originating in or dispatched from certain third countries or regions thereof be subject, prior to dispatch, to specific treatment or controls;
- c the requirement that the animals and goods referred to in paragraph 1 originating in or dispatched from certain third countries or regions thereof be subject, upon entry into the Union, to specific treatment or controls;
- d the requirement that consignments of the animals and goods referred to in paragraph 1 of this Article originating in or dispatched from certain third countries or regions thereof, be accompanied by an official certificate, an official attestation, or by any other evidence that the consignment complies with requirements established by the rules referred to in Article 1(2) or with requirements recognised to be at least equivalent thereto;
- e the requirement that the evidence referred to in point (d) be provided in accordance with a specific format;
- f other measures necessary to contain the risk.

3 When adopting the measures referred to in paragraph 2, account shall be taken of:

- a the information collected in accordance with Article 125;
- b any other information that the third countries concerned have provided; and
- c where necessary, the results of Commission controls provided for in Article 120(1).

4 On duly justified imperative grounds of urgency relating to human health and animal health or, as regards GMOs and plant protection products, also to the protection of the environment, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 145(3).

Article 129

Equivalence

1 In the areas governed by the rules referred to in Article 1(2), with the exclusion of points (d), (e), (g), and (h) of Article 1(2), the Commission may, by means of implementing acts, recognise that measures applied in a third country, or regions thereof, are equivalent to the requirements laid down in those rules, on the basis of:

- a a thorough examination of information and data provided by the third country concerned pursuant to Article 125(1); and
- b where appropriate, the satisfactory outcome of a control performed in accordance with Article 120(1).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

2 The implementing acts referred to in paragraph 1 shall set out the practical arrangements for the entry of animals and goods into the Union from the third country concerned, or regions thereof, and may include:

- a the nature and content of the official certificates or attestations that have to accompany the animals or goods;
- b specific requirements applicable to the entry into the Union of the animals or goods and the official controls to be performed at entry into the Union;
- c where necessary, procedures for drawing up and amending lists of regions or establishments in the third country concerned from which the entry of animals and goods into the Union is permitted.

3 The Commission shall, by means of implementing acts, repeal without delay the implementing acts provided for in paragraph 1 of this Article where any of the conditions for the recognition of equivalence cease to be fulfilled. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

CHAPTER III

Training of staff of the competent authorities and of other authorities

Article 130

Training and exchange of staff

1 The Commission may organise training activities for the staff of the competent authorities and, where appropriate, for staff of other authorities of the Member States involved in investigations of possible infringements of this Regulation and of the rules referred to in Article 1(2).

The Commission shall organise those activities in cooperation with the Member States concerned.

2 The training activities referred to in paragraph 1 shall facilitate the development of a harmonised approach to official controls and other official activities in Member States. They shall include, as appropriate, training on:

- a this Regulation and the rules referred to in Article 1(2);
- b control methods and techniques relevant for the official controls and for the other official activities of the competent authorities;
- c production, processing and marketing methods and techniques.

3 The training activities referred to in paragraph 1 may be open to staff of the competent authorities of third countries and may be organised outside the Union.

4 Competent authorities shall ensure that the knowledge acquired through the training activities referred to in paragraph 1 of this Article is disseminated as necessary and appropriately used in the staff training activities referred to in Article 5(4).

Training activities aimed at disseminating such knowledge shall be included in the training programmes referred to in Article 5(4).

5 The Commission may organise, in cooperation with the Member States, programmes for the exchange of staff of the competent authorities performing official controls or other official activities between two or more Member States.

Such exchange may take place through the temporary secondment of staff of the competent authorities from one Member State to the other or through the exchange of such staff between the relevant competent authorities.

6 The Commission may, by means of implementing acts, lay down rules on the organisation of the training activities referred to in paragraph 1, and of the programmes referred to in paragraph 5, of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

CHAPTER IV

Information management system

Article 131

Information management system for official controls (IMSOC)

1 The Commission shall, in collaboration with the Member States, set up and manage a computerised information management system for official controls (IMSOC) for the integrated operation of the mechanisms and tools through which data, information and documents concerning official controls and other official activities are managed, handled, and automatically exchanged.

2 The processing of personal data by the Member States and the Commission through the IMSOC and any one of its components shall only be carried out for the purpose of performing official controls and other official activities in accordance with this Regulation and with the rules referred to in Article 1(2).

Article 132

General functionalities of the IMSOC

The IMSOC shall:

- (a) allow for the computerised handling and exchange of information, data and documents necessary for the performance of official controls, resulting from the performance of official controls or the recording of the performance or outcome of official controls in all cases where this Regulation, the rules referred to in Article 1(2) or the delegated and implementing acts provided for in Articles 16 to 27 provide for the exchange among competent authorities, between the competent authorities and the Commission, and where appropriate with other authorities and the operators, of such information, data and documents;
- (b) provide a mechanism for the exchange of data, information and documents in accordance with Articles 102 to 108;
- (c) provide a tool to collect and manage the reports on official controls provided by Member States to the Commission;
- (d) allow for the production, handling and transmission, including in electronic form, of the journey log referred to in Article 5(4) of Regulation (EC) No 1/2005, of the records obtained by the navigation system referred to in Article 6(9) of that Regulation, of official certificates and of the CHED referred to in Article 56 of this Regulation; and
- (e) integrate the existing computerised systems managed by the Commission and used for the rapid exchange of data, information and documents in relation to risks to human, animal health and welfare, and plant health, as established by Article 50 of Regulation (EC) No 178/2002, Article 20 of Regulation (EU) 2016/429 and Article 103 of Regulation (EU) 2016/2031 and provide appropriate links between those systems and its other components.

Article 133

Use of the IMSOC in the case of animals and goods subject to certain official controls

1 In the case of animals or goods whose movements within the Union or placing on the market are subject to specific requirements or procedures established by the rules referred to in Article 1(2), the IMSOC shall enable the competent authorities at the place of dispatch and other competent authorities responsible for performing official controls on those animals or goods to exchange, in real time, data, information and documents concerning animals or goods being moved from one Member State to another and on official controls performed.

The first subparagraph of this paragraph shall not apply to goods subject to the rules referred to in points (g) and (h) of Article 1(2).

2 In the case of exported animals and goods for which Union rules apply in relation to the issuance of the export certificate, the IMSOC shall enable the competent authorities of the place of dispatch and other competent authorities responsible for performing official controls to exchange, in real time, data, information and documents concerning such animals and goods and the outcome of controls performed on those animals and goods.

3 In the case of animals or goods subject to the official controls referred to in Articles 44 to 64, the IMSOC shall:

- a enable the competent authorities at the border control posts and other competent authorities responsible for performing official controls on those animals or goods to exchange, in real time, data, information and documents concerning those animals and goods and on controls performed on those animals or goods;

- b enable the competent authorities at the border control posts to share and exchange relevant data, information and documents with customs authorities and other authorities responsible for performing controls on animals or goods entering the Union from third countries, and with operators involved in entry procedures, in accordance with the rules adopted pursuant to Articles 15(4) and 75(2) and with other relevant Union rules; and
 - c support and operate the procedures referred to in point (a) of Article 54(3) and in Article 65(6).
- 4 The IMSOC shall, for the purpose of this Article, integrate the existing Traces system.

Article 134

The functioning of the IMSOC

The Commission shall adopt implementing acts for the functioning of the IMSOC which lay down:

- (a) the technical specifications of the IMSOC and its system components, including the electronic data exchange mechanism for exchanges with existing national systems, identification of applicable standards, definition of message structures, data dictionaries, exchange of protocols and procedures;
- (b) the specific rules for the functioning of the IMSOC and of its system components to ensure protection of personal data and security of exchange of information;
- (c) the specific rules for the functioning and use of the IMSOC and of its components, including the rules to update and create the necessary links between the systems referred to in point (e) of Article 132 and in Article 133(4);
- (d) contingency arrangements to be applied in the event of unavailability of any of the functionalities of the IMSOC;
- (e) the cases where, and the conditions under which, the third countries and international organisations concerned may be granted partial access to the functionalities of the IMSOC and the practical arrangements of such access;
- (f) the cases where, and the conditions under which, the data, information and documents are to be transmitted using the IMSOC;
- (g) the rules concerning an electronic system under which electronic certificates issued by the competent authorities of third countries are to be accepted by the competent authorities; and
- (h) the cases where, and the conditions under which, exemptions from the use of the IMSOC can be granted to occasional users.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

Article 135

Data protection

- 1 Directive 95/46/EC and Regulation (EC) No 45/2001 of the European Parliament and of the Council⁽¹⁾ shall apply to the extent that the information processed through the IMSOC

contains personal data as defined in point (a) of Article 2 of Directive 95/46/EC and in point (a) of Article 2 of Regulation (EC) No 45/2001.

2 In relation to their responsibilities to transmit the relevant information to the IMSOC and the processing of any personal data that might result from that activity, the competent authorities of the Member States shall be regarded as controllers as defined in point (d) of Article 2 of Directive 95/46/EC.

3 In relation to its responsibility to manage the IMSOC and the processing of any personal data that might result from that activity, the Commission shall be regarded as controller as defined in point (d) of Article 2 of Regulation (EC) No 45/2001.

4 Member States may restrict the rights and obligations under Article 6(1), Article 10, Article 11(1) and Article 12 of Directive 95/46/EC as necessary to safeguard the interest referred to in points (d) and (f) of Article 13(1) of that Directive.

5 The Commission may restrict the rights and obligations under Article 4(1), Article 11, Article 12(1) and Articles 13 to 17 of Regulation (EC) No 45/2001 where such restriction constitutes a necessary measure to safeguard the interests referred to in points (a) and (e) of Article 20(1) of that Regulation during the period in which actions are being planned or performed to verify compliance with food or feed law or to ensure the enforcement of food or feed law in the specific case to which the information relates.

Article 136

Data security

Member States and the Commission shall ensure that the IMSOC complies with the rules on data security adopted by the Commission under Article 17 of Directive 95/46/EC and Article 22 of Regulation (EC) No 45/2001 respectively.

- (1) Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data ([OJ L 8, 12.1.2001, p. 1](#)).