

Commission Implementing Regulation (EU) 2019/1715 of 30  
September 2019 laying down rules for the functioning of the  
information management system for official controls and its system  
components ('the IMSOC Regulation') (Text with EEA relevance)

**CHAPTER 1**

**Subject matter, scope and definitions**

*Article 1*

**Subject matter and scope**

- 1 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;
  - 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 in the information management system for official controls (IMSOC) 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 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:

- (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’s competent authority, the Commission, an EU agency, a third country’s competent authority or an international organisation that has access to at least one component;
- (4) ‘contact point’ means the contact point designated by the network member 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 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 risks as defined in point 8, 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 (21);
- (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 RASFF network member;
- (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 RASFF network member;
- (17) ‘information notification for follow-up’ means an information notification related to a product that is or may be placed on the market of another RASFF network member’s country;
- (18) ‘information notification for attention’ means an information notification related to a product that:
- (i) either is present only in the notifying network member’s country; or
  - (ii) has not been placed on the market; or
  - (iii) is no longer on the market;
- (19) ‘news notification’ means a notification in iRASFF concerning a 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 has an informal source, contains unverified information or concerns as yet an unidentified product;
- (20) ‘border rejection notification’ means a notification in iRASFF of a rejection due to a risk as defined in point 8 of a batch, container or cargo of food, food contact material or feed as referred to in point (c) of Article 50(3) of Regulation (EC) No 178/2002;
- (21) ‘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;
- (22) ‘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;
- (23) ‘follow-up notification’ means a notification in iRASFF that contains additional information in relation to an original notification;
- (24) ‘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;
- (25) ‘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;

- (26) ‘notifying network member or contact point’ means the network member or contact point addressing a notification to another network member or contact point;
- (27) ‘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;
- (28) ‘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;
- (29) ‘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;
- (30) ‘ADIS network’ means the network composed of the Commission and Member States’ competent authorities for the functioning of ADIS;
- (31) ‘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;
- (32) ‘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;
- (33) ‘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;
- (34) ‘EUROPHYT interception network’ means the network composed by the Commission and Member States’ competent authorities for EUROPHYT interception notifications;
- (35) ‘EUROPHYT outbreak network’ means the network composed by the Commission and Member States’ competent authorities for the functioning of EUROPHYT;
- (36) ‘TRACES’ means the computerised system referred to in Article 133(4) of Regulation (EU) 2017/625 for the purposes of exchanging data, information and documents;
- (37) ‘TRACES network’ means the network composed by the Commission and Member States’ competent authorities for the functioning of TRACES;

- (38) ‘electronic signature’ means an electronic signature as defined in point (10) of Article 3 of Regulation (EU) No 910/2014;
- (39) ‘advanced electronic signature’ means an electronic signature complying with the technical specifications laid down in the Annex to Implementing Decision (EU) 2015/1506;
- (40) ‘qualified electronic signature’ means an electronic signature as defined in point (12) of Article 3 of Regulation (EU) No 910/2014;
- (41) ‘advanced electronic seal’ means an electronic seal complying with the technical specifications laid down in the Annex to Implementing Decision (EU) 2015/1506;
- (42) ‘qualified electronic seal’ means an electronic seal as defined in point (27) of Article 3 of Regulation (EU) No 910/2014;
- (43) ‘qualified electronic time stamp’ means an electronic time stamp as defined in point (34) of Article 3 of Regulation (EU) No 910/2014;
- (44) ‘control point’ means a control point as referred to in point (a) of Article 53(1) of Regulation (EU) 2017/625;
- (45) ‘control unit’ means a unit that has the technology and equipment necessary for the efficient operation of the relevant component and designated as follows for that purpose:
- (a) ‘central control unit’ for the central competent authority of a Member State;
  - (b) ‘regional control unit’ for any regional competent authority of a Member State;
  - (c) ‘local control 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 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*

### **Components, networks and contact points**

- 1 Each 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 of, identify priorities for and monitor the correct implementation of the IMSOC. The governance 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 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 component.
- 2 Each signatory, competent authority to which a signatory belongs or competent authority creating an electronic 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 components**

- 1 Links between components shall be aimed at:
  - a complementing data, information or documents in one or more components by 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 in accordance with the rules set for each component in this Regulation; 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(6) 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 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 component and use XML, CMS or PDF formats;
  - b use the specific data dictionaries and business rules provided for in the relevant component.
- 2 The Commission shall provide the Member States with:
- a the frequency of identity checks and physical checks referred to in point (c)(i) of Article 6(1);
  - b the frequency rates and the outcome of the coordinated performance by competent authorities of the intensified official controls referred to in point (c)(iii) of Article 6(1);
  - 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 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 the IT infrastructure of the components.
- 2 The Commission shall have access to all data, information and documents in each 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 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 allow the good functioning 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 not include access to personal data processed in the component(s) 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 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 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 the competent authorities of the Member States shall be joint controllers of data processing operations in each of the 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 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 components may be granted;
  - d notifying and communicating any personal data breach of the 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 competent authorities of the Member States shall be responsible for:
- a ensuring that data subject's 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 component;
  - d ensuring that staff accessing each component are adequately trained to perform their tasks in accordance with Regulation (EU) 2016/679 and, where relevant, Directive (EU) 2016/680.
- 4 The competent authorities of the Member States may designate different 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

### Components, networks and contact points

#### SECTION 1

#### iRASFF

##### *Article 12*

#### **Liaison bodies responsible for the exchange of certain types 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 the notifications, requests or responses 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 alert and cooperation network contact points shall complete the relevant fields of a notification to enable clear identification of the product, 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 the possible non-compliance;
  - 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 by telephone call to the emergency phone number of the Commission contact point and specify which RASFF network member's countries are concerned. The Commission contact point shall inform the RASFF network contact points concerned 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.

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 network 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 network member shall provide information in a follow-up notification on the action taken on the returned product.
- 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 to the Commission contact point for verification and transmission to the alert and cooperation network contact points within the delays laid down in Article 17 or Article 18.

## Article 23

### Access to iRASFF notifications

- 1 All alert and cooperation network members shall have access to alert, information, news or border rejection notifications.
- 2 Without prejudice to the Commissions' right of access pursuant to Article 8(2), only the notifying, notified and requested alert and cooperation network members shall have access to non-compliance notifications. However, other network members shall have access to the information referred to in points (a), (b) and (e) of Article 16(1).
- 3 Without prejudice to the Commissions' right of access pursuant 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 alert, information, border rejection and non-compliance notifications, with information on the classification and status of the notification, the product and risk(s) identified, the country of origin, the countries in which the product was 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, border rejection 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:
- a no follow-up requests are pending; or
  - b all requests have received a response; or
  - c no response to the last request is provided within 6 months of its transmission.
- 2 Personal data from closed notifications shall be stored for no longer than 10 years.

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*Status: This is the original version (as it was originally adopted).*

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### *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 required to 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 via email;
- 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 in it 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.

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 purpose of the notification and reporting provided for in 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 to the EUROPHYT outbreak network;
- (b) a contact point responsible for:
  - (i) supervising the submission of EUROPHYT interception notifications to the EUROPHYT interception network, in accordance with Article 33, for consignments of plants, plant products and other objects entering the Union;
  - (ii) submitting EUROPHYT interception notifications to the relevant third countries and international organisations, for consignments of plants, plant products and other objects entering the Union;
  - (iii) submitting EUROPHYT interception notifications to the EUROPHYT interception network, 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 the Commissions' right of access pursuant to Article 8(2), only the EUROPHYT network concerned shall have access to EUROPHYT outbreak or interception notifications.

#### *Article 32*

#### **Submission of EUROPHYT outbreak notifications to the EUROPHYT outbreak network**

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 to this Regulation 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 to the EUROPHYT interception network**

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 any further information on the interception where available.

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 Without prejudice to Article 4(2), each TRACES network member shall designate one or more contact points for 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 handle, produce or transmit data, information or documents in TRACES, they shall have access to all such data, information and documents.

4 Without prejudice to the Commissions' right of access pursuant 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 of this Article, 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 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 the advanced or qualified electronic seal of the issuing third country's competent authority, or 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 of this Article.

### *Article 40*

#### **Format of the CHED and instructions for its presentation and use**

1 The CHED shall contain entries for the information set out in Part 1 of Annex II to this Regulation and be used by the operator and the competent authorities in accordance with Article 56(3) of Regulation (EU) 2017/625 in one of the following formats, depending on the category of the consignment established in Article 47(1) of that Regulation:

- a a CHED-A drawn up in accordance with the template in Section A of Part 2 of Annex II to this Regulation, for consignments of animals that are:

- (i) referred to in point (a) of Article 47(1) of Regulation (EU) 2017/625; or
    - (ii) subject at their entry into the Union to measures provided for in points (e) or (f) of Article 47(1) of Regulation (EU) 2017/625;
  - b a CHED-P drawn up in accordance with the template in Section B of Part 2 of Annex II to this Regulation, for consignments of products that are:
    - (i) referred to in point (b) of Article 47(1) of Regulation (EU) 2017/625; or
    - (ii) subject at their entry into the Union to measures provided for in points (d), (e) or (f) of Article 47(1) of Regulation (EU) 2017/625;
  - c a CHED-PP drawn up in accordance with the template in Section C of Part 2 of Annex II to this Regulation, for consignments of:
    - (i) plants, plant products and other objects referred to in point (c) of Article 47(1) of Regulation (EU) 2017/625; 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 Article 47(1) of Regulation (EU) 2017/625; 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 to this Regulation, for consignments of feed and food of non-animal origin subject at their entry into the Union to any 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 to this Regulation, 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 by the operator responsible for the consignment with his/her electronic signature;
  - (ii) it is signed by the certifying officer at border control posts or control points with his/her advanced or qualified electronic signature;
  - (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 by the operator responsible for the consignment with his/her electronic signature;
  - (ii) it is signed by the certifying officer at border control posts or control points with his/her advanced or qualified electronic signature;
  - (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.

#### *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 of this Article shall insert in TRACES information regarding each designated border control post and control point using

- a the format set out in Annex I to Commission Implementing Regulation (EU) 2019/1014<sup>(1)</sup> 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.

#### *Article 45*

##### **List of establishments**

1 Each TRACES network contact point shall maintain and keep up to date in TRACES the following lists of establishments:

- a food business establishments that its Member State has approved in accordance with Article 6(3) of Regulation (EC) No 852/2004;
- b establishments, plants and operators handling animal by-products or derived products that its Member State has approved or registered in accordance with Article 47 of Regulation (EC) No 1069/2009.

2 The contact point referred to in paragraph 1 shall insert in TRACES information regarding each establishment referred to in that paragraph using the technical specifications for the format of lists of establishments provided by the Commission.

3 The Commission shall assist the Member States in making the lists referred to in paragraph 1 available to the public through its internet page or TRACES.

#### 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 Directive 94/3/EC, Decisions 92/486/EEC, 2003/24/EC, 2003/623/EC, 2004/292/EC, 2004/675/EC and 2005/123/EC, 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 those repealed acts 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 twentieth day following that of its publication in the *Official Journal of the European Union*.

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*Status: This is the original version (as it was originally adopted).*

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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, 30 September 2019.

*For the Commission*

*The President*

Jean-Claude JUNCKER



- (1) Commission Implementing Regulation (EU) 2019/1014 of 12 June 2019 to lay down detailed rules on minimum requirements for border control posts, including inspection centres, and for the format, categories and abbreviations to use for listing border control posts and control points ([OJ L 165, 21.6.2019, p. 10](#)).