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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of XXX

**laying down implementing measures for the Rapid alert system for food and feed, and rules as regards the computerised information system for notifying and reporting on listed animal diseases, the notification of the presence of, and protective measures taken against, plant pests, administrative assistance and cooperation between Member States' authorities, and the functioning of the information management system for official controls
(‘the IMSOC Regulation’)**

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety¹, and in particular Article 51 thereof,

Having regard to 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 health² (‘Animal Health Law’), and in particular point (c) of the first paragraph of Article 23 thereof,

Having regard to 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/EC³, and in particular points (a), (b) and (c) of the first paragraph of Article 104 thereof,

Having regard to 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

¹ OJ L 31, 1.2.2002, p. 1.

² OJ L 84, 31.3.2016, p. 1.

³ OJ L 317, 23.11.2016, p. 4.

and 97/78/EC and Council Decision 92/438/EEC⁴ ('Official Controls Regulation'), in particular point (a) of the first paragraph of Article 58, points (a), (b) and (c) of the first paragraph of Article 75(2), point (f) of the first paragraph of Article 90, points (a) and (b) of the first paragraph of Article 102(6), Article 103(6) and the first paragraph of points (a) to (h) of Article 134 thereof,

Whereas:

- (1) Regulation (EU) 2017/625 establishes *inter alia* rules for the Member States' performance of official controls and other official activities on animals and goods entering the Union in order to ensure the correct application of the Union agri-food chain legislation.
- (2) It requires the Commission, in collaboration with Member States, to set up and manage a computerised information management system for official controls (IMSOC) to manage, handle and automatically exchange data, information and documents in relation to official controls. The IMSOC should integrate and upgrade as necessary the information systems managed by the Commission and act as an interoperability schema connecting those systems and the existing national systems of the Member States.
- (3) The information systems for the exchange of information between Member States and with the Commission should therefore be integrated in the IMSOC; these include
 - the Rapid alert system for food and feed (RASFF) for notifying direct or indirect risk to human health deriving from food or feed, as established by Article 50 of Regulation (EC) No 178/2002;
 - the system for notifying and reporting information on listed diseases, to be established pursuant to Article 22 of Regulation (EU) 2016/429;
 - the system for notifying and reporting the presence of pests and notifying cases of non-compliance, to be established pursuant to Article 103 of Regulation (EU) 2016/2031;
 - the technical tools for administrative assistance and cooperation (AAC) referred to in Article 103(6) of Regulation (EU) 2017/625;
 - the TRACES system referred to in Article 133 of Regulation (EU) 2017/625.
- (4) The information systems were established at different times and have since been modified on legal and operational grounds. Therefore, in order to upgrade and integrate them as required by Regulation (EU) 2017/625 it is appropriate to gather in the same act all provisions relating to the functioning of the IMSOC and its system components on the basis of the powers conferred on the Commission by Regulations (EC) No 178/2002, (EU) 2016/429, (EU) 2016/2031 and (EU) 2017/625.
- (5) This Regulation should establish the necessary links between the Commission's information systems for official controls ('the IMSOC components') and the national information systems of the Member States that existed when Regulation (EU) 2017/625 entered into force, so that they can exchange data, information and documents that are relevant for the performance of official controls.

⁴ OJ L 95, 7.4.2017, p. 1.

- (6) Although each IMSOC component has its own specificities, this Regulation should establish the general principles which all components need to comply with, regarding ownership and responsibility for data, information and documents and connection with the national information systems of the Member States and with third countries and international organisations. It should also establish the Commission's obligations and rights as regards the IMSOC and personal data protection provisions in Regulation (EU) 2016/679 of the European Parliament and of the Council⁵, Directive (EU) 2016/680 of the European Parliament and of the Council⁶ and Regulation (EU) 2018/1725 of the European Parliament and of the Council⁷.
- (7) Regulation (EU) 2017/625 provides that the Member States and the Commission should process personal data through the IMSOC and any of its components only for the purposes of official controls and other official activities performed for the verification of compliance with relevant Union rules in the areas referred to in Article 1(2) of that Regulation, including the operators' past records as regards compliance with those rules. Therefore, considering the shelf life of products, life-span of animals and the duration of official controls and other official activities, it is appropriate to establish a maximum storage period of ten years of personal data processed in each IMSOC component.
- (8) In order to implement measures that adhere to the 'data protection by design' principle laid down in Regulations (EU) 2016/679 and (EU) 2018/1725, the IMSOC components should be given a limited capacity to insert unstructured information. In any case, it will be possible to use this capacity only where the same information cannot be provided efficiently in a structured manner. Moreover, even in the absence of explicit references to them, personal data protection principles are embedded in each provision of this Regulation, in particular as regards storage periods of personal data, access to personal data, transmission and transfer of personal data and data security.
- (9) The governance of the IMSOC by the Commission, in collaboration with the Member States, is necessary to ensure that system components are developed and used in a coherent way, so as to limit administrative burden and the establishing of different procedures where this is not strictly necessary.
- (10) To this end, it is appropriate to establish a network of members, including the Commission and, where appropriate, EU agencies, for each IMSOC system component, and for the Commission to establish governance structures to gather ongoing feedback from Member States on planned changes and new features to steer the development of the IMSOC and its components.
- (11) This Regulation should lay down specific rules for the functioning of each IMSOC system component in relation to data visibility, so as to ensure the security of the electronic exchange of data, information and documents.

⁵ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

⁶ Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA (OJ L 119, 4.5.2016, p. 89).

⁷ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

- (12) Regulation (EU) 2017/625 provides that the IMSOC should be capable of helping Member States' competent authorities to share data, information and documents to facilitate administrative assistance and cooperation on cross-border violations of Union agri-food chain legislation that are perpetrated through fraudulent or deceptive practices ('food fraud') and/or may constitute a risk to human, animal or plant health, animal welfare or the environment as regards genetically modified organisms and plant protection products.
- (13) For that purpose and to ensure an effective administrative assistance and cooperation between competent authorities of Member States, Regulation (EU) 2017/625 empowers the Commission to specify the technical tools to be used, and the procedures, for communication on such cases of non-compliance between the liaison bodies designated in accordance with Article 103(1) of that Regulation. It also requires the Commission to establish a standard format for requests for assistance and for common and recurrent notifications and responses.
- (14) Commission Implementing Decision (EU) 2015/1918⁸ governs the establishment and use of the administrative assistance and cooperation system (the AAC system) for the exchange of information between Member States' authorities and between those authorities and the Commission. Since the provisions of Title IV of Regulation (EC) No 882/2004 and the implementing measures in Decision (EU) 2015/1918 are now included in Title IV of Regulation (EU) 2017/625, this Regulation should lay down operational rules for the exchange of information on instances of cross-border non-compliance in accordance with the power conferred on the Commission by Regulation (EU) 2017/625.
- (15) Regulation (EC) No 178/2002 established the RASFF, as managed by the Commission and involving the Member States and the Commission, to provide control authorities with an effective tool for notifying risks to human health deriving from food, food contact material and feed. It also established the European Food Safety Authority to provide the Commission and the Member States with information for risk analysis.
- (16) Regulation (EC) No 183/2005 of the European Parliament and of the Council⁹ broadened the scope of the RASFF to include serious risks to animal health or the environment from feed used for animals not kept for food production.
- (17) Regulation (EC) No 178/2002 provides that third countries may participate in the RASFF on the basis of agreements concluded pursuant to that Regulation. Article 10 of Regulation (EC) No 178/2002 requires the public authorities to inform the public of risks to human health inter alia. The Commission should provide summary information about the RASFF notifications transmitted and annual reports highlighting the trends in food safety issues notified through RASFF and the evolution of the network itself to inform members, stakeholders and the general public.
- (18) As Regulation (EU) 2017/625 provides that the IMSOC is to integrate the RASFF, this Regulation should lay down implementing measures for the efficient operation of the RASFF within the IMSOC that are similar to:

⁸ Commission Implementing Decision (EU) 2015/1918 of 22 October 2015 establishing the Administrative Assistance and Cooperation system ('AAC system') pursuant to Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 280, 24.10.2015, p. 31). The Decision was adopted pursuant to Regulation (EC) No 882/2004, which was subsequently repealed by Regulation (EU) 2017/625.

⁹ Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (OJ L 35, 8.2.2005, p. 1).

- the conditions and procedures applicable to the transmission of notifications, as currently established by Commission Regulation (EU) No 16/2011¹⁰; and
- the definitions of the different types of notification classified according to risks to human health deriving from food or feed, as also established by that Regulation

It should also include:

- the rules laid down in that Regulation on the publication by the Commission of information on RASFF notifications; and
 - the measures to ensure that food safety authorities in third countries are notified of, and receive relevant information with regard to, notifications and any direct or indirect risk to human health deriving from food or feed.
- (19) At the Ministerial Conference on 26 September 2017¹¹, following an incident of fipronil contamination, the Commission and the Member States agreed on concrete measures and coordinated action against food fraud. They identified bridging the gap between the RASFF and the AAC system by means of a combined platform as one measure to ensure that information is exchanged as efficiently as possible. Therefore, this Regulation should ensure that the IMSOC provides the RASFF members and the liaison bodies designated for the purpose of AAC and food fraud with a common computerised tool (iRASFF) for the exchange of information required by Regulation (EC) No 178/2002 and Regulation (EU) 2017/625. In order to ensure the correct and efficient functioning of iRASFF, this Regulation should also establish common rules for the contact points for the RASFF, AAC and food fraud networks (which together makes up the ‘alert and cooperation network’) and for the Commission’s coordinating role in verifying notifications and helping to identify recurrent hazards and operators reported in them.
- (20) Given the complex nature of certain cases of non-compliance where risks may not be immediately identified and in order to ensure swift and appropriate coordination between different competent authorities (in particular in the context of police or judicial investigations), the European Police Office (Europol), which, where relevant, informs the European Union’s Judicial Cooperation Unit (Eurojust) of such investigations, should take part in the food fraud network and that the contact points of the Member States’ RASFF and AAC networks be represented in an entity called Single contact point. The latter should consist of persons managing both networks, whether or not physically located in the same administrative unit, relay information to the appropriate competent authority within the country and routinely be the first contact point for the Commission.
- (21) Regulation (EU) 2016/429 lays down rules on animal diseases that are transmissible to animals or humans, including requirements for disease notification and reporting. It requires the Commission to set up and manage a computerised information system for the operation of the mechanisms and tools for those requirements and, for that purpose, empowers the Commission to lay down rules with respect to procedures for the establishment and use of such a system, which should be integrated into the IMSOC in accordance with Regulation (EU) 2017/625.

¹⁰ Commission Regulation (EU) No 16/2011 of 10 January 2011 laying down implementing measures for the Rapid alert system for food and feed (OJ L 6, 11.1.2011, p. 7).

¹¹ https://ec.europa.eu/food/safety/rasff/fipronil-incident_en

- (22) The animal disease notification system (ADNS) established pursuant to Directive 82/894/EEC¹² and repealed by Regulation (EU) 2016/429 allows Member States and other participating countries to report to each other and the Commission information on outbreaks of certain animal diseases on their territory. The OIE web-based world animal health information system (WAHIS) is used by Member States and other OIE member countries to submit information relating to animal diseases.
- (23) In order to help Member States fulfil their obligations towards it and the OIE to report information on outbreaks of animal diseases and zoonoses, the Commission has set up a web-based animal disease information system (ADIS) that should serve as a single entry point for that purpose. This Regulation should therefore lay down procedures for the establishment and use of the ADIS, as one of the IMSOC components that should be applicable from the date of application of Regulation (EU) 2016/429.
- (24) Regulation (EU) 2016/2031 lays down measures to prevent the entry or spread of plant pests in EU territory, including notification requirements for pest presence and phytosanitary measures taken. It requires the Commission to establish an electronic system through which the Member States are to submit notifications and which should be connected to, and compatible with, the IMSOC.
- (25) For that purpose, that Regulation empowers the Commission to lay down specific rules on notifications, in particular on the items to be included, a form and how to fill it in and deadlines for the submission of particular items.
- (26) The *EUROPHYT-Interceptions* web-based notification system¹³ is a network developed by the Commission, with the Member States, for notifying interception of consignments of plants and plant products from other Member States or third countries that may present an imminent danger of introducing or spreading pests. The procedure and standard form to be used for notifying interception of such consignments from a third country are laid down in the Annex to Commission Directive 94/3/EC¹⁴.
- (27) A parallel web-based notification system, *EUROPHYT-Outbreaks*, was developed with a view to helping Member States to notify official confirmation of the presence of pests on their territory, and measures taken to eradicate or prevent the spread of the pest, whether or not regulated at EU level as harmful. Implementing Decision 2014/917/EU¹⁵ sets out the information to be included in such notifications and the deadline for submitting them. It also requires the notifying Member State to provide updates as soon as possible if it receives new relevant information or takes new relevant measures.
- (28) To allow the Member States to notify interceptions and outbreaks as required by Regulation (EU) 2016/2031, this Regulation should provide that *EUROPHYT* be integrated in the IMSOC, as one of its components, and lay down rules on notifying

¹² Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community (OJ L 378, 31.12.1982, p. 58).

¹³ The system was originally established by Council Directive 77/93/EEC of 21 December 1976 on protective measures against the introduction into the Member States of harmful organisms of plants or plant products (OJ L 26, 31.1.77, p. 20). That Directive was repealed by Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community (OJ L 169 10.7.2000, p. 1), which was in turn repealed by Regulation (EU) 2016/2031 as of 14 December 2019.

¹⁴ Commission Directive 94/3/EC of 21 January 1994 establishing a procedure for the notification of interception of a consignment or a harmful organism from third countries and presenting an imminent phytosanitary danger (OJ L 32, 5.2.1994, p. 37).

¹⁵ Commission Implementing Decision 2014/917/EU of 15 December 2014 setting out detailed rules for the implementation of Council Directive 2000/29/EC as regards the notification of the presence of harmful organisms and of measures taken or intended to be taken by the Member States (OJ L 360, 17.12.2014, p. 59).

interceptions and outbreaks following procedures similar to those used for interceptions under Commission Directive 94/3/EC and outbreaks under in Implementing Decision 2014/917/EU.

- (29) Because the notifications submitted to EUROPHYT-*Interceptions* are similar to the data and information on imports of and intra-Union trade in animals and products of animal origin submitted to the TRACES system, the functionalities of EUROPHYT-*Interception* for commodities intercepted at the border and within the Union should be provided within TRACES rather than within EUROPHYT.
- (30) Regulation (EU) 2017/625 also provides that the IMSOC should allow the production, handling and transmission of:
- official certificates attesting compliance with specific requirements for the placing on the market or the movement of certain animals or goods;
 - common health entry documents (CHEDs) used, for the relevant parts, by:
 - the operators responsible for consignments of animals and goods referred to in Article 47(1) of that Regulation, in order to notify the authorities at the border control post in advance of the arrival of the consignments; and
 - the authorities at the border control post, in order to record the outcome of official controls and any decisions taken.
- (31) Regulation (EU) 2017/625 empowers the Commission to lay down rules on the format of the CHEDs, instructions for their presentation and use, taking account of international standards, and rules for the issuance of electronic certificates and the use of electronic signatures.
- (32) The common veterinary entry document (CVED) template for products in Annex III to Regulation (EC) No 136/2004¹⁶ should serve as a basis to establish in this Regulation a template for a CHED (CHED-P) with entries that are relevant for products of animal origin, germinal products and animal by-products, as referred to in point (b) of Article 47(1) of Regulation (EU) 2017/625.
- (33) The CVED template for animals set out in Annex I to Regulation (EC) No 282/2004¹⁷ for animals should serve as a basis to establish in this Regulation a template for a CHED (CHED-A) with entries that are relevant for animals, as referred to in point (a) of Article 47(1) of Regulation (EU) 2017/625.
- (34) The CED template set out in Annex II to Regulation (EC) No 669/2009¹⁸ for certain feed and food of non-animal origin should serve as a basis to establish in this Regulation a template for a CHED (CHED-D) with entries that are relevant for feed and food of non-animal origin subject at their entry into the Union to:
- a temporary increase of controls, as referred to in point (d) of Article 47(1) of Regulation (EU) 2017/625;
 - an emergency measure, as referred to in point (e) of that Article;

¹⁶ Commission Regulation (EC) No 136/2004 of 22 January 2004 laying down procedures for veterinary checks at Community border inspection posts on products imported from third countries (OJ L 21. 28.1.2004, p. 11).

¹⁷ Commission Regulation (EC) No 282/2004 of 18 February 2004 introducing a document for the declaration of, and veterinary checks on, animals from third countries entering the Community (OJ L 49, 19.2.2004, p. 11).

¹⁸ Commission Regulation (EC) No 669/2009 of 24 July 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC (OJ L 194, 25.7.2009, p. 11).

- conditions or measures referred to in point (f) of that Article.
- (35) To allow the prior notification of the arrival of consignments provided for in Regulation (EU) 2017/625 for plants, plant products and other objects introduced from third countries for which a phytosanitary certificate is required, this Regulation should also lay down a template for a CHED (CHED-PP) with entries that are relevant for:
- plants, plant products and other objects, as referred to in point (c) of Article 47(1) of Regulation (EU) 2017/625;
 - specific plants, plant products and other objects of a particular origin or provenance, as provided for in Commission Implementing Regulation (EU) 2019/66¹⁹;
 - plants, plant products and other objects subject at their entry into the Union to measures or conditions referred to in points (d), (e) or (f) of Article 47(1) of that Regulation.

Those entries should be the same as the items to be included in the notifications of interceptions of consignments of plants, plant products or other objects that are imported from third countries or traded in the Union and capable of presenting an imminent danger of introducing or spreading pests.

- (36) Each relevant CHED template should include:
- a part to be filled in by the person responsible for the consignment and transmitted to the authorities of the border control post before its physical arrival;
 - a part to be completed by those authorities as soon as they have carried out the checks referred to in Article 49(1) of Regulation (EU) 2017/625 and taken a decision on the consignment;
 - a part to be completed by the authorities of the border control post, control point or control unit with regard to follow-up actions on the consignment.
- (37) This Regulation should also set out instructions for completing each part of the CHED, including language requirements.
- (38) The provisions of Commission Implementing Decision (EU) 2018/1553²⁰ should serve as a basis to lay down in this Regulation rules for the issuance of electronic certificates and the use of electronic signatures pursuant to Regulation (EU) 2017/625. In particular, compliance with the standards established by the United Nations Centre for Trade Facilitation and Electronic Business (UN/CEFACT) concerning paperless trade facilities, the Secretariat of the International Plant Protection Convention (IPPC) and OIE standards concerning international harmonisation of veterinary measures, and the use of formats such as the ‘eXtensible markup language’ (XML), the ‘cryptographic message syntax’ (CMS) and the ‘portable document format’ (PDF) should constitute the basic requirements for the issuance in the Union of electronic documents such as official certificates or CHEDs.

¹⁹ Commission Implementing Regulation (EU) 2019/66 of 16 January 2019 on rules on uniform practical arrangements for the performance of official controls on plants, plant products and other objects in order to verify compliance with Union rules on protective measures against pests of plants applicable to those goods (OJ L 15, 17.1.2019, p. 1).

²⁰ Commission Implementing Decision (EU) 2018/1553 of 15 October 2018 on conditions for the recognition of electronic phytosanitary certificates issued by the national plant protection organisations of third countries (OJ L 260, 17.10.2018, p. 22).

- (39) Moreover, in order to maintain an adequate level of security of electronic means of identification and electronic certification, digitalise the certification process in line with the Commission's communication of 6 May 2015 on '*A digital single market strategy for Europe*'²¹ and harmonise standards across Member States, the issuance of electronic official certificates and CHEDs should meet the standards for electronic signatures, electronic seals and electronic timestamps in their different levels of identity assurance set by Regulation (EU) No 910/2014²², and the technical specifications for advanced electronic signature and seal laid down in the Annex to Decision (EU) 2015/1506²³ adopted pursuant to that Regulation.
- (40) However, as Regulation (EU) 2016/2031 provides that electronic phytosanitary certificates for the introduction into the Union territory of plants, plant products and other objects are to be accepted only where they are provided through, or in electronic exchange with the IMSOC, this Regulation should establish rules for the issuance of such certificates that are more stringent than the rules for that of other official certificates.
- (41) Close cooperation between authorities in relation to consignments of animals and goods entering the Union is key to the efficiency of official controls. Regulation (EU) 2017/625 empowers the Commission to lay down rules on uniform cooperation arrangements that competent authorities, customs authorities and other authorities are to put in place to ensure:
- competent authorities' access to information on consignments of animals and goods entering the Union and subject to official controls at a border control post;
 - reciprocal updates of information on those consignments; and
 - the swift communication of decisions taken by authorities on the basis of that information.
- (42) Decision No 70/2008/EC of the European Parliament and of the Council²⁴ requires the Commission and the Member States to set up secure, integrated, interoperable and accessible electronic customs systems to provide single window services for the seamless flow of data between economic operators and customs authorities, between customs authorities and the Commission, and between customs authorities and other administrations or agencies. They should enable economic operators to lodge all information required for import or export clearance with a single entry, including that required under non-customs-related legislation. The interconnection of such systems forms the EU Single Window environment for customs. Since these objectives are similar to those of Regulation (EU) 2017/625, this Regulation should provide for similar cooperation arrangements between authorities dealing with animals and goods entering the Union and operating in TRACES.

²¹ COM(2015) 192 final.

²² Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC.

²³ Commission Implementing Decision (EU) 2015/1506 of 8 September 2015 laying down specifications relating to formats of advanced electronic signatures and advanced seals to be recognised by public sector bodies pursuant to Articles 27(5) and 37(5) of Regulation (EU) No 910/2014 of the European Parliament and of the Council on electronic identification and trust services for electronic transactions in the internal market (OJ L 235, 9.9.2015, p. 37).

²⁴ Decision No 70/2008/EC of the European Parliament and of the Council of 15 January 2008 on paperless environment for customs and trade (OJ L 23, 26.1.2008, p. 21).

- (43) In order to ensure the consistent collection of information and avoid the pollution of Member States and Commission databases, data exchanges between TRACES and the national systems of the Member States should use reference data provided by the Commission in TRACES.
- (44) The provisions of Commission Directive 94/3/EC, Commission Regulation (EU) No 16/2011, and Implementing Decisions 2014/917/EU, (EU) 2015/1918 and (EU) 2018/1553 have been reviewed and are now incorporated in this Regulation. For the sake of clarity and consistency those acts should be repealed with effect from the date of application of Regulation (EU) 2017/625.
- (45) Commission Decisions 92/486/EEC²⁵, 2003/24/EC²⁶, 2003/623/EC²⁷, 2004/292/EC²⁸, 2004/675/EC²⁹ and 2005/123/EC³⁰, adopted in relation to the TRACES system pursuant to Council Directive 90/425/EEC³¹ and Council Decision 92/438/EEC³², have become obsolete. For the sake of clarity and consistency, those Decisions should also be repealed with effect from the date of application of Regulation (EU) 2017/625.
- (46) This Regulation has been discussed with the European Food Safety Authority.
- (47) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Chapter 1

Subject matter, scope and definitions

Article 1 *Subject matter and scope*

This Regulation lays down:

- (a) specific conditions and procedures applicable to the transmission of notifications and supplementary information for the Rapid alert system for food and feed (RASFF) to be established pursuant to Regulation (EC) No 178/2002;
- (b) procedures for the establishment and use of the computerised system for Union notification and reporting of diseases to be set up and managed by the Commission in accordance with Article 22 of Regulation (EU) 2016/429;

²⁵ Commission Decision 92/486/EEC of 25 September 1992 establishing the form of cooperation between the Animo host centre and Member States (OJ L 291, 7.10.1992, p. 20).

²⁶ 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).

²⁷ Commission Decision 2003/623/EC of 19 August 2003 concerning the development of an integrated computerised veterinary system known as Traces (OJ L 216, 28.8.2003, p. 58).

²⁸ Commission Decision 2004/292/EC of 30 March 2004 on the introduction of the Traces system and amending Decision 92/486/EEC (JO L 94, 31.3.2004, p. 63).

²⁹ Commission Decision of 29 September 2004 establishing logistical support for the Traces system (OJ L 309, 6.10.2004, p. 26).

³⁰ Commission Decision 2005/123/EC of 9 February 2005 amending Decision 2004/292/EC on the introduction of the TRACES system and amending Decision 92/486/EEC (OJ L 39, 11.2.2005, p. 53).

³¹ 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).

³² 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).

- (c) specific rules, including deadlines, for the submission of notifications, to be laid down pursuant to Regulation (EU) 2016/2031;
- (d) rules for the computerised handling and exchange of information, data and documents necessary for the performance of the official controls provided for in Regulation (EU) 2017/625, as regards:
 - (i) the format of the common health entry document (CHED) referred to in Article 56 of Regulation (EU) 2017/625, including its electronic equivalent, and the instructions for its presentation and use;
 - (ii) uniform arrangements for cooperation between customs authorities, competent authorities and other authorities, as referred to in Article 75 of Regulation (EU) 2017/625;
 - (iii) the issuance of electronic certificates and the use of electronic signatures for the official certificates referred to in Article 87 of Regulation (EU) 2017/625;
 - (iv) standard formats for information exchange in the framework of administrative assistance and cooperation, as referred to in Title IV of Regulation (EU) 2017/625, concerning:
 - requests for assistance,
 - common and recurrent notifications and responses,
 - (v) specifications of the technical tools and procedures for communication between liaison bodies designated in accordance with Article 103(1) of Regulation (EU) 2017/625;
 - (vi) the proper functioning of the information management system for official controls (IMSOC) referred to in Chapter IV of Title VI of Regulation (EU) 2017/625.

Article 2 *Definitions*

For the purposes of this Regulation, the following definitions shall apply in addition to those set out in Regulation (EU) No 910/2014:

- (1) ‘component’ means an electronic system integrated in the IMSOC;
- (2) ‘network’ means a group of members having access to a specific component;
- (3) ‘network member’ means a Member State, the Commission, an EU agency, a third country or an international organisation that has access to at least one of the IMSOC components;
- (4) ‘contact point’ means the contact point designated by the member of a network to represent it;
- (5) ‘Member State’s national system’ means a computerised information system owned and set up before the date of entry into force of Regulation (EU) 2017/625 by a Member State for the purpose of managing, handling and exchanging data, information and documents on official controls, and capable of electronically exchanging data with the relevant IMSOC component;

- (6) 'international organisation' means any of the internationally recognised bodies listed in point (g) of Article 121 of Regulation (EU) 2017/625, or similar intergovernmental organisations;
- (7) 'iRASFF' means the electronic system implementing the RASFF and AAC procedures described in Article 50 of Regulation (EC) No 178/2002 and Articles 102 to 108 of Regulation (EU) 2017/625 respectively;
- (8) 'risk' means any direct or indirect risk to human health in connection with food, food contact material or feed in accordance with Article 50 of Regulation (EC) No 178/2002 or a serious risk to animal health or to the environment in connection with feed, including feed for animals not kept for food production, in accordance with Article 29 of Regulation (EC) No 183/2005;
- (9) 'RASFF network' means the Rapid alert system for the notification of direct or indirect risk to human health deriving from food or feed, established as a network by Article 50 of Regulation (EC) No 178/2002;
- (10) 'AAC network' means the network composed of the Commission and the liaison bodies designated by the Member States in accordance with Article 103(1) of Regulation (EU) 2017/625 for the purpose of facilitating communication between competent authorities;
- (11) 'food fraud network' means the network composed of the Commission, Europol and the liaison bodies designated by the Member States in accordance with Article 103(1) of Regulation (EU) 2017/625 for the specific purpose of facilitating the exchange of information on food fraud notifications as defined in point (19);
- (12) 'alert and cooperation network' means a network composed of the RASFF, AAC and food fraud networks;
- (13) 'single contact point' means a contact point composed of the RASFF and AAC contact points in each Member State, whether or not physically located in the same administrative unit;
- (14) 'non-compliance notification' means a notification in iRASFF of a non-compliance that does not present a risk within the meaning of Article 50 of Regulation (EC) No 178/2002 and Article 106(1) of Regulation (EU) 2017/625, except non-serious risks to animal health and risks to plant health or animal welfare;
- (15) 'alert notification' means a notification in iRASFF of a serious direct or indirect risk deriving from food, food contact material or feed within the meaning of Article 50 of Regulation (EC) No 178/2002 and Article 29 of Regulation (EC) No 183/2005 that requires or might require rapid action by another member of the RASFF network;
- (16) 'information notification' means a notification in iRASFF of a direct or indirect risk deriving from food, food contact material or feed according to Article 50 of Regulation (EC) No 178/2002 and Article 29 of Regulation (EC) No 183/2005 that does not require rapid action by another member of the RASFF network;
 - (a) 'information notification for follow-up' means an information notification related to a product that is or may be placed on the market in another member of the RASFF network's country;
 - (b) 'information notification for attention' means an information notification related to a product that:

- (i) either is present only in the notifying country of the member of the network; or
 - (ii) has not been placed on the market; or
 - (iii) is no longer on the market;
- (17) ‘news notification’ means a notification in iRASFF concerning a risk deriving from food or feed within the meaning of Article 50 of Regulation (EC) No 178/2002 and Article 29 of Regulation (EC) No 183/2005 that has an informal source, contains unverified information or concerns as yet unidentified products;
- (18) ‘border rejection notification’ means a notification in iRASFF of a rejection, due to a direct or indirect risk to human health, of a batch, container or cargo of food or feed within the meaning of Article 50 of Regulation (EC) No 178/2002;
- (19) ‘food fraud notification’ means a non-compliance notification in iRASFF concerning suspected intentional action by businesses or individuals for the purpose of deceiving purchasers and gaining undue advantage therefrom, in violation of the rules referred to in Article 1(2) of Regulation (EU) 2017/625;
- (20) ‘original notification’ means a non-compliance notification, an alert notification, an information notification, a news notification, a food fraud notification or a border rejection notification;
- (21) ‘follow-up notification’ means a notification in iRASFF that contains additional information in relation to an original notification;
- (22) ‘request’ means a request for administrative assistance in iRASFF based on an original or follow-up notification and enabling the exchange of information pursuant to Articles 104 to 108 of Regulation (EU) 2017/625;
- (23) ‘response’ means a response to a request for administrative assistance in iRASFF based on an original or follow-up notification and enabling the exchange of information pursuant to Articles 104 to 108 of Regulation (EU) 2017/625;
- (24) ‘notifying network member or contact point’ means the network member or contact point addressing a notification to another network member or contact point;
- (25) ‘notified network member or contact point’ means the network member or contact point to which a notification is addressed by another network member or contact point;
- (26) ‘requested network member or contact point’ means the network member or contact point to which a notification is addressed by another network member or contact point for the purpose of receiving a response;
- (27) ‘ADIS’ means the computerised information system for the notification and reporting of diseases to be set up and managed by the Commission in accordance with Article 22 of Regulation (EU) 2016/429;
- (28) ‘EUROPHYT’ means the electronic notification system to be established by the Commission and to be connected to, and compatible with, the IMSOC for Member States’ submission of EUROPHYT outbreak notifications in accordance with Article 103 of Regulation (EU) 2016/2031;
- (29) ‘EUROPHYT outbreak notification’ means a notification to be submitted in EUROPHYT of any of the following:

- (a) the officially confirmed presence on the Union territory of a Union quarantine pest, as referred to in points (a) and (b) of the first paragraph of Article 11 of Regulation (EU) 2016/2031;
 - (b) the officially confirmed presence of a pest not included in the list of Union quarantine pests, as referred to in Article 29(1) of Regulation (EU) 2016/2031;
 - (c) the presence in, or the imminent danger of entry into, or spread within, the Union territory of a pest not included in the list of Union quarantine pests, as referred to in Article 30(1) of Regulation (EU) 2016/2031;
 - (d) the officially confirmed presence of a protected zone quarantine pest, as referred to in Article 33(1) of Regulation (EU) 2016/2031;
- (30) ‘EUROPHYT interception notification’ means a notification to be submitted in TRACES in any of the situations described in point (c) of the first paragraph of Article 11, Article 40(4), Article 41(4), Article 46(4), the second, third and fourth subparagraphs of Article 49(6), Article 53(4), Article 54(4), Article 77(2) and Article 95(5) of Regulation (EU) 2016/2031;
- (31) ‘TRACES’ means the computerised system referred to in Article 133 of Regulation (EU) 2017/625 for the purposes of exchanging data, information and documents;
- (32) ‘control point’ means a control point as referred to in point (a) of Article 53(1) of Regulation (EU) 2017/625;
- (33) ‘control unit’ means a unit that has the technology and equipment necessary for the efficient operation of the relevant IMSOC component and designated as follows for that purpose:
- (a) ‘central unit’ for the central competent authority of a Member State;
 - (b) ‘regional unit’ for any regional competent authority of a Member State;
 - (c) ‘local unit’ for any local competent authority of a Member State.

Chapter 2

General principles and data protection

Article 3 *IMSOC components*

1. The IMSOC shall be composed of the following system components:
 - (a) iRASFF;
 - (b) ADIS;
 - (c) EUROPHYT;
 - (d) TRACES.
2. The components referred to in paragraph 1 shall operate in compliance with the general principles and data protection rules laid down in this Chapter.

Article 4

IMSOC system components, networks and contact points

1. Each IMSOC component shall have a network of which the Commission shall be part.
2. Network members shall each designate at least one contact point and communicate that designation and its contact details to the Commission contact point. They shall inform the Commission contact point immediately of any changes in this respect.
3. The Commission contact point shall maintain and keep up to date a list of contact points and make it available to all network members.
4. The Commission shall establish a governance structure to steer the development, identify priorities and monitor the correct implementation of the IMSOC. The structure shall be composed of:
 - (a) an operations management board, in collaboration with the Member States, to discuss, at least once a year, priorities for and the development of each IMSOC component;
 - (b) sub-groups within the operations management board that regularly discuss priorities for and the development of specific functionalities of each component.

Article 5

Ownership and responsibilities for data, information and documents

1. Each network member shall own and be responsible for the data, information and documents its contact point or users acting under its responsibility have inserted or produced in the relevant IMSOC component.
2. Each signatory, competent authority to which a signatory belongs or competent authority creating a seal shall own and be responsible for the part of the documents it signs or seals in TRACES.
3. Where more than one signatory signs a document in TRACES, each signatory shall own and be responsible for the part of the document that it signs.

Article 6

Links between IMSOC components

1. Links between IMSOC components shall be aimed at:
 - (a) complementing data, information or documents already present in another component; and
 - (b) providing relevant and up-to-date information to each network member for the performance of its tasks; and
 - (c) supporting and operating the procedures for
 - (i) determining and modifying the frequency rates of identity checks and physical checks to be performed on consignments of categories of animals and goods referred to in points (a), (b) and (c) of Article 47(1) of Regulation (EU) 2017/625;

- (ii) applying the frequency of identity checks and physical checks to be performed on consignments of categories of animals or goods referred to in points (d), (e) and (f) of that Article;
 - (iii) the coordinated performance by competent authorities of the intensified official controls in case of suspicions of non-compliance referred to in Article 65(4) of that Regulation.
- 2. The links referred to in paragraph 1 shall consist in links between:
 - (a) iRASFF and TRACES, allowing the exchange of data concerning border rejection notifications and common health entry documents;
 - (b) EUROPHYT and TRACES, allowing the exchange of data concerning EUROPHYT outbreak and interception notifications;
 - (c) iRASFF, EUROPHYT and TRACES, allowing the exchange of data concerning operators' past records as regards compliance with the rules referred to in Article 1(2) of Regulation (EU) 2017/625.

Article 7

Electronic data exchange between IMSOC components and other electronic systems

1. Data exchanges between the IMSOC and other electronic systems, including the Member States' national systems, shall:
 - (a) be based on international standards that are relevant for the system component and use XML, CMS or PDF formats;
 - (b) use the specific data dictionaries and business rules provided for in the relevant IMSOC component.
2. The Commission shall provide the Member States with:
 - (a) the frequency rates and the outcome of intensified official controls referred to in points (b)(i) and (b)(iii) of Article 6;
 - (b) the frequency of identity checks and physical checks referred to in point (b)(ii) of Article 6;
 - (c) the data dictionaries and business rules referred to in point (b) of paragraph 1.
3. In collaboration with the Member States, the Commission shall draw-up a service-level agreement governing the maintenance of the electronic data exchange between the relevant IMSOC component and other electronic systems, including the Member States' national systems.

Article 8

Obligations and rights of the Commission

1. The Commission shall ensure the functioning, maintenance, support and any necessary updating or development of the software and IT infrastructure of the IMSOC components.
2. The Commission shall have access to all data, information and documents in each IMSOC component in order to monitor the exchange of data, information and documents inserted or produced therein for identifying activities that are, or appear to

be, not in compliance with the rules referred to in Article 1(2) of Regulation (EU) 2017/625, and

- (a) either have, or might have, ramifications in more than one Member State; or
- (b) are, or appear to be, taking place in more than one Member State.

Article 9

Conditions for the granting of partial access to the IMSOC to third countries and international organisations

1. On receipt of a duly justified application, the Commission, in collaboration with the Member States, may grant the competent authority of a third country or an international organisation partial access to the functionalities of one or more IMSOC components and to specific data, information and documents inserted or produced therein, provided the applicant demonstrates, in respect of the component(s) in question, that it meets the following requirements:
 - (a) it has the legal and operational capacity to provide, without undue delay, the assistance necessary to fulfil the purpose of the component to which partial access is requested;
 - (b) it has designated a contact point for that purpose;
2. The partial access referred to in paragraph 1 shall never include access to personal data processed in the IMSOC component to which the partial access is granted.
3. By way of derogation from paragraph 2, partial access may include access to personal data where the conditions for lawful transfers of personal data established by Regulations (EU) 2016/679 and (EU) 2018/1725 are fulfilled by the applicant third country or international organisation.

Article 10

Personal data processing

1. Personal data shall be processed in each IMSOC system component for the purpose of performing official controls and other official activities. In particular, personal data shall belong to one of the following categories:
 - (a) contact points, operators, importers, exporters, transporters and laboratory technicians when personal data is required by Union law;
 - (b) users of each IMSOC component.
2. In processing personal data pursuant to this Regulation, Member States shall comply with Regulation (EU) 2016/679 and Directive (EU) 2016/680 and the Commission with Regulation (EU) 2018/1725.

Article 11

Data controllers and joint controllership

1. The Commission and each contact point designated in accordance with Article 4(2) shall be joint controllers of data processing operations in each of the IMSOC components.
2. The Commission shall be responsible for:

- (a) determining and implementing the technical means to enable data subjects to exercise their rights, and ensuring that those rights are exercised in compliance with Regulation (EU) 2018/1725;
 - (b) ensuring the security of processing within each IMSOC component pursuant to Article 33 of Regulation (EU) 2018/1725;
 - (c) determining the categories of its staff and external providers to whom access to the IMSOC components may be granted;
 - (d) notifying and communicating any personal data breach of the IMSOC components to the European Data Protection Supervisor pursuant to Article 34 of Regulation (EU) 2018/1725 and to the data subject pursuant to Article 35 of that Regulation respectively;
 - (e) ensuring that its staff and external providers are adequately trained to perform their tasks in accordance with Regulation (EU) 2018/1725.
3. The contact points for each IMSOC component shall each be responsible for:
- (a) ensuring that rights are exercised in compliance with Regulation (EU) 2016/679 and this Regulation;
 - (b) ensuring the security and confidentiality of personal data pursuant to Section 2 of Chapter IV of Regulation (EU) 2016/679;
 - (c) designating the staff that are to have access to each IMSOC component;
 - (d) ensuring that staff accessing each IMSOC component are adequately trained to perform their tasks in accordance with Regulation (EU) 2016/679 and, where relevant, Directive (EU) 2016/680.
4. Contact points for each IMSOC component may designate other joint controllers within the same Member State for the purpose of fulfilling one or more of the obligations referred to in paragraph 3.

Chapter 3

System components and their networks and contact points

SECTION 1

IRASFF

Article 12

Liaison bodies responsible for the exchange of certain type of information

Member States shall indicate which of the liaison bodies designated in accordance with Article 103(1) of Regulation (EU) 2017/625 are responsible for exchanging information on food fraud notifications.

Article 13

Single contact point

1. The Single contact point in each Member State shall be responsible for:
 - (a) setting up effective arrangements for the smooth exchange of relevant information with all relevant competent authorities within its jurisdiction, allowing the immediate transmission of notifications, requests or responses to

- the competent authorities for appropriate action, and maintaining them in good order;
- (b) determining its roles and responsibilities and those of the relevant competent authorities within its jurisdiction as regards preparing and transmitting notifications, requests and responses, and assessing and distributing notifications, requests and responses from other members of the alert and cooperation network.
2. Member States may include their food fraud network contact point in their Single contact point.
 3. Communication within the RASFF network shall take place through the Single contact point.

Article 14

Duties of the members of the alert and cooperation network

1. Members of the alert and cooperation network shall ensure the efficient functioning of their networks within their jurisdiction.
2. Each designated alert and cooperation network contact point shall communicate to the Commission contact point detailed information regarding the persons operating it and their contact details. For that purpose, it shall use the contact point information template provided by the Commission.
3. RASFF network contact points shall ensure that an on-duty officer is available for emergency communications on a 24/7 basis.

Article 15

Information exchanged in iRASFF

1. Information exchanges between alert and cooperation network contact points for the purposes of Article 50 of Regulation (EC) No 178/2002 and Title IV of Regulation (EU) 2017/625 shall be made in iRASFF only and in the form of notifications, requests and responses.
2. The relevant fields of a notification shall be completed to enable clear identification of the product(s), risk(s), instances of non-compliance and suspected fraud concerned, provide traceability information where possible and identify contact points responsible for any follow-up to a notification or response to a request.
3. Notifications may be transmitted in the form of original or follow-up notifications.
4. Requests and responses shall indicate the alert and cooperation network contact point(s) to which the request or response is addressed.

Article 16

Non-compliance notifications

1. Alert and cooperation network contact points shall exchange without undue delay non-compliance notifications including at least the following:
 - (a) the name of the competent authority dealing with the notification, if different from the contact point;
 - (b) a description of the possible non-compliance;

- (c) the identification, where possible, of the operators associated with it;
 - (d) details of the animals or goods involved;
 - (e) any information concerning suspected risks;
 - (f) an indication as to whether the notification relates to a possible instance of non-compliance perpetrated through fraudulent practices.
2. The Commission contact point shall verify each non-compliance notification after it has been exchanged, without undue delay.

Article 17
Alert notifications

1. RASFF network contact points shall submit alert notifications to the Commission contact point without undue delay and in any event within 48 hours of the risk being reported to them.
2. Alert notifications shall include all available information required by Article 16(1) and any information on the risk and the product from which it derives. However, the fact that not all relevant information has been collected shall not unduly delay transmission of alert notifications.
3. The Commission contact point shall verify alert notifications and transmit them to the alert and cooperation network contact points within 24 hours of receiving them.
4. Outside Commission office hours, RASFF network contact points shall announce the transmission of an alert notification or follow-up to an alert notification, flagging another member of the network for follow-up by a telephone call to the emergency phone number of the Commission contact point. The Commission contact point shall inform the RASFF network contact points flagged for follow-up by a telephone call to their emergency phone numbers.

Article 18
Information notifications

1. RASFF network contact points shall submit information notifications to the Commission contact point without undue delay.
2. Information notifications shall include all available information required by Article 16(1) and any information on the risk and the product from which it derives.
3. The Commission contact point shall verify information notifications and transmit them to the alert and cooperation network contact points without undue delay on receiving them.

Article 19
News notifications

1. Alert and cooperation network contact points may submit news notifications to the Commission contact point.
2. News notifications shall include all the information required by Article 16(1), where available.

3. The Commission contact point shall verify news notifications and transmit them to the alert and cooperation network contact points without undue delay on receiving them.

Article 20

Border rejection notifications

1. RASFF network contact points shall transmit border rejection notifications to the alert and cooperation network contact points without undue delay.
2. Border rejection notifications shall include all information required by Article 16(1) and any information on the risk and the product from which it derives.
3. The information referred to in paragraph 2 shall be transmitted through TRACES to all border control posts as defined in point (38) of Article 3 of Regulation (EU) 2017/625.
4. The Commission contact point shall verify each border rejection notification after it has been transmitted.

Article 21

Food fraud notifications

1. Food fraud network contact points shall exchange food fraud notifications including at least the following:
 - (a) all the information required by Article 16(1);
 - (b) a description of the suspected fraudulent practice;
 - (c) the identification, where possible, of the operators involved;
 - (d) information as to whether there are ongoing police or judicial investigations into the suspected fraudulent practice;
 - (e) information on any instruction from the police or judiciary authority as soon as it is available and can be disclosed.
2. Food fraud network contact points shall communicate any information concerning health risks to their RASFF network contact point without undue delay.
3. The Commission contact point shall verify each food fraud notification after it has been exchanged, without undue delay.

Article 22

Follow-up notifications

1. Where an alert and cooperation network member has additional information relating to an original notification, the contact point(s) concerned shall immediately transmit a follow-up notification to that network.
2. Where a contact point referred to in paragraph 1 has requested follow-up information relating to an original notification, the alert and cooperation network shall be provided with such information to the extent possible and without undue delay.
3. Where a RASFF network member takes action on receipt of an original notification in accordance with Article 50(5) of Regulation (EC) No 178/2002, its contact point

shall immediately transmit a detailed follow-up notification to the alert and cooperation network.

4. Where the action referred to in paragraph 3 consists of detaining a product and returning to a dispatcher in the country of another RASFF network member,
 - (a) the member taking the action shall provide relevant information about the returned product in a follow-up notification, unless that information was already included in full in the original notification;
 - (b) the other member shall provide information in a follow-up notification on the action taken on the returned products.
5. By way of derogation from paragraph 1, where a follow-up notification changes the classification of an original notification to an alert or an information notification, the alert and cooperation network member shall submit it for verification to the Commission contact point in accordance with Article 17 or Article 18.

Article 23

Access to iRASFF notifications

1. All members of the alert and cooperation network shall have access to alert, information, news or border rejection notifications.
2. Without prejudice to Article 8(2), only the notifying, notified and requested members of the alert and cooperation network shall have access to non-compliance notifications. However, other members shall have access to the information referred to in points (a), (b) and (e) of Article 16(1).
3. Without prejudice to Article 8(2), only the notifying, notified and requested contact points of the food fraud network shall have access to food fraud notifications.

Article 24

Verification and publication of notifications

1. The Commission contact point's verification of notifications shall cover:
 - (a) the completeness and legibility of the notification;
 - (b) the correctness of the legal basis supporting the notification; however an incorrect legal basis shall not prevent transmission of the notification if a risk has been identified;
 - (c) whether the notification falls within the scope of the RASFF network;
 - (d) whether the essential information in the notification is provided in a language that the alert and cooperation network contact point will easily understand;
 - (e) compliance with this Regulation;
 - (f) possible recurrences of the same operator and/or hazard and/or country of origin.
2. By way of derogation from paragraph 1, verification of non-compliance, food fraud and border rejection notifications shall cover points (b), (c) and (e) of that paragraph.
3. Once the Commission contact point has verified a notification in accordance with paragraph 1 or 2, it may publish a summary of all alert, information and border rejection notifications, with information on the classification and status of the

notification, the product(s) and risk(s) identified, the country of origin, the countries in which the products were distributed, the notifying network member, the basis for the notification and the measures taken.

4. The Commission shall publish an annual report on the notifications transmitted in iRASFF.

Article 25

Notification withdrawal and amendments

1. Where the action to be taken appears to be based on unfounded information or the notification was transmitted erroneously, any alert and cooperation network contact point may ask:
 - (a) a notifying contact point to withdraw a non-compliance, food fraud or follow-up notification;
 - (b) the Commission contact point, with the agreement from the notifying contact point, to withdraw an alert, information or news notification.
2. Any alert and cooperation network contact point may request amendments to a notification with the agreement of the notifying contact point.
3. A follow-up notification shall not be considered an amendment to a notification and may therefore be transmitted without the agreement of any other network member, unless such follow-up notification changes the classification of the notification.

Article 26

Closure of a notification and storage period of personal data

1. A notification is automatically closed in iRASFF if no follow-up requests are pending and all requests have received a response.
2. Personal data from closed notifications shall be kept for 10 years.

Article 27

Exchange of information with third countries

1. Where an alert, information or border rejection notification concerns a product originating in or distributed to a third country that does not have access to iRASFF or TRACES, the Commission shall inform that third country without undue delay.
2. Where a non-compliance or food fraud notification concerns a product originating in or distributed to a third country that does not have access to iRASFF or TRACES, the Commission may inform that third country.

Article 28

Contingency arrangements for iRASFF

1. Where iRASFF is unavailable:
 - (a) the RASFF network contact points shall announce the transmission of an email concerning an alert notification or follow-up to an alert notification by a telephone call to the emergency phone number of the Commission contact point. The Commission contact point shall inform the RASFF network contact

- points flagged for follow-up by a telephone call to their emergency phone numbers;
- (b) the AAC network contact points shall exchange information via email;
 - (c) the food fraud network contact points shall exchange information on food fraud notifications through secure emails;
 - (d) the exchanges referred to in points (b) and (c) shall not trigger the request and response mechanism.
2. Once iRASFF becomes available again, the alert and cooperation network contact points shall insert the information exchanged outside the system.

SECTION 2

ADIS

Article 29

ADIS network

1. Each ADIS network member may designate more than one contact point for the submission in ADIS of
 - (a) notifications of outbreaks pursuant to Article 19 of Regulation (EU) 2016/429;
 - (b) reports, as provided for in Article 20 of Regulation (EU) 2016/429, on
 - (i) the detection of listed diseases,
 - (ii) the results of surveillance to detect the presence of listed diseases,
 - (iii) the results of the implementation of Union surveillance programmes.
2. Each ADIS network contact point shall maintain and keep up to date in ADIS the list of notification and reporting regions established by its Member State for the purposes of Article 19 and Article 20 of Regulation (EU) 2016/429.

SECTION 3

EUROPHYT

Article 30

EUROPHYT network

Each EUROPHYT network member shall designate:

- (a) a contact point responsible for submitting EUROPHYT outbreak notifications;
- (b) a contact point responsible for:
 - (i) supervising the submission of EUROPHYT interception notifications, in accordance with Article 33, for consignments of plants, plant products and other objects entering the Union to the EUROPHYT interception network;
 - (ii) submitting EUROPHYT interception notifications for consignments of plants, plant products and other objects entering the Union to the relevant third countries and international organisations;
 - (ii) submitting of EUROPHYT interception notifications for consignments of plants, plant products and other objects traded in the Union.

Article 31

Access to EUROPHYT outbreak and interception notifications

Without prejudice to Article 8(2), only the EUROPHYT network contact points concerned shall have access to EUROPHYT outbreak or interception notifications.

Article 32

Submission of EUROPHYT outbreak notifications

1. EUROPHYT network contact points shall submit in EUROPHYT an outbreak notification containing at least the information indicated in points 1.1, 1.3, 2.1, 2.2, 3.1, 4.1, 5.1, 5.2, 6.4 and 8 of Annex I no later than eight working days after the date of the official confirmation by the responsible official body of the presence of a pest as referred to in points (a) and (b) of the first paragraph of Article 11, Article 29(1), Article 30(1) and Article 33(1) of Regulation (EU) 2016/2031.
2. Where the presence of a pest is officially confirmed pursuant to paragraph 1, the notification shall also contain the information indicated in point 5.6 of Annex I.
3. The network contact points shall submit in EUROPHYT a notification containing the information indicated in points 1.2, 3.2, 4.2, 4.3, 4.4, 5.3 to 5.6, 6.1, 6.2, 6.3, 6.5, 6.6, 6.7, 7.1 to 7.6, 9 and 10 of Annex I no later than thirty days after the relevant date referred to in paragraph 1.
4. EUROPHYT network contact points shall update the notifications referred to in paragraphs 1 and 3 as soon as they have verified any relevant new information that has been made available to them or the competent authority has taken new measures.

Article 33

Use of TRACES for the submission of EUROPHYT interception notifications

1. The official plant health officer taking the decision on consignments of plants, plant products and other objects entering the Union in accordance with point (b) of Article 55(2) of Regulation (EU) 2017/625 shall submit EUROPHYT interception notifications on those consignments in TRACES within two working days of their interception.
2. The notifications referred to in paragraph 1 shall include the following information:
 - (a) the information to be recorded in the CHED referred to in point (c) of Article 40(1);
 - (b) additional information on the measures taken on the consignment;
 - (c) information on the quarantine imposed;
 - (d) further information on the interception.
3. EUROPHYT network contact points shall submit EUROPHYT interception notifications on consignments of plants, plant products and other objects traded in the Union in TRACES within two working days of their interception. Those notifications shall include the information referred to in paragraph 2.

Article 34

Storage period of personal data for EUROPHYT outbreak notifications

EUROPHYT shall store personal data from EUROPHYT outbreak notifications for no more than 10 years.

SECTION 4 TRACES

Article 35

TRACES network

1. Each TRACES network member may designate a contact point for each of the functionalities provided for in point (d) of Article 132 and in Article 133 of Regulation (EU) 2017/625 or in other Union legislation referring to TRACES.
2. Contact points designated for the submission of EUROPHYT interception notifications shall also be considered contact points for that functionality in TRACES.

Article 36

Access to data, information and documents in TRACES

1. Each operator shall have access to the data, information or documents it handles, produces or transmits in TRACES.
2. Each competent authority shall have access to data, information or documents handled, produced or transmitted under its area of responsibility in TRACES, whether by its own staff or by the operators it manages in TRACES.
3. Where more than one competent authority, including authorities from the countries involved in the placing on the market or movement concerned, handle, produce or transmit data, information or documents in TRACES, all such competent authorities shall have access to all such data, information and documents.
4. Without prejudice to Article 8(2), entities that have not contributed to the handling, production or transmission of data, information or documents in TRACES, or are not involved in the placing on the market or the movement concerned, shall not have access to such data, information or documents.
5. By way of derogation from paragraph 4, competent authorities shall have access to data, information and documents concerning a decision to refuse entry of a consignment or an order to take an action, recorded in TRACES in accordance with Article 66(5) of Regulation (EU) 2017/625.

Article 37

Exchanges between TRACES and other electronic systems

1. Data exchanges between TRACES and other electronic systems, including the Member States' national systems, shall be synchronous, reciprocal and based on UN/CEFACT, IPPC and OIE standards.
2. Data exchanges between TRACES and the Member States' national systems shall make use of reference data provided for in TRACES.

Article 38

Cooperation between authorities in Member States in relation to consignments entering the Union

1. For the purpose of the cooperation provided for in Article 75(1) of Regulation (EU) 2017/625, the Member States' customs authorities shall have access to data, information and documents relating to animals and goods entering the Union from third countries and to decisions taken on the basis of official controls carried out in accordance with Chapter V of Title II of that Regulation, through
 - (a) TRACES or their Member States' national systems; or
 - (b) the EU Single Window environment for customs based on the electronic customs systems referred to in Decision No 70/2008/EC and interconnected with TRACES.
2. Where the access referred to in paragraph 1 is not available, Member States shall ensure without undue delay that their customs and competent authorities reciprocally exchange in a timely manner, the relevant data, information and documents.

Article 39

Issuance of electronic official certificates and use of electronic signatures

1. Electronic official certificates for consignments of animals and goods entering the Union shall meet all of the following requirements:
 - (a) they shall be issued in one of the following systems
 - (i) TRACES;
 - (ii) a Member State's national system;
 - (iii) a third country or an international organisation's electronic certification system that is capable of exchanging data with TRACES;
 - (iv) a third country or an international organisation's electronic certification system that is capable of exchanging data with a Member State's national system;
 - (b) they shall be signed by an authorised officer with an advanced or qualified electronic signature;
 - (c) they shall bear the advanced or qualified electronic seal of the issuing competent authority, or the advanced or qualified electronic signature of its legal representative;
 - (d) they shall use a qualified electronic time stamp.
2. Where electronic official certificates are issued in accordance with point (a)(iii) or (iv) of paragraph 1, TRACES or the Member State's national system shall acknowledge the exchange of data through respectively:
 - (a) the advanced or qualified electronic seal of the issuing third country's competent authority; or
 - (b) the advanced or qualified electronic signature of its legal representative.

In such cases, the signature of the authorised officer referred to in point (b) of paragraph 1 is not required.

3. The Commission shall be notified in advance of the issuance of electronic official certificates in accordance with point (a)(iv) of paragraph 1.
4. The competent authority shall accept electronic phytosanitary certificates, as required for the introduction of plants, plant products and other objects into the Union territory in accordance with Section 1 of Chapter VI of Regulation (EU) 2016/2031, only where they are issued in accordance with point (a)(i) or (iii) of paragraph 1.

Article 40

Format of the CHED and instructions for its presentation and use

1. The CHED to be used by the operator and the competent authorities in accordance with Article 56(3) of Regulation (EU) 2017/625 shall contain entries for the information set out in Part 1 of Annex II and be in one of the following formats depending on the nature of the consignment:
 - (a) a CHED-A drawn up in accordance with the template in Section A of Part 2 of Annex II, for consignments of animals that are:
 - (i) referred to in point (a) of Article 47(1) of that Regulation; or
 - (ii) subject at their entry into the Union to measures provided for in points (e) or (f) of that Article;
 - (b) a CHED-P drawn up in accordance with the template in Section B of Part 2 of Annex II, for consignments of products of animal origin, germinal products and animal by-products that are:
 - (i) referred to in point (b) of that Article; or
 - (ii) subject at their entry into the Union to measures provided for in points (d), (e) or (f) of that Article;
 - (c) a CHED-PP drawn up in accordance with the template in Section C of Part 2 of Annex II, for consignments of:
 - (i) plants, plant products and other objects referred to in point (c) of that Article; or
 - (ii) plants, plant products and other objects subject at their entry into the Union to one of the measures or conditions provided for in points (d), (e) or (f) of that Article; or
 - (iii) specific plants, plant products and other objects of a particular origin or provenance for which a minimum level of official controls is necessary to respond to recognised uniform hazards and risks to plant health as provided for in Implementing Regulation (EU) 2019/66;
 - (d) a CHED-D drawn up in accordance with the template in Section D of Part 2 of Annex II, for consignments of feed and food of non-animal origin subject at their entry into the Union to either of the measures or conditions provided for in points (d), (e) or (f) of Article 47(1) of Regulation (EU) 2017/625.
2. The CHED referred to in paragraph 1 shall be
 - (a) drawn up in at least one of the official languages of the Member State of entry;

- (b) duly completed in at least one of the official languages of the Member State of entry in accordance with the explanatory notes provided for in Part 1 of Annex II, by:
- (i) the operator responsible for the consignment, as regards the information on the details of the consignment, as described in Part I of the templates in Sections A to D of Part 2 of that Annex;
 - (ii) the competent authority at a border control post or control point, as regards the information on the decision taken on the consignment, as described in Part II of the templates in Sections A to D of Part 2 of that Annex;
 - (iii) the competent authority at the border control post of exit or final destination, or by the local competent authority, as regards the information on the follow-up measures taken on the consignment after a decision has been taken, as described in Part III of the templates in Sections A to D of Part 2 of that Annex.
3. By way of derogation from paragraph 2(a), a Member State may consent to a CHED being drawn up in an official EU language other than that of the Member State of entry.

Article 41

Use of an electronic CHED

1. An operator's or a competent authority's use of a CHED in an electronic format shall be by means of one of the following systems:
- (a) TRACES, provided that the CHED meets all of the following requirements:
 - (i) it is signed with the electronic signature of the operator responsible for the consignment;
 - (ii) it is signed with the advanced or qualified electronic signature of the certifying officer at border control posts or control points;
 - (iii) it bears the advanced or qualified electronic seal of the issuing competent authority;
 - (iv) it is sealed by TRACES with an advanced or qualified electronic seal;
 - (b) the national system of a Member State, provided that the CHED meets all of the following requirements:
 - (i) it is signed with the electronic signature of the operator responsible for the consignment;
 - (ii) it is signed with the advanced or qualified electronic signature of the certifying officer at border control posts or control points;
 - (iii) it bears the advanced or qualified electronic seal of the issuing competent authority;
 - (iv) it is transmitted to TRACES at the latest at the time when the decision is taken on the basis of the official controls and the transmission is sealed by the advanced or qualified electronic seal of the issuing competent authority;

2. TRACES shall acknowledge the transmission referred to in point (b)(iv) of paragraph 1 with its advanced or qualified electronic seal.
3. The required steps referred to in paragraphs 1 and 2 shall each be timestamped with a qualified electronic time stamp.

Article 42

Periods of storage of electronic certificates and CHEDs and personal data therefrom

1. For the purpose of maintaining the integrity of certificates and CHEDs issued in accordance with Article 39 and Article 41 respectively, relevant data concerning electronic signatures, electronic seals, timestamps and electronic exchanges shall be stored by TRACES and the Member States' national systems for at least 3 years.
2. Personal data from the certificates and CHEDs referred to in paragraph 1 shall be stored by TRACES and the Member States' national systems for no more than 10 years.
3. Personal data from EUROPHYT interception notifications referred to in Article 33(2) shall be stored by TRACES for no more than 10 years.

Article 43

List of control units

Each TRACES network contact point shall maintain and keep up to date in TRACES the list of control units that its Member State has designated for the purposes of TRACES in accordance with the definitions in point (33) of Article 2.

Article 44

List of border control posts and control points

1. Each TRACES network contact point shall maintain and keep up to date in TRACES the list of border control posts and control points that its Member State has designated in accordance with Article 59(1) and Article 53(2), respectively, of Regulation (EU) 2017/625 for the purpose of performing official controls on one or more of the categories of animals and goods referred to in Article 47(1) of that Regulation.
2. The contact point referred to in paragraph 1 shall insert in TRACES information regarding each designated border control post and control point using
 - (a) the format set out in Annex I to Implementing Regulation (EU) 2019/xxx³³ to provide the information referred to in Article 60(1) of Regulation (EU) 2017/625;
 - (b) the abbreviations and specifications set out in Annex II to that Implementing Regulation.

³³

Document SANTE/7106/2018 (voted on 11 April 2019 at PAFF CIC)

Article 45
List of food business establishments

1. Each TRACES network contact point shall maintain and keep up to date in TRACES the list of food business establishments that its Member State has approved in accordance with Article 6(3) of Regulation (EC) No 852/2004.
2. The contact point referred to in paragraph 1 shall insert in TRACES for each approved food business establishment the approval number assigned by the competent authority and the name and address of the operator.

Article 46
Contingency arrangements for TRACES and Member States' national systems in the event of unplanned or planned unavailability

1. TRACES network contact points shall maintain a public repository on the internet containing a fillable template of all documents that may be issued in TRACES or in the Member State's national system in accordance with this Regulation.
2. Where a Member State's national system, TRACES or one of their functionalities is unavailable for more than an hour, their users may use a fillable printed or electronic template, as referred to in paragraph 1, to record and exchange information.
3. Once the systems or functionalities referred to in paragraph 2 become available again, their users shall use the information recorded in accordance with paragraph 2 to produce electronically the documents required under this Regulation.
4. Where TRACES, a Member State's national system or one of their functionalities is unavailable, Member States may temporarily produce and electronically exchange all necessary documents in the available system and obligations regarding TRACES functionalities shall not apply. The Commission and the owners of the national systems shall perform an *ad-hoc* bulk exchange of those documents as soon as availability is restored.
5. Documents produced in accordance with paragraphs 2 and 4 shall bear the text 'produced during contingency'.
6. The Commission shall inform users through TRACES two weeks in advance of any planned unavailability, how long it will last and the reason for it.

Chapter 4
Final provisions

Article 47
Repeals

1. Commission Directive 94/3/EC, Commission Decisions 92/486/EEC, 2003/24/EC, 2003/623/EC, 2004/292/EC, 2004/675/EC and 2005/123/EC, Commission Regulation (EU) No 16/2011, and Implementing Decisions 2014/917/EU, (EU) 2015/1918 and (EU) 2018/1553 are repealed as from 14 December 2019.
2. References to the repealed Directive, Regulation and Implementing Decisions shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex III.

Article 48
Entry into force and application

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 14 December 2019, except for Section 2 of Chapter 3, which shall apply from 21 April 2021.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER

DRAFT