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Draft

**COMMISSION REGULATION (EU) No .../..**

**of [...]**

**laying down implementing measures for the Rapid Alert System for Food and Feed**

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<sup>1</sup>, and in particular Article 51 thereof,

Whereas:

- (1) Regulation (EC) No 178/2002 establishes a rapid alert system for food and feed (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 Regulation (EC) No 178/2002 sets out the scope and requirements for the RASFF to operate.
- (2) Article 51 requires the Commission to establish implementing measures for Article 50, 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 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<sup>2</sup>. The RASFF supports the Member States' action 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<sup>3</sup> 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

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<sup>1</sup> OJ L 31, 1.2.2002, pp. 1-24.

<sup>2</sup> OJ L 165, 30.4.2004, pp. 1-141.

<sup>3</sup> OJ L 35, 8.2.2005, pp. 1-22.

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. It is necessary to differentiate between notifications requiring rapid action (alert notifications) and other notifications (information notifications) in order for members of the network to give priority to the former.
- (6) For the RASFF to operate efficiently, requirements should be formulated for members of the network and for the procedure for transmission of the different types of notifications. The role of the Commission as manager of the network should be detailed.
- (7) The content of this Regulation was discussed with the European Food Safety Authority.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

#### *Article 1*

#### *Definitions*

For the purposes of this Regulation:

- (1) the definitions of Regulations (EC) No 178/2002 and (EC) No 882/2004 apply;
- (2) a ‘member of the network’ is a country (‘member country’) or organisation (‘member organisation’) that is a member of the RASFF network or has become a member by way of an agreement as provided for in Article 50 of Regulation (EC) No 178/2002;
- (3) a ‘member flagged for follow-up’ is a member of the network asked to provide follow-up to the notification;
- (4) a ‘member flagged for attention’ is a member of the network addressed by the notification but not asked to provide follow-up;
- (5) ‘contact point’ means the national contact point of a member country or the contact point of a member organisation, referred to by the name of the organisation + ‘contact point’;

- (6) ‘professional operators’ are 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 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC<sup>4</sup>;
- (7) ‘notifications’ are structured communications, transmitted over the RASFF network, usually referring to one or more consignments of a specific food or food contact material that present a risk to human health or feed that presents a risk to human health, to animal health or to the environment;
- (8) There are the following notification types:
- (a) An ‘original notification’ is a notification with new findings in relation to a product and risk that were not previously notified to the RASFF and that are not reported in a follow-up to a previous RASFF notification.

An original notification is classified as:

- (i) an ‘alert notification’ or ‘alert’ if, based on the assessment by the notifying member of all the available information and data, the seriousness of the risk requires or might require rapid action in another member country;
- (ii) an ‘information notification’ if, based on the assessment by the notifying member of all the available information and data and the seriousness of the risk, it appears that there is no need for rapid action in another member country, whereby:
- an ‘information notification — for follow-up’ is sent if the product for which a notification is issued is or may be placed on the market in another member country
  - an ‘information notification — for attention’ is sent if the product for which the notification is issued is present only in the notifying country, has not reached the market or is no longer on the market
- (iii) a ‘border rejection notification’ if the product for which the notification is issued is refused entry into the territory of the European Union by the notifying country;
- (iv) a ‘news notification’, to report any other type of information related to the safety of food or feed which has not been communicated as an alert or information notification, but which is considered relevant for competent authorities in the member countries.

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<sup>4</sup> OJ L 338, 13.11.2004, p. 4.

- (b) A ‘follow-up notification’ is a notification that contains additional information concerning an original notification.

## *Article 2*

### *Requirements for members of the network*

1. Member of the network shall ensure the efficient functioning of the network and assign sufficient resources to the operation of the RASFF inside their countries and organisations.
2. Each member of the network shall designate one contact point and communicate this designation to the Commission contact point, as well as detailed information regarding the persons operating it and how they can be contacted. For this purpose they shall use the contact point information template to be provided by the Commission contact point.
3. The requirement in paragraph 2 is without prejudice to the possibility of having multiple contact points for different areas of competence.

In such cases, it shall be ensured that:

- there is one designated contact point to receive all incoming information;
  - the designated contact point immediately relays that information to the contact point in whose area of competence the notified subject falls.
4. The Commission contact point shall maintain 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.
  5. The Commission contact point shall provide members of the network with templates to be used for notification purposes.
  6. The national and organisation contact point shall ensure effective communication between national competent authorities and the Commission contact point for the purposes of the RASFF. In particular, it shall:
    - set up and maintain an effective communication network with all relevant competent authorities in the country, allowing immediate transmission of a RASFF notification to the competent authorities for appropriate action, and maintain it in permanent good order;
    - define the roles and responsibilities of the national contact point and the relevant competent authorities in the country with regard to 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;

7. 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. The member of the network shall send an alert notification to the Commission contact point without undue delay and in any event within 48 hours from the incident being reported to the contact point. The notification shall include all information available regarding, in particular, the risk and the product in which the risk may be present. However, the fact that not all relevant information has been collected shall not unduly delay transmission of the alert notification.
2. The Commission contact point shall transmit alert notifications to all members of the network within 24 hours, following verification as referred to in Article 7.
3. Outside office hours, the member 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 and border rejection notifications*

1. The member of the network shall send an information or border rejection notification to the Commission contact point without undue delay. The notification shall include all information available regarding, in particular, the risk and the product in which the risk may be present.
2. The Commission contact point shall transmit information notifications to all members of the network without undue delay following verification as referred to in Article 7.
3. The Commission shall transmit border rejection notifications to border inspection posts as defined in Directive 97/78/EC laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries<sup>5</sup> and to designated points of entry as referred to in Regulation (EC) No 882/2004.

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<sup>5</sup> OJ L 24, 30.1.1998, pp. 9-30.

## Article 5

### *Follow-up notifications*

1. Whenever a member of the network has any additional information relating to the risk or product mentioned in an original notification, it shall immediately transmit a follow-up notification to the Commission contact point.
2. When follow up information relating to a notification has been requested by a member of the network, such information shall be provided to the extent possible and without undue delay.
3. As provided for in Article 50(5) of Regulation (EC) No 178/2002, when action is taken following receipt of a notification, the member of the network shall immediately transmit the details of the action taken to the Commission contact point by way of a follow-up notification. In particular:
  - if a product was detained and returned to a dispatcher residing in another member country, the member country taking this action shall provide relevant information about the returned product by way of a follow-up notification if this information was not already included in full in the original notification;
  - the competent authority in 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.
4. The Commission contact point shall transmit follow-up notifications to all members of the network within the deadline specified for the type of the original notification.

## Article 6

### *Notification submission*

1. A notification 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), the available traceability information and the risk(s) involved. Data dictionaries provided by the Commission contact point shall be used to the maximum extent possible.
3. The notification shall be classified according to the definitions given in Article 1(8)(a) and members flagged for follow-up and for attention shall be identified.
4. All relevant documents shall be added to the notification and sent to the Commission contact point without undue delay

## *Article 7*

### *Verification of the notification*

1. Before transmitting the notification to all members of the network, the Commission contact point shall, as appropriate:
  - (a) verify the completeness and legibility of the notification, including whether the appropriate data from the RASFF data dictionaries were selected;
  - (b) verify the correctness of the legal basis given for the cases of non-compliance found;
  - (c) verify that the subject of the notification falls within the scope of the RASFF as laid down in Article 50 of Regulation (EC) No 178/2002;
  - (d) verify or provide the translation of the essential information in the notification;
  - (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.

## *Article 8*

### *Notification withdrawal and amendments*

1. Any member of the network may request that a notification transmitted through the RASFF system be withdrawn by the Commission contact point following the agreement of the notifying member if the information upon which the action to be taken is based turns out to be unfounded or if the notification was transmitted erroneously.
2. Any member of the network may request an amendment to a notification following the agreement of 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 9*

### *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. If the third country concerned agrees, the Commission contact point shall establish contact with a designated single contact point in the third country with a view to reinforcing communication, including through the use of information technology. The Commission contact point shall send notifications to this contact point for information or for action based on the seriousness of the risk.

#### *Article 10*

##### *Publication of RASFF information*

The Commission may publish:

- a summary of all alert and information notifications, providing information on 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;
- an annual report on the notifications transmitted through the RASFF.

#### *Article 11*

This Regulation shall enter into force on the [...] day following that of 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, [...]

*For the Commission*

[...]

*The President*