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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.

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### 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;

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- (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;
- '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;
- '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;
- '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;
- '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;

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- 'notifying network member or contact point' means the network member or contact point addressing a notification to another network member or contact point;
- '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;
- '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;
- 'TRACES network' means the network composed by the Commission and Member States' competent authorities for the functioning of TRACES;

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- '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;
- '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;
- '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.

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