

COMMISSION REGULATION (EU) No 16/2011
of 10 January 2011
laying down implementing measures for the Rapid alert system for food and feed
(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 safety⁽¹⁾, and in particular Article 51 thereof,

Whereas:

- (1) Regulation (EC) No 178/2002 establishes a Rapid alert system for food and feed (hereinafter — ‘RASFF’), managed by the Commission and involving the Member States, the Commission and the European Food Safety Authority, to provide the control authorities with an effective tool for the notification of risks to human health deriving from food or feed. Article 50 of that Regulation sets out the scope and requirements for the RASFF to operate.
- (2) Article 51 of Regulation (EC) No 178/2002 requires the Commission to establish implementing measures for Article 50 of that Regulation, in particular as regards the specific conditions and procedures applicable to the transmission of notifications and supplementary information.
- (3) Member States are primarily responsible for the enforcement of the EU legislation. They perform official controls, the rules for which are laid down in Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules⁽²⁾. The RASFF supports the Member States’ actions by allowing the rapid exchange of information on risks posed by food or feed and on measures taken or to be taken to counter such risks.
- (4) Article 29 of Regulation EC No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene⁽³⁾ extends the scope of the RASFF to serious risks to animal health and to the environment. Therefore, the

term ‘risk’ used in this Regulation is to be understood as a direct or indirect risk to human health in connection with food, food contact material or feed in accordance with Regulation (EC) No 178/2002 or as a serious risk to human health, animal health or the environment in connection with feed in accordance with Regulation (EC) No 183/2005.

- (5) Rules should be established to allow the RASFF to operate correctly both in relation to cases where a serious risk within the meaning of Article 50(2) of Regulation (EC) No 178/2002 is identified and in relation to other cases where, even though a risk of lesser gravity or urgency is identified, an efficient exchange of information is necessary between and among the members of the RASFF network. Notifications are classified into alert, information and border rejection notifications to allow for a more efficient handling by members of the network.
- (6) For the RASFF to operate efficiently, requirements should be formulated for the procedure for transmission of the different types of notifications. Alert notifications should be transmitted and treated with priority. Border rejection notifications are particularly relevant to controls carried out at border inspection posts and designated points of entry along the European Economic Area border. Templates and data dictionaries enhance the legibility and understanding of the notifications. Flagging members of the network for certain notifications draws their attention to particular notifications ensuring thereby that they are handled quickly.
- (7) In accordance with Regulation (EC) No 178/2002, the Commission, the Member States and EFSA have designated contact points, which represent the members of the network in order to benefit from a correct and fast communication. In application of Article 50 of that Regulation and in order to avoid possible mistakes in the transmission of the notifications, only one designated contact point should exist for each member of the network. This contact point should facilitate the rapid transmission to a competent authority inside a member country.
- (8) In order to ensure the correct and efficient functioning of the network between its members, common rules for duties of the contact points should be established. Provisions concerning the coordinating role of the Commission should also be set out, including the verification of the notifications. In this respect, the Commission should also assist members of the network in taking appropriate measures by identifying recurrent hazards and operators reported in the notifications.

⁽¹⁾ OJ L 31, 1.2.2002, p. 1.

⁽²⁾ OJ L 165, 30.4.2004, p. 1.

⁽³⁾ OJ L 35, 8.2.2005, p. 1.

- (9) In case that, notwithstanding the checks carried out by the notifying member and by the Commission, a transmitted notification turns out to be erroneous or unfounded, then a procedure providing for either its amendment or its withdrawal from the system should be laid down.
- (10) According to paragraphs 3 and 4 of Article 50 of Regulation (EC) No 178/2002 the Commission is required to inform third countries of certain RASFF notifications. Therefore, without prejudice to specific provisions in agreements concluded pursuant to Article 50.6 of Regulation (EC) No 178/2002, the Commission should ensure direct contact with food safety authorities in third countries in order to send out notifications to these third countries and at the same time ensure the exchange of relevant information with regard to these notifications and any direct or indirect risk to human health deriving from food or feed.
- (11) 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.
- (12) This Regulation has been discussed with the European Food Safety Authority.
- (13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,
- (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 country;
- (b) 'information notification for attention' means an information notification related to a product that:
- (i) is present only in the notifying member country; or
 - (ii) has not been placed on the market; or
 - (iii) is no longer on the market;
6. 'border rejection notification' means a notification of a rejection of a batch, container or cargo of food or feed as referred to in Article 50(3)(c) of Regulation (EC) No 178/2002;
7. 'original notification' means an alert notification, an information notification or a border rejection notification;
8. 'follow-up notification' means a notification that contains additional information in relation to an original notification;
9. 'professional operators' means food business operators and feed business operators as defined in Regulation (EC) No 178/2002 or business operators as defined in Regulation (EC) No 1935/2004 of the European Parliament and of the Council ⁽¹⁾.

Article 2

Duties of members of the network

HAS ADOPTED THIS REGULATION:

Article 1

Definitions

For the purposes of this Regulation the following definitions shall apply in addition to those set out in Regulations (EC) No 178/2002 and (EC) No 882/2004:

1. 'network' means the rapid alert system for the notification of a direct or indirect risk to human health deriving from food or feed, as established by Article 50 of Regulation (EC) No 178/2002;
 2. 'member of the network' means a Member State, the Commission, the European Food Safety Authority and any applicant country, third country or international organisation having concluded an agreement with the European Union in accordance with Article 50(6) of Regulation (EC) No 178/2002;
 3. 'contact point' means the designated contact point that represents the member of the network;
 4. 'alert notification' means a notification of a risk that requires or might require rapid action in another member country;
 5. 'information notification' means a notification of a risk that does not require rapid action in another member country;
1. Members of the network shall ensure the efficient functioning of the network within their jurisdiction.
 2. Members of the network shall each designate one contact point and communicate that designation to the Commission contact point, as well as detailed information regarding the persons operating it and their contact details. For that purpose they shall use the contact point information template to be provided by the Commission contact point.
 3. The Commission contact point shall maintain and update the list of contact points and make it available to all members of the network. Members of the network shall inform the Commission contact point immediately of any changes in their contact points and contact details.
 4. The Commission contact point shall provide members of the network with templates to be used for notification purposes.
 5. Members of the network shall ensure effective communication between their contact points and competent authorities within their jurisdiction on the one hand and between their contact points and the Commission contact point on the other hand for the purposes of the network. In particular they shall:
 - (a) set up an effective communication network between their contact points and all relevant competent authorities within

⁽¹⁾ OJ L 338, 13.11.2004, p. 4.

their jurisdiction allowing immediate transmission of a notification to the competent authorities for appropriate action, and maintain it in permanent good order;

(b) define the roles and responsibilities of their contact points and those of the relevant competent authorities within their jurisdiction, as regards the preparation and transmission of notifications sent to the Commission contact point, as well as the assessment and distribution of notifications received from the Commission contact point.

6. All contact points shall ensure the availability of an on-duty officer reachable outside office hours for emergency communications on a 24-hour/7-day-a-week basis.

Article 3

Alert notifications

1. Members of the network shall send alert notifications to the Commission contact point without undue delay and in any event within 48 hours from the moment the risk was reported to them. Alert notifications shall include all information available regarding, in particular, the risk and the product from which the risk derives. However, the fact that not all relevant information has been collected shall not unduly delay transmission of alert notifications.

2. The Commission contact point shall transmit alert notifications to all members of the network within 24 hours after reception, upon verification as referred to in Article 8.

3. Outside office hours, members of the network shall announce the transmission of 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 members of the network flagged for follow-up by a telephone call to their emergency phone numbers.

Article 4

Information notifications

1. Members of the network shall send information notifications to the Commission contact point without undue delay. The notification shall include all information available regarding, in particular, the risk and the product from which the risk derives.

2. The Commission contact point shall transmit information notifications to all members of the network without undue delay upon verification as referred to in Article 8.

Article 5

Border rejection notifications

1. Members of the network shall send border rejection notifications to the Commission contact point without undue delay. The notification shall include all information available regarding, in particular, the risk and the product from which the risk derives.

2. The Commission contact point shall transmit border rejection notifications to border inspection posts as defined in

Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries⁽¹⁾ and to designated points of entry as referred to in Regulation (EC) No 882/2004.

Article 6

Follow-up notifications

1. Whenever a member of the network has any additional information relating to the risk or product referred to in an original notification, it shall immediately transmit a follow-up notification through its contact point to the Commission contact point.

2. When follow up information relating to an original notification has been requested by a member of the network, such information shall be provided to the extent possible and without undue delay.

3. When action is taken upon receipt of an original notification as referred to in Article 50(5) of Regulation (EC) No 178/2002, the member which took the action shall immediately transmit detailed information thereof to the Commission contact point by way of a follow-up notification.

4. If the action referred to in paragraph 3 consists of a product being detained and returned to a dispatcher residing in another member country:

(a) the member taking the action shall provide relevant information about the returned product by way of a follow-up notification unless that information was already included in full in the original notification;

(b) the member country to which the products were returned shall inform on the action taken on the returned products, by way of a follow-up notification.

5. The Commission contact point shall transmit follow-up notifications to all members of the network without undue delay and within 24 hours for follow-up notifications to alerts.

Article 7

Notification submission

1. Notifications shall be submitted using the templates provided by the Commission contact point.

2. All relevant fields of the templates shall be completed to enable clear identification of the product(s) and risk(s) involved and to provide the traceability information. Data dictionaries provided by the Commission contact point shall be used to the maximum extent possible.

3. Notifications shall be classified according to the definitions provided in Article 1 in one of the following categories:

(a) original notification

(i) alert notification;

(ii) information notification for follow-up;

⁽¹⁾ OJ L 24, 30.1.1998, p. 9.

- (iii) information notification for attention;
 - (iv) border rejection notifications;
- (b) follow-up notification
4. Notifications shall identify members of the network that are asked to provide follow-up to the notification.
5. All relevant documents shall be added to the notification and sent to the Commission contact point without undue delay.

Article 8

Verification of the notification

Before transmitting a notification to all members of the network, the Commission contact point shall:

- (a) verify the completeness and legibility of the notification, including whether the appropriate data from the dictionaries referred to in Article 7(2) were selected;
- (b) verify the correctness of the legal basis given for the cases of non-compliance found; however an incorrect legal basis shall not prevent transmission of the notification if a risk was identified;
- (c) verify that the subject of the notification falls within the scope of the network as laid down in Article 50 of Regulation (EC) No 178/2002;
- (d) ensure that the essential information in the notification is provided in a language easily understandable by all members of the network;
- (e) verify compliance with the requirements laid down in this Regulation;
- (f) identify recurrences of the same professional operator and/or hazard and/or country of origin in notifications.

In order to respect the delay for transmission, the Commission can make small changes to the notification provided that they are agreed with the notifying member prior to transmission.

Article 9

Notification withdrawal and amendments

1. Any member of the network may request that a notification transmitted through the network be withdrawn by the

Commission contact point upon agreement from the notifying member if the information upon which the action to be taken is based appears to be unfounded or if the notification was transmitted erroneously.

2. Any member of the network may request amendments to a notification upon agreement from the notifying member. A follow-up notification shall not be considered an amendment to a notification and may therefore be transmitted without the agreement of any other member of the network.

Article 10

Exchange of information with third countries

1. If the notified product originates from or is distributed to a third country, the Commission shall inform the third country without undue delay.
2. Without prejudice to specific provisions in agreements concluded pursuant to Article 50(6) of Regulation (EC) No 178/2002, the Commission contact point shall establish contact with a designated single contact point in the third country, if any, with a view to reinforce communication, including through the use of information technology. The Commission contact point shall send notifications to that contact point in the third country for attention or for follow-up based on the seriousness of the risk.

Article 11

Publications

The Commission may publish:

- (a) a summary of all alert, information and border rejection notifications, providing information on the classification and the status of the notification, the products and risks identified, the country of origin, the countries where the products were distributed, the notifying member of the network, the basis for the notification and the measures taken;
- (b) an annual report on the notifications transmitted through the network.

Article 12

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

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

Done at Brussels, 10 January 2011.

For the Commission
The President
José Manuel BARROSO