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Unit DDG2.G4.: Food, alert system and training

RASFF
Rapid Alert System for Food and Feed

Standard operating procedures of the Rapid Alert System for Food and Feed

version 1 revision 5 (January 2016)

Abbreviations and definitions used in the SOPs

AAC	Administrative Assistance and Cooperation
ADI	Acceptable Daily Intake
ARfD	Acute Reference Dose
CFU	Colony Forming Units
CIRCABC	Communication and Information Resource Centre for Administrations, Businesses and Citizens (https://circabc.europa.eu)
EC	European Commission
ECCP	European Commission's Contact Point: manager of the RASFF network
EEA	European Economic Area
EFSA	European Food Safety Authority
EU	European Union
IARC	International Agency for Research on Cancer
INFOSAN	International Food Safety Authorities Network
iRASFF	The new generation electronic and interactive notification platform of RASFF
GM(O)	Genetically Modified (Organism)
ML	Maximum Level of contaminants of food as defined in Commission Regulation (EC) No 1881/2006 and of undesirable substances in feed as defined in Directive 2002/32/EC
MRL	Maximum Residue Limit (for residues of pharmacologically active substances) as defined in Regulation (EC) No 470/2009 and for residues of pesticides as defined in Regulation (EC) No 396/2005)
MRPL	Minimum Required Performance Limit as defined in Commission Decision 2002/657/EC
NCP	National Contact Point: the designated contact point representing the network member in the RASFF
PDF	Portable Document Format: electronic document format used by Adobe Acrobat

POAO	Products of animal origin
RASFF	Rapid Alert System for Food and Feed
REC	Reinforced checks
RPA	Reference Point for Action as provided for in Articles 18 and 19 of Regulation (EC) No 470/2009
RTE	Ready-to-eat
SAAS	SANTE Authentication System
(DG) SANTE	Directorate General for Health and Food Safety
SOP	Standard Operating Procedure
TDI	Tolerable Daily Intake
TRACES	TRAde Control and Expert System introduced by Commission Decision 2004/292/EC
TSEs	Transmissible Spongiform Encephalopathies
WI	Working Instruction: annex to a SOP with detailed practical information needed for the functioning of the RASFF network

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Introduction and scope of the RASFF SOPs

1. PURPOSE OF THE RASFF SOPS

Article 50 of Regulation (EC) No 178/2002 (hereinafter, "the General Food Law Regulation")[1] establishes the Rapid Alert System for Food and Feed ('RASFF'). Its scope covers any direct or indirect risk to human health deriving from food or feed.

Article 29 of Regulation (EC) No 183/2005 (hereinafter, 'the Feed Hygiene Regulation')[2] extends the scope of the RASFF to serious risks to animal health and to the environment.

Commission Regulation (EU) No 16/2011 lays down the implementing measures for RASFF (hereinafter 'the RASFF Regulation').[3]

On the basis of the existing legal framework, the RASFF SOPs codify the experience gained over the years by the members of the network, in particular the European Commission's RASFF contact point (ECCP), regarding the following key elements:

- types of notifications
- duties of the members of the network
- requirements for transmitting the different types of notifications
- Commission's contact point's specific tasks
- withdrawal and amendment of a notification
- exchange of information with third countries

The RASFF SOPs are the subject of regular review. Changes can be proposed by any member of the network and considered and discussed with all members of the network in a RASFF working group meeting prior to incorporation into the SOPs. The ECCP coordinates the versioning of the SOPs and makes the updated RASFF SOPs public on the RASFF web pages of DG SANTE.

Other guidance and procedures that refer to RASFF are:

- General Guidance on Implementation and Interpretation of Article 24 of Council Directive 97/78/EC – Reinforced Checks (hereinafter "REC guidance")
  This document relates to the finding of serious and repeated infringements through veterinary checks on products entering the EU. It makes a link with the RASFF notifications and sets out the procedure for the setting up of reinforced checks at the border.[4]

[1] Regulation (EC) No 178/2002 of the European Parliament and of the Council 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, OJ L 31, 1.2.2002, p.1.
[2] Regulation (EC) No 183/2005 of the European Parliament and of the Council laying down requirements for feed hygiene, OJ L 35, 8.2.2005, p. 1.
[3] OJ L 6, 11.1.1011, p 7
[4] To be found at:
http://ec.europa.eu/food/food/biosafety/animalbyproducts/guidance_article_24_1125_5_2012_en.pdf

- Commission Guidance on the implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (EC) No 178/2002 on general food law.[5]

2. SOP 1: BEST PRACTICES FOR NCPS

This SOP provides guidance regarding the requirements laid down in Article 2 of the RASFF Regulation. It lays down "best practice", resulting from the experience gained with its application, for operating in the context of a simple structure involving all food and feed control authorities to ensure that there is effective communication between the contact points and the authorities competent for control.

3. SOP 2: SCOPE OF RASFF - CRITERIA TO DETERMINE WHEN A NOTIFICATION TO THE RASFF IS REQUIRED

The scope of RASFF, as laid down in Article 50 of General Food Law Regulation, Article 29 of the Feed Hygiene Regulation, and in the RASFF Regulation covers direct or indirect risks to human health in relation to food, food contact material or feed as well as serious risks to human health, animal health or the environment in relation to feed.

This SOP provides guidance regarding the scope of RASFF and in particular the criteria determining whether a notification to the RASFF is required.

4. SOP 3: PREPARING AN ORIGINAL NOTIFICATION

This SOP provides guidance on the preparation of an original RASFF notification including the collection of information, use of notification templates, language used, handling of documents and role of the NCP.

5. SOP 4: PREPARING A FOLLOW-UP NOTIFICATION

SOP 4 provides guidance as to when and how a follow-up notification is to be prepared.

6. SOP 5: TRANSMITTING A NOTIFICATION TO THE ECCP

This SOP complements the two previous SOPs by describing what steps need to be taken from when a RASFF notification is prepared to when the notification is transmitted to the ECCP, including the applicable time-limits. It gives guidance on possible checks to ensure correctness and completeness of information notified and of the transmission procedure.

7. SOP 6: ECCP VERIFICATION AND DISTRIBUTION OF RASFF NOTIFICATIONS TRANSMITTED BY THE NCPS

This SOP describes how the ECCP receives the notifications from the NCP, verifies them and distributes them to the NCPs. It also clarifies the procedure for the withdrawal of a notification, the closure of an alert, the distribution of RASFF notifications to third countries and the weekly review by the ECCP.

[5] To be found at: http://ec.europa.eu/food/food/foodlaw/guidance/docs/guidance_rev_8_en.pdf, at pp. 10-11.

8. SOP 7: DISTRIBUTION OF RASFF NOTIFICATIONS RECEIVED FROM THE ECCP

This SOP provides advice on how notifications received from the ECCP should be distributed by the NCPs to the relevant competent authorities within the same Member State.

9. SOP 8: ASSESSING A NOTIFICATION RECEIVED FROM THE ECCP

This SOP enumerates what elements of the notification need to be assessed by an NCP to enable a decision by the competent authorities responsible for enforcement action or other follow-up, where needed. The SOP describes how specific information regarding action taken by those authorities should be fed back into the RASFF in the form of follow-up notifications.

10. SOP 9: ARCHIVING AND CONSULTING RASFF NOTIFICATIONS AND RELATED INFORMATION

In this SOP advice on good practice for archiving and consulting RASFF notifications at the level of an NCP is provided.

11. SOP 10: CONFIDENTIALITY RULES FOR RASFF

This SOP explains how the requirements of Article 52 for making information of the RASFF available to the public can be respected. Advice is given on how to respect the requirement for non-disclosure of information covered by professional secrecy.

RASFF SOP 1: Best practices for NCPs

RASFF Regulation, Article 2

Duties of members of the network

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 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.

1. SCOPE

This SOP lays down 'best practice' to facilitate the Member States' fulfilment of their obligations under Article 2 of the RASFF Regulation, namely the efficient functioning of the RASFF within their jurisdiction, the 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.

2. BEST PRACTICES FOR THE MEMBERS OF THE NETWORK

(1) The national contact point (NCP) should be a clearly identified single unit, established in the structure of national competent authorities.

(2) The procedure for making available and updating the contact points' information, as required by Article 2(2) is provided in WI 1.1.

(3) The NCP can be placed in more than one organisation within the competent authorities responsible for the enforcement of food law and feed law to enhance the efficiency of the information flow: e.g. one food and one feed NCP. If this is the case, all partial NCPs should inform the ECCP of its details and contact persons using the procedure in WI 1.1. The network

member should assign the partial NCP which is to be considered the main contact for the ECCP, even though the other partial NCPs can transmit notifications directly to the ECCP and will be included in transmissions and distribution of notifications by the ECCP.

(4) It is possible that, in addition to its role as NCP, the NCP is also the contact point for a competent authority in a specific area of the food/feed chain. Other contact points can be identified in other areas which would report to the NCP at the national level in the context of RASFF. Details of such other contact points, if they are not identified as NCP, do not need to be sent to the ECCP; these contact points cannot transmit notifications directly to the ECCP. The NCP might however delegate certain tasks to them. Even though these contact points are not part of the NCP (and are not a partial NCP), while referring to the NCP, some information on best practices included in the RASFF SOPs could apply to these contact points as well. These contact points could for example be responsible for:

(a) "filtering" notifications to identify those that need to be forwarded to regional and/or local level

(b) transmission of the notifications to:

– scientific experts to provide advice on the seriousness of the risks identified as a guidance to the proposed classification of the notification and to the measures to be taken

– competent authorities for the assessment of the notification and appropriate measures to be taken;

– regional/local units for monitoring the market for a product notified and for inspection, sampling or taking measures at identified food/feed business operators;

– border posts for reinforced checking at the border.

(c) the collection of information needed for the creation of an original or a follow-up notification and transmission of this information to the NCP

(5) Member States may consider setting up clearly identified RASFF units / RASFF contact persons in regional and/or local levels, to ensure effective communication between the NCP at the national level and the regional/local level.

(6) Details of the on-duty arrangements, pursuant to Article 2(6) of the RASFF Regulation are given in WI 1.2.

(7) It is critical for the NCP to be adequately equipped to receive and send notifications rapidly and reliably, from and to, its network of competent authorities and from and to the ECCP. It is recommended that written procedures are maintained, detailing how communication in the context of RASFF is carried out.

(8) To ensure that it is adequately equipped to receive and send notifications rapidly and reliably, from and to, its network of NCPs, the ECCP develops and maintains an IT infrastructure which is designed and optimised for this purpose. It also prepares and maintains written standard operating procedures, detailing how communication in the context of RASFF is carried out.

3. OTHER POSSIBLE TASKS THAT MAY BE ASSIGNED TO THE NCP:

- deciding or giving advice as to whether a notification should be sent: see SOP 2;
- preparing an original notification: see SOP 3;
- preparing a follow-up notification: see SOP 4;
- ensuring that essential information in original/follow-up notifications is available in English: see SOPs 3 and 4;
- proposing a classification for a notification: see SOP 5;
- advising as to what follow-up actions might be taken with regard to a notification; this role should be without prejudice to the responsibilities of the competent authorities for follow-up action and enforcement in accordance with the rules of Union food and feed law: see SOP 8;
- archiving notifications: see SOP 9;
- publishing information about RASFF notifications, recalls or identified risks : see SOP 10;
- analysing hazards notified to the RASFF, identifying trends as an input for the setting of priorities in food/feed monitoring programmes.

RASFF SOP 2: Scope of RASFF - criteria to determine when a notification to the RASFF is required

General Food Law Regulation, Article 50

Rapid alert system

1. A rapid alert system for the notification of a direct or indirect risk to human health deriving from food or feed is hereby established as a network. It shall involve the Member States, the Commission and the Authority. The Member States, the Commission and the Authority shall each designate a contact point, which shall be a member of the network. The Commission shall be responsible for managing the network.

2. Where a member of the network has any information relating to the existence of a serious direct or indirect risk to human health deriving from food or feed, this information shall be immediately notified to the Commission under the rapid alert system. The Commission shall transmit this information immediately to the members of the network. The Authority may supplement the notification with any scientific or technical information, which will facilitate rapid, appropriate risk management action by the Member States.

3. Without prejudice to other Community legislation, the Member States shall immediately notify the Commission under the rapid alert system of:
(a) any measure they adopt which is aimed at restricting the placing on the market or forcing the withdrawal from the market or the recall of food or feed in order to protect human health and requiring rapid action;
(b) any recommendation or agreement with professional operators which is aimed, on a voluntary or obligatory basis, at preventing, limiting or imposing specific conditions on the placing on the market or the eventual use of food or feed on account of a serious risk to human health requiring rapid action;
(c) any rejection, related to a direct or indirect risk to human health, of a batch, container or cargo of food or feed by a competent authority at a border post within the European Union.

The notification shall be accompanied by a detailed explanation of the reasons for the action taken by the competent authorities of the Member State in which the notification was issued. It shall be followed, in good time, by supplementary information, in particular where the measures on which the notification is based are modified or withdrawn.

The Commission shall immediately transmit to members of the network the notification and supplementary information received under the first and second subparagraphs. Where a batch, container or cargo is rejected by a competent authority at a border post within the European Union, the Commission shall immediately notify all the border posts within the European Union, as well as the third country of origin.

4. Where a food or feed which has been the subject of a notification under the rapid alert system has been dispatched to a third country, the Commission shall provide the latter with the appropriate information.

5. The Member States shall immediately inform the Commission of the action implemented or measures taken following receipt of the notifications and supplementary information transmitted under the rapid alert system. The Commission shall immediately transmit this information to the members of the network.

6. Participation in the rapid alert system may be opened up to applicant countries, third countries or international organisations, on the basis of agreements between the Community and those countries or international organisations, in accordance with the procedures defined in those agreements. The latter shall be based on reciprocity and shall include confidentiality measures equivalent to those applicable in the Community.

Feed Hygiene Regulation, Article 29

Rapid Alert System

Should a specific feed, including feed for animals not kept for food production, present a serious risk to human or animal health or to the environment, Article 50 of Regulation (EC) No 178/2002 shall apply mutatis mutandis.

Recital 4 of the RASFF Regulation

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 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.

RASFF 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;

(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).

1. SCOPE

This SOP provides guidance as to the scope of RASFF and on criteria determining whether a notification to the RASFF is required and of what type (alert, information (for follow-up/ for attention), border rejection).

2. SCOPE OF RASFF

The scope of RASFF covers ***direct or indirect risks to human health*** in relation to food, food contact material or feed as well as ***serious risks to animal health or the environment in relation to a specific feed***. It includes notifications on food contact materials, if the use of such materials could lead to a risk in the food it contains or will contain e.g. for reason of migration of chemical substances or because of other defects in the material.

RASFF must not be confused with the mechanisms for administrative assistance and cooperation as established in Regulation (EC) No 882/2004[6] (Article 34-40), although in some cases both mechanisms are relevant and to be activated.

The two systems have in common that they both enable Member States to discharge their cross-border cooperation obligations by enabling them to exchange information.

They have however different objectives: while the RASFF's general objective is to enable food and feed control authorities to rapidly exchange and disseminate information on risks detected in relation to food or feed (and on measures taken to counter such risks), **for the purpose of enabling those authorities to take rapid remedial action**, rules on administrative assistance and cooperation enable – and require – competent authorities in different Member States to cooperate with each other **to ensure the effective enforcement of food law and feed law in cases which have a cross-border dimension/impact**.

Cooperation within the framework of administrative assistance may take different forms, from exchange of information to requests for more specific assistance e.g. the performance of *ad hoc* inspections or of joint inspections. It is important to note that the obligations for administrative assistance and cooperation are relevant and applicable also in cases where the cross-border non-compliance does not result directly or indirectly in a risk for health.
In other words, administrative assistance aims to ensure that all violations of EU food chain law (not only food and feed law) with a potential cross-border dimension are effectively pursued both in the Member State where the non-compliance is first detected and in the Member State where it has taken place or originates.

Of special relevance here is the specific type of administrative assistance codified in Article 38 of Regulation 882/2004, which applies to cases of non-compliance with food chain legislation which create a risk for health. That provision requires the Member State of destination which has performed the official control and found the non-compliance to inform the concerned Member States of dispatch so that it can take appropriate action. The Article also provides for the possibility of joint inspections and of coordinated action by the Commission.

[6] Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, *OJ L 165, 30.4.2004, p. 1–141*

There is a dedicated IT tool to assist the competent authorities' exchanges of information and support them in the framework of their obligations on administrative assistance and cooperation. The "Administrative Assistance and Cooperation" (AAC) tool was put in place in particular for those cross border violations which may constitute cases of food fraud.

This SOP might therefore be revised in the light of the outcome of the ongoing work in the areas of administrative assistance and cooperation and food fraud, to account for those cases which are at the same time potentially relevant both for the RASFF and for the mechanisms of administrative assistance.

A. CASES WHERE RASFF IS NOT APPLICABLE

If there is ***no direct or indirect risk*** to human health in relation to food or feed or no serious risk to animal health or to the environment in relation to feed, then ***RASFF is not applicable***.

Of course, irrespective of the risk posed, in cases where the food-feed is non-compliant with applicable rules the competent authorities are under the obligation to take action to remedy the non-compliance and, where appropriate, to activate the mechanisms for administrative assistance and cooperation laid down in Regulation 882/2004.

Article 14(7) of the General Food Law Regulation provides that food that complies with specific Union provisions governing food safety shall be deemed to be safe insofar as the aspects covered by the specific Union provisions are concerned. Competent authorities, despite such conformity, are not barred from taking appropriate action if they suspect the food to be unsafe. Conversely, food that does not comply with specific safety Union provisions shall be deemed to be unsafe, unless a risk assessment proves otherwise. This approach is further developed in the Commission Guidance on the implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (EC) No 178/2002 on general food law, and in particular under Section I.3.6 thereof.[7]

As the objective of the RASFF is, as said above, to enable Member States' competent authorities to exchange information necessary to take rapid action in case of risk, not all non-compliances with legislation should be reported to the RASFF.

The assessment whether or not there is a risk involved in non-compliant food/feed, and whether the risk is such as to require the notification to the RASFF is the responsibility of the members of the network. Listed[8] below are cases where MS have considered that the risk was not such as to require a notification to the RASFF:

a) failing hygiene, spoilage or insect infestation which could render a food unfit for human consumption pursuant to Article 14(2)(b) of the General Food Law Regulation without posing a direct or indirect risk to human health, e.g. there is no risk if there is no possibility of the consumption of the food/feed concerned;

b) food or feed products with live parasites of no public health concern and food products that are obviously contaminated with dead parasites;

[7] To be found at: http://ec.europa.eu/food/food/foodlaw/guidance/docs/guidance_rev_8_en.pdf.

[8] The list is given for illustrative purpose and is without prejudice to the assessment of the different cases that might be given by the competent authorities.

c) rupture of the cold chain or incorrect temperature during storage/transport of a food that does not affect the safety of the food;

d) unauthorised substance in food or in feed when a risk assessment shows that the substance does not present a risk to human health or in case of feed a serious risk to animal health or to the environment at the levels found;

e) exceedance of a legal limit for a substance when a risk assessment shows that the substance does not present a risk to human health or in case of feed a serious risk to animal health or to the environment at the levels found;

f) unauthorised novel food[9] when a risk assessment shows that it does not present a risk to human health;

g) food or feed consisting, containing or produced from a GMO, where the placing on the market has been authorised according to Regulation (EC) 1829/2003;

h) use of unauthorised substances in food contact materials for which a positive list is established at EU level if the quantity of the substance that can migrate does not lead to a risk to human health;

i) food contact materials that bring about unacceptable changes in the composition or organoleptic properties if such changes do not lead to a risk to human health

j) incorrect or misleading labelling, advertising or presentation of a food, feed or a food contact material that does not lead to a potential or actual health risk for specific consumers or consumer groups;

k) improper or absence of health certificates or certified analytical reports for which no risk could be related to the documentary irregularities, e.g. in case of fraud;

B. CASES WHERE A RISK REQUIRES OR POSSIBLY REQUIRES RAPID ACTION IN ANOTHER MEMBER COUNTRY (ALERT NOTIFICATIONS)

A notification to the RASFF ***is required***:

> *I. When a risk (as defined in Article 50 of General Food Law Regulation and Article 29 of the Feed Hygiene Regulation)* ***requires*** *or* ***might require*** *rapid action[10] (alert notification):*

This is the case where rapid action is needed to counter a serious risk.

As to the source of the information about the serious risk, although most notifications result from official controls performed by the competent authorities, a notification reporting on a

[9] Food or food ingredient that has not been used for human consumption to a significant degree in the EU before 15 May 1997; see Regulation (EC) No. 258/97 concerning novel foods and novel food ingredients that may present risks to human health, *OJ L 43, 14.2.1997, p. 1*.

[10] Article 1(4) of the RASFF Regulation read together with recital (4).

serious risk can also be based on company own-checks. In the latter case, it is for the competent authorities to assess as much as possible the reliability of the information on which the notification is based (e.g special care should be used with analytical results obtained through non-accredited laboratories or methods, and the use of a non-accredited laboratories or methods should be clearly indicated in the notification).

Listed[11] below are cases where MS have considered that the risk was such as to require rapid action:

a) food or feed containing substances prohibited according to European Union or national legislation; substances for which a reference point for action (RPA) according to Reg.(EC) No. 470/2009[12] or Decision 2005/34[13] has been set only if the RPA has been reached or exceeded;

b) food or feed containing unauthorised substances according to European Union or national legislation for which a risk assessment shows that the substance presents a serious risk to human health or (in case of feed) to animal health or to the environment at the levels found;

c) food containing residues of pesticides or metabolites resulting from their degradation for which the predicted short term intake is higher than the acute reference dose (ARfD) for the substance found;

d) food containing (potentially) mutagenic or carcinogenic substances (IARC group 1, 2A and 2B) or substances toxic for reproduction for which the level found exceeds a legal limit laid down in the Union legislation or, in the absence thereof, a legal limit laid down in national legislation unless a particular risk assessment allows defining a higher alert threshold;

e) food containing (potentially) mutagenic or carcinogenic substances (IARC group 1, 2A and 2B) or substances toxic for reproduction for which no legal limit is set but for which the predicted short term intake exceeds the acute reference dose (ARfD) or the tolerable daily intake (TDI) or the margin of exposure (MOE) is too low taking into account the predicted short term intake;

f) food in which fungi, bacteria or their toxins, algal toxins, metabolic products, viruses or prions by type, number or quantity have been found to exceed food safety criteria set in the EU legislation or any national food safety criteria duly notified to and agreed by the European Commission;

g) Live parasites that may represent a health hazard to the consumer in foods that are not meant to undergo a treatment before consumption sufficient to kill parasites;

[11] The list is given for illustrative purpose and is without prejudice to the assessment of the different cases that might be given by the competent authorities.

[12] Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, OJ L 152, 16.06.2009, p. 11–22

[13] Commission Decision of 11 January 2005 laying down harmonised standards for the testing for certain residues in products of animal origin imported from third countries, OJ L 16, 20.01.2005, p. 61–63

h) food in which the maximum cumulated radioactivity (of e.g. Cs-134 and Cs-137) exceeds the maximum levels set in the legislation (EU or national);

i) pre-packaged food items in which the presence of an allergenic ingredient, as required by Regulation 1169/2011[14], is not labelled;

j) food or feed consisting, containing or produced from an unauthorised GMO, according to Regulation (EC) 1829/2003, for which the EFSA scientific risk assessment shows that the substance presents a serious risk to human health or (in case of feed) a serious risk to animal health or to the environment.

Listed[15] below are cases where MS have considered that the risk was such as to possibly require rapid action (in some cases following an ad hoc risk evaluation):

As regards food:

a) food containing substances other than those mentioned above, exceeding a maximum level according to Union legislation or, in the absence thereof, a maximum level laid down in national legislation or in an international standard;

b) food containing substances used without authorisation and/or contrary to a requirement of official approval according to Union or national legislation;

c) food containing residues of pesticides or metabolites resulting from their degradation for which no ARfD has been set (unless it was decided that no ARfD is needed or applicable) but for which an acceptable daily intake (ADI) exists and the predicted short term intake exceeds the ADI;

d) food in which fungi or fungal toxins, bacteria or their toxins, algal toxins, metabolic products, viruses or prions by type, number or quantity have been found at levels which could present a significantly increased risk for causing disease, taking into account the normal conditions of use of the food by the consumer;

e) food presenting a physical risk to human health, especially foreign bodies;

f) ready-to-eat food that has suffered from a serious rupture in the cold chain, rendering the food unsafe;

g) food where mandatory tests for the detection of a serious direct or indirect risk to human health have either not been conducted or conducted in an improper way;

h) food for particular nutritional use (baby food, food for medical patients etc.) that does not meet the required compositional criteria for its intended use;

[14] Regulation 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, OJ L 304, 22.11.2011, p. 18.

[15] The list is given for illustrative purpose and is without prejudice to the assessment of the different cases that might be given by the competent authorities.

i) food to which vitamins or minerals were added, the daily consumption of which would lead to exceeding a tolerable upper intake level for one or more of the vitamins or minerals added;

j) food in which an unintentional presence of allergenic substances is detected, which is not mentioned on the label;

k) foods that have been adversely affected through contact with materials and articles as defined in Regulation (EC) No. 1935/2004[16];

l) food contact materials, as defined in Regulation (EC) No. 1935/2004, that are not suitable to be used in contact with food (e.g. exceeded migration limits);

m) food or food contact material of which the declaration or presentation on the label or packaging may result in a health risk through the food if used accordingly or where there is insufficient information to allow its safe use;

n) food that is unfit for human consumption because of spoilage or the use of unfit ingredients or any other reason posing a direct or indirect risk to human health, unless it is obviously non-consumable;

o) unauthorised novel food for which there is an unfavourable or inconclusive opinion or no available opinion from EFSA;

p) unauthorised GM food as defined in Regulation (EC) No. 1829/2003[17] for which there is an unfavourable or inconclusive opinion or no available opinion from EFSA;

q) any other risk, including emerging risks, requiring a risk evaluation (see under heading 3) identifying whether a serious direct or indirect risk is involved.

As regards feed[18]:

a) exceedance of the EU-maximum level of an undesirable substance according to Directive 2002/32/EC[19];

b) exceedance of the maximum residue limit for pesticide residues according to Regulation (EC) No. 396/2005[20];

c) exceedance of a maximum level (national or other) of other undesirable substances than mentioned under a;

d) presence of additives that are not authorised for the target animal species or category and exceeding the established carry-over level;

[16] Regulation (EC) No. 1935/2004 on materials and articles intended to come into contact with food, OJ L 338, 13.11.2004, p. 4.
[17] Regulation (EC) No 1829/2003 on genetically modified food and feed, *OJ L 268, 18.10.2003, p. 1*.
[18] Article 50(2) of General Food Law Regulation and Article 29 of Feed Hygiene Regulation.
[19] Directive 2002/32/EC on undesirable substances in animal feed, *OJ L 140, 30.5.2002, p. 10*.
[20] Regulation (EC) No 396/2005 of the European Parliament and of the Council on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC, *OJ L70, 16.3.2005, p. 1-16*.

e) presence of unauthorised veterinary medicinal products or use of veterinary medicinal substances outside of their approval conditions;

f) exceedance of the maximum permitted level for feed additives according to Regulation (EC) No. 1831/2003[21];

g) presence (above technically unavoidable concentrations) of prohibited materials according to Annex III to Regulation (EC) No. 767/2009[22];

h) presence (above technically unavoidable concentrations) of animal by-products that may not be fed to certain animal species according to Regulation (EC) No 1069/2009[23];

i) presence (above technically unavoidable concentrations) of animal by-products that may not be fed at all or not to the animal species concerned according to Regulation (EC) No 999/2001[24];

j) unauthorised GM feed as defined in Regulation (EC) No 1829/2003 for which there is an unfavourable or inconclusive opinion or no available opinion from EFSA;

k) any other risk, including emerging risks, requiring a risk evaluation (see under heading 3) identifying whether a serious direct or indirect risk is involved.

C. CASES WHERE FOOD OR FEED WERE REJECTED AT THE BORDER

A notification to the RASFF ***is required***:

II.	*When a rejection related to a direct or indirect risk to human health of a batch, container or cargo of food or feed by a competent authority at a border post within the European Union has taken place[25]* ***(border rejection notification);***

III.	*When a rejection related to a serious risk to human or animal health or to the environment of a batch, container or cargo of feed by a competent authority at a border post within the European Union has taken place[26]* ***(border rejection notification).***

D . INFORMATION NOTIFICATIONS (FOR FOLLOW-UP, FOR ATTENTION)

[21] Regulation (EC) No. 1831/2003 on additives for use in animal nutrition, *OJ L 268, 18.10.2003, p. 29–43*
[22] Regulation (EC) No. 767/2009 on the placing on the market and use of feed, *OJ L 229, 1.9.2009, p. 1–28*
[23] Regulation (EC) No 1069/2009 laying down health rules concerning animal by-products and derived products not intended for human consumption, *OJ L 300, 14.11.2009, p. 1–33*
[24] Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies, *OJ L 147, 31.5.2001, p. 1–40*
[25] Article 50(3)(c) of the General Food Regulation.
[26] Article 29 of Feed Hygiene Regulation read together with Article 50(3)(c) of the General Food Regulation.

In addition to cases where a risk requires or might require rapid action across borders, the RASFF system as currently enables Member States to transmit "information notifications" in cases involving a ***risk which does not require a rapid action in another member country***. Two types of information notifications are provided for in Article 1.5 of the RASFF Regulation:

- **Information for follow-up (e.g. a food product that is placed on the market in other member countries presenting a health risk but the risk is evaluated as not serious and therefore does not require rapid action)**

- **Information for attention (e.g. a food product in which a serious health risk was found but that has been placed on the market only in the notifying country)**

Because of the potential overlap between these categories and those cases where administrative assistance obligations may apply, the design of these specific categories and this guidance may possibly evolve as work will progress on the dedicated mechanism for administrative assistance and cooperation (which, as said above, includes specific provisions for assistance in cases where the non-compliance results in a risk for health).

It is to be noted that, as a rule, **a notification** to the RASFF does not satisfy the specific requirements for administrative assistance and cooperation as laid down in Regulation (EC) No 882/2004**.**

3. RISK EVALUATION

Unless the seriousness of the risk at hand is straightforward, the risk evaluation on which the notification is based should be made available with the notification or exceptionally - in urgent cases - as a follow-up to it, based on available information regarding the risk. Relevant information regarding the risk may be available at the business operator(s) involved and can be taken into account upon verification to decide upon the seriousness of the risk.

The risk evaluation should be performed based on the hypothesis that the product is available to the consumer. The decision about the risk is recorded in the risk section of the notification. The actual risk is reflected in the notification classification which also takes into account the availability of the product to the consumers (see also SOP 5).

In case a risk evaluation already exists for a similar notification that has occurred in the past, it can be used, if necessary with the required adjustments. The NCP should however always verify if the risk evaluation is valid for the notification concerned. The risk evaluation should include references to the information on the basis of which it is made. The risk evaluation can include data from analytical reports.

The risk evaluation does not replace a full risk assessment but instead builds on assessments available in literature or previous notifications. In case it concerns a new type of risk, for which no past relevant evaluations are available, the members of the network must provide a full risk assessment in addition to their evaluation of the risk. In the absence of such assessment, the ECCP should request EFSA for a full risk assessment.

The Commission services maintain a repository of existing risk evaluations, based on past notifications. Previous risk evaluations are to be given and updated in WI 2.1.

RASFF SOP 3 – Preparing an original notification

RASFF Regulation, Article 7

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;

(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.

1. SCOPE

This SOP provides guidance on how an original RASFF notification should be prepared including sources of information, what templates to use, what documents to collect etc.

2. GUIDANCE FOR PREPARING A NOTIFICATION

(1) The NCP is responsible for collecting all the required information to complete the RASFF notification. This will involve liaising with all the relevant control authorities, enforcement agencies and testing laboratories and may also involve food/feed business operators. Laboratory reports showing unsatisfactory results, reports from investigating officers or reports by food/feed business operators may be the sources of this information, but in many cases the reports may not contain all the information as required for the notification. Where information is missing the NCP will need to request the additional information.

(2) The NCP may also contact the other members of the network by means of informal communication in order to collect information required for RASFF purposes.

(3) When issuing a notification, the iRASFF online notification template should be used unless iRASFF is temporarily unavailable or there is another technical problem making transmission of the notification impossible. In such case, the "offline" template should be used (downloadable from CIRCABC). The NCP must ensure that all essential information is entered in the notification. An example of the template with explanation of all relevant

fields is provided in WI. 3.1. In order to achieve a harmonised approach, the template should be filled in using the guidance given in WI 3.1.

(4) The notification can be written in any of the EU official languages, but it is encouraged that, in addition to this, the version sent to the ECCP be filled as far as possible in English, especially fields such as hazard, name and description of the product, action taken and distribution to other member countries, particularly if other member countries are required to take rapid action. In case of a very urgent notification, the ECCP will ensure that the essential information is available in English, prior to transmitting the information through the RASFF network.

(5) It is important that the risk section (in the offline template as well as in iRASFF) is filled and that a decision is made as to whether the notification concerns a serious risk, not a serious risk or a decision is not (yet) taken (undecided). If it concerns a hazard or hazards for which no guidance is available in SOP 2, summary information should be entered in the "Motivate serious risk" box and if necessary documents attached to demonstrate the risks concerned.

(6) Official (e.g. analytical reports) and commercial (e.g. delivery note, invoice) documents are very helpful for other NCP and should in principle be attached to the notification. Efforts should be made to ensure that the quality of the documents is as high as possible. When documents are not in English, it may be helpful to attach a note highlighting the result or explaining the content of the document, the units used, or the legend as appropriate (e.g. for recipients lists that weren't issued with the standard template). Information unnecessary to the handling of the notification (e.g. prices) should be blackened in the invoices. These documents should be handled with due consideration to their confidential nature (see SOP 10) and should not be distributed any wider than strictly necessary.

(7) When appropriate and whenever possible, a separate recipients list using the template (downloadable from CIRCABC) provided by the ECCP should be attached for each country the notified product has been distributed to. Details of distribution should be as detailed as possible to facilitate action in a recipient member country.

(8) For notifications reporting on unauthorised GM food or feed, the GMO-annex (downloadable from CIRCABC), completed by the laboratory that performed the analysis, should be added to the notification.

(9) Wherever possible copies of laboratory reports should be obtained and these can be transmitted along with the notification template giving details about the analytical methods and the results obtained, possibly including an evaluation of the results and the risks involved. There should be no delays in getting the required information.

(10) All attached documents should be scanned copies of original wherever possible. Copies of poor quality such as faxes should be avoided.

(11) It is critical that the information is accurate and wherever possible, details should be obtained from the source in writing rather than by telephone. The accuracy of the information should be checked. In line with the requirements of Article 7(2) of the RASFF Regulation, exact details of the product including name, batch details, durability date, pack size and packaging description should be indicated, along with manufacturer and distribution details. Clear and high resolution pictures of products/label should be provided whenever possible. Insofar possible, while observing the time limits for transmission, the information should be verified with the business operator(s) involved prior to transmission in the RASFF.

(12) Where some information is not available immediately, such as full distribution details, the known information should be presented in the notification form with an additional note indicating what further information is to follow.

(13) Before transmitting the notification to the ECCP, the NCP should make final checks to ensure the accuracy and completeness of the document, in particular that all the information is coherent (e.g. that the information in the notification form corresponds with the attached documents as regards weights, batch numbers, delivery dates etc.), all essential information is entered and that the proper legislation is quoted (notification verification). It should be clear whether there is a national or EU basis for the action being taken. It is advisable that final checks are carried out by a different person than the one completing the template. The requirement for completeness of the document may be less strictly observed for urgent notifications, provided that the missing information is supplemented as soon as possible by means of a follow-up notification.

3. ROLE OF THE NCP

Before transmitting the notification to the ECCP, the NCP should indicate whether it concerns a serious risk, its proposed classification (into alert, information for attention, information for follow-up or border rejection), countries to be flagged for attention and for follow-up (see SOP 5 "Transmitting the notification to the ECCP") and should validate the notification. The ECCP verifies the classification and consults the notifying NCP with the aim of reaching agreement if its classification differs from the one proposed by the notifying NCP.

RASFF SOP 4: Preparing a follow-up notification

RASFF Regulation, Article 6

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.

1. SCOPE

According to Article 1(8) of the RASFF Regulation, a 'follow-up notification' is a notification that contains additional information in relation to an original notification. This SOP provides information about when and how a follow-up notification should be issued.

2. WHEN TO ISSUE A FOLLOW-UP NOTIFICATION

(1) A follow-up notification is particularly useful for other members of the network for the handling of the notification. This is the case if the product was distributed to or originated from another member country and the product may be present on the market (alert notification or information notification for follow-up) or if information in the original notification was incomplete or incorrect.

A system for flagging countries for follow-up or for attention is set up to assist countries in knowing whether follow-up is expected from them. The flags are indicated by the notifying member and verified, confirmed and monitored by the ECCP. Details of this system are set down in WI 4.1.

(2) In application of Article 6(2) of the RASFF Regulation, when an NCP has been requested by the ECCP or by another contact point to provide follow-up to a notification, the NCP concerned should reply without undue delay in order not to delay the necessary action following the notification. If the information is unavailable, the NCP concerned should give a (holding) reply explaining why the information requested is not (yet) available and when it may become available.

When a request is made for a recipients list[27] in the context of a recall or withdrawal, the requesting member of the network should provide a justification of its request in case it concerns an information notification, considering that there could be different factors taken into account in the risk evaluation performed by the requesting country compared to the one performed by the country receiving the request. If the justification can apply to all member countries, recipients' details for all countries need to be provided (including third countries). If the justification applies specifically to the requesting country, it can suffice to provide only recipients details for the requesting country.

(3) A follow-up notification is required in case action was implemented or measures were taken on the product following receipt of the notification by a member country in order to inform the members of the network and in accordance with Article 6(3) of the RASFF Regulation.

(4) The ECCP issues follow-up notifications with information provided by itself or provided to it by third parties that are not members of the network, such as third countries or international organisations. If the ECCP receives follow-up information from business operators or from business operator associations, it will first consult the NCPs involved before considering to transmit this information in the network.

3. HOW TO PREPARE A FOLLOW-UP NOTIFICATION

The follow-up notification should always be issued in iRASFF, in which case the follow-up information is entered into the original notification in the online iRASFF system. If the original notification is not available in iRASFF, the offline follow-up template (downloadable from CIRCABC) should be used. While issuing a follow-up notification the quality requirements set down in SOP 3 "Preparing an original notification" should be taken into account.

4. BILATERAL EXCHANGE OF INFORMATION FOLLOWING A NOTIFICATION

Detailed follow-up information, such as a detailed address for a recipient or details of deliveries, not of concern or interest to other member countries and only involving two member countries, can be exchanged bilaterally between the NCP. The correspondence in question should refer to the relevant RASFF notification. A copy of it should be sent to the ECCP.

[27] A list of operators having received one or more parts of the lots/consignments in question. A template is available for creating the list.

RASFF SOP 5: Transmitting a notification to the ECCP

RASFF Regulation, Article 3
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.

1. SCOPE

This SOP provides guidance about what steps need to be taken from when a RASFF notification is completed to when the notification is received by the ECCP, including the applicable time-limits.

2. TIME-LIMITS WITHIN WHICH A NOTIFICATION IS TRANSMITTED TO THE ECCP, AS SPECIFIED IN THE RASFF REGULATION

A. time limits within which an original notification should be transmitted:

- alert notification within 48 hours from the moment a serious risk was reported to the competent authority (RASFF Regulation Art. 3);
- information notifications and border rejections without undue delay (RASFF Regulation Art. 4 and 5).

B. time limits within which follow-up notifications should be transmitted:

- immediately whenever the network member has any additional information (RASFF Regulation Art. 6(1)) of relevance to other members of the network
- immediately when action is taken following a RASFF notification (RASFF Regulation Art. 6(3))
- without undue delay upon request of another network member (RASFF Regulation Art.6(2))

When there are several different follow-ups, even with the requirement to transmit them immediately, it can be an added value if the NCP can consolidate various follow-ups from different regions and/or bodies within the country if it has the authority to do so.

"Without undue delay" means that any substantial delay can be accounted for and explained. The NCP should therefore keep track of the timing of the transmission and the reasons for any delay.

3. VALIDATING THE NOTIFICATION

Before transmission, the NCP should verify and validate the notification to ensure its compliance with regard to the criteria for notification. In particular, the NCP should check the correctness and the completeness of the information – in case of an alert including whether essential information can be sufficiently and rapidly understood – and required documents (see SOP 3 on preparing an original notification).

4. HOW IS THE NOTIFICATION TRANSMITTED THROUGH THE NETWORK OF CONTACT POINTS?

Depending on the tool used, the procedure for notification transmission will differ: currently notifications can be transmitted through iRASFF or through TRACES. Email is only used if the appropriate application (iRASFF or TRACES) is not available. The different procedures are outlined in WI 5.1. General points for attention are given here below:

(1) The originator of the notification (original or follow-up) transmits the notification to the NCP. It is possible that there is no direct transmission from originator to NCP and that there are several in-between relay points e.g. local RASFF contact point, regional contact point, competent authority contact point etc., each possibly carrying out a validation before forwarding the notification. In such case it is important that national procedures and control mechanisms exist to verify correct transmission without any avoidable delay. For a member of the network that has already implemented iRASFF at least at two levels, the iRASFF notification is transmitted to the NCP via iRASFF.

(2) iRASFF ensures a safe and reliable transmission of the notifications. In case a notification is not validated within the set time or the NCP has doubts about its correct transmission in iRASFF, the NCP should enquire with the ECCP. In case iRASFF is not available and the notification is sent using email, the NCP should request acknowledgement of receipt of the message transmitting the notification (see WI 5.1 for further details).

(3) All accompanying documents should be attached in iRASFF in a format which can be easily read by the recipient, preferably as PDF files, except for recipients lists. For recipients lists, the preferred format is a spreadsheet which is more practical to work with, especially for long lists. The documents should not be protected against printing and copying, to allow the ECCP to compile all documents into a single PDF. All the documents should be in such a quality that the information is easily readable by the recipients, especially when faxed documents are attached.

(4) After validation, the NCP immediately transmits the notification to the ECCP via iRASFF (*submit* function) or via e-mail (for urgent notifications if iRASFF is unavailable).

(5) Once identified as an alert, the words "RASFF alert notification" and a number identifying the notification should be mentioned in the subject of messages concerning or transmitting the notification and no one handler of the notification on the notification's path should hold it for longer than 24 hours. Additional information that could not be obtained within this period should be sent at a later stage as a follow-up. The original notification will make a reference to missing information that is to follow. Messages concerning follow-up to an alert notification should be identified by the words "RASFF follow-up to alert notification" and the notification reference number in the subject.

(6) Outside office hours, the transmission of an alert notification or follow-up to an alert notification should be accompanied by a phone call to the ECCP's emergency RASFF phone number. In case transmission is not possible

through iRASFF or through TRACES, email is used. If this is for some reason impossible, the information can be sent per fax. When transmission in written form is not immediately possible outside office hours, information should be given through a phone call to the ECCP's emergency RASFF phone number.

(7) Office hours for the RASFF are defined as follows: Monday – Thursday from 9:00 until 18:00 and Friday from 9:00 until 17:00. Time is indicated in Brussels time (GMT +1). Members of the network are expected to monitor their functional mailboxes during this time. They should put measures in place to ensure that they can continue to monitor their mailbox should they be out of the office during the above defined time period. Outside of this period, the ECCP will inform them by telephone of an alert notification or follow-up to an alert notification concerning their country using the assigned emergency telephone number(s).

(8) The ECCP maintains a list of emergency contact persons and their emergency phone numbers as forwarded by the NCP. This list is published on CIRCABC and updated at least monthly. NCPs should inform the ECCP immediately of any change in the emergency contact information.

5. CLASSIFICATION

Before transmitting an original notification to the ECCP, the NCP classifies the notification in accordance with the definitions given in the RASFF Regulation, Article 1 (see WI 5.2. "guidance for the classification of a notification"). If the NCP assigns also a notification classification specific to its own country, it should ensure that this classification is not confused with the classification to be assigned according to the criteria laid down in this SOP.

6. WHEN TO FLAG A COUNTRY?

Before transmitting a notification, the notifying member indicates which other network members are concerned and are expected to react. These network members are then flagged by the ECCP when distributing the notification. When all recipients of the product are not yet known or if the information about the recipients is not clear, additional flagging can be done at the later stage (follow-up notification). More guidance on a harmonised use of flagging between members of the network is given in WI 4.1.

SOP 6: ECCP verification and distribution of RASFF notifications transmitted by the NCPs

RASFF Regulation,

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.

1. SCOPE

This SOP describes how the ECCP receives the notifications from the NCP, verifies them and distributes them to the NCPs.

2. RECEPTION OF RASFF NOTIFICATIONS FROM THE NCP

(1) The NCP transmits the notification to the ECCP through iRASFF or through TRACES. If for any reason these systems are not available, the NCP can transmit the notification to the ECCP by email to the SANTE RASFF functional mailbox.

(2) The ECCP will first check whether the notification falls within the scope of the RASFF. If the ECCP considers that it does not, it will inform the NCP immediately, proposing that the notification be rejected from distribution and giving the reasons therefore. The ECCP will then verify the notification's subject and classification and will give priority to alert notifications and their follow-up. Should the ECCP not agree with the given classification on the basis of the information provided, it will contact the NCP immediately in order to seek the necessary clarifications and reach a common understanding of the notification's grounds.

3. VERIFICATION OF THE NOTIFICATION BY THE ECCP

(1) When classification and scope are clear, the ECCP will carry out further verifications as required in Article 8 of the RASFF Regulation. If there are certain issues that the ECCP considers can be improved to the notification, it will record information about its verification with regard to:

- legal basis
- legibility and completeness
- risk evaluation
- compliance with these SOPs.

(2) The ECCP will provide feedback about its verification to the NCP for the purpose of improving the notification or any future notifications. The ECCP can also add questions for additional information about certain elements of the notification such as e.g. analysis, risk evaluation, traceability etc.

(3) If it is necessary for the notification to be easily understood, the ECCP will provide translation into English of the notification and - exceptionally - of any essential attached documents.

4. PREPARATION AND DISTRIBUTION OF THE NOTIFICATION

The ECCP will check the recurrence of hazards and operators identified in the notification based on the following criteria:

- a country of origin is identified as recurrent for a particular hazard if the hazard is notified six times or more for that particular country in a period of six months;

- an operator is identified as recurrent if the operator is notified three times or more in a period of three months

Depending on whether the notification is transmitted through iRASFF, through TRACES or via email, a different procedure for preparation and distribution of the notification is followed.

A. Email- and CIRCABC-based procedure

The ECCP encodes essential information from the notification in the RASFF (Microsoft Access) database in English. A cover page is generated from the information in the database and compiled with all attached documents into one Acrobat PDF file. The ECCP will verify the countries flagged by the NCP in the notification and will ensure that the proper countries are flagged for follow-up and for attention in the database. A daily table of notifications is sent to all NCPs at the end of the working day, including the flagged countries and other summary information regarding the notifications distributed on that day. There is one table for original notifications and another for follow-up notifications. At the same time the notifications prepared that day are uploaded "in bulk" on CIRCABC. Nevertheless, the ECCP can decide to distribute notifications "manually", immediately after preparing it. It will use this procedure for all alert notifications and for urgent follow-ups to alert notifications. Using the "manual" procedure, the ECCP generates and immediately sends notification emails to all NCPs.

B. iRASFF-based procedure

(1) The ECCP receives notifications submitted by the NCP in its task list as well as through a notification mail generated by iRASFF. Considering that not yet all notifications are introduced in iRASFF (in particular the notifications generated through TRACES), the ECCP will continue to encode in the RASFF database, prepare cover page and PDF file as described above.

(2) If the notification is considered incomplete, the ECCP can request additional information in iRASFF, after which the NCP can complete the notification and re-submit it ("suspended" status). The ECCP can also suspend the notification if it does not agree with certain elements in the notification that it may request the NCP to modify first. The ECCP can also propose rejection of the notification in iRASFF, giving the reason why.

(3) If the ECCP makes some edits to the notification, in agreement with the notifying country, it should perform these changes as a follow-up to the notification, rather than editing the notification prior to validation; in order to ensure full transparency of the modified information.

(4) Once the ECCP has verified all elements of the notification, it validates the notification in iRASFF. ECCP validation makes the notification available to all members of the network. After validation, the ECCP should flag the proper countries for follow-up or for attention (see WI 4.1) with the flag

function in iRASFF. Flagged countries receive the notification in their dashboard for follow-up or for attention.

C. TRACES-based procedure

(1) The ECCP receives a notification mail from TRACES informing that the NCP has confirmed the RASFF notification in TRACES. The ECCP will open the notification in TRACES and perform verification. If there are changes to be made to the notification, the ECCP can add these changes if it has received additional information from the NCP. In other cases, and also if the notification lacks essential information, the ECCP should request the NCP for additional information, placing the notification on hold.

(2) If the ECCP accepts the notification for distribution through the RASFF, it will validate the notification in TRACES with or without reinforced checks, based on whether reinforced checks were requested by the NCP or not. Before validating with reinforced checks, the ECCP will verify whether the criteria for launching reinforced checks are fulfilled. This means that a recurrent hazard or operator is identified or a serious risk is present. If the criteria for reinforced checks are fulfilled but the NCP has not requested them, the ECCP will inform the REC team in DG SANTE. If the criteria are not fulfilled according to the ECCP, the ECCP will validate the notification without reinforced checks, giving the arguments therefore in the ECCP Comment box in TRACES. Further details can be found in the REC guidance.

(3) After validation in TRACES, the ECCP compiles a PDF file of the notification and accompanying documents as in the email-based procedure under point A.

5. WITHDRAWAL OF A RASFF NOTIFICATION

(1) In accordance with Article 9(1) of the Regulation, any member of the network can ask for withdrawal of the notification, for the following 2 reasons:

a) if the information upon which the action to be taken is based appears to be unfounded; or,
b) if the notification was transmitted erroneously.

(2) With the request for withdrawal, sufficient evidence to support the request should be provided. If such evidence so warrants, the ECCP withdraws the notification with the agreement of the notifying country.

(3) The withdrawal is made known to network members by a follow-up notification of type "withdrawal of original notification" or "withdrawal of follow-up notification" depending on the type of notification that is being

withdrawn. This follow-up notification contains the motivation for the withdrawal.

(4) If it concerns a withdrawal of a follow-up notification, the necessary changes should be applied to the information in iRASFF by way of a follow-up notification. The withdrawal of a follow-up notification currently does not remove the information added by that follow-up notification automatically, considering that information may have been added at later stages that builds upon the information given in the follow-up notification that should be withdrawn. This may change in later versions of iRASFF.

(5) If it concerns withdrawal of an original notification, the summary of the follow-up notification containing the reason for the withdrawal is made available through RASFF Portal. The follow-up notification is then also made available to any third country concerned by the notification. Immediately following the notification withdrawal, NCPs should ensure that concerned business operators are notified of the notification withdrawal if it has any possible effect or consequence for them. Only the ECCP can withdraw an EC validated notification by changing the notification status to "withdrawn". In iRASFF, the “withdrawn” status currently only exists for original notifications.

6. DISTRIBUTION OF RASFF NOTIFICATIONS TO THIRD COUNTRIES

(1) iRASFF does not yet include a facility to make available a notification to a third country. The distribution of the RASFF notifications depends on a system involving the RASFF database and RASFF Window, although for some countries it remains email-based.

(2) When a country that is not a member of the network is involved in a RASFF notification as a country to which the product concerned was distributed or from which the product concerned originates, the ECCP encodes this country in the RASFF database. The PDF files of the original notification and selected follow-ups that contain information of importance to the country in question are linked to the country in question. Where there is information which is commercially sensitive or is covered by professional secrecy, it is removed as far as possible and a specific PDF file is created and distributed to the country(ies) in question. That information is also made available to INFOSAN if the criteria for informing INFOSAN are met or if requested specifically by the notifying country (see WI 3.2).

(3) The specific PDF files of notifications concerning third countries (for the purpose of informing them) are made available to NCPs for their information via the daily upload on CIRCABC.

A. RASFF Window-based procedure

At the end of the working day, the RASFF database is synchronised with the RASFF Window platform. New notifications (original + follow-up) are made available in RASFF Window as a result and automated notification emails are sent out to the contact points for the third countries that are informed through RASFF Window. These contact points can be contact points assigned by the third countries themselves or for some countries, the EC Delegation in the country in question. The contact points have user accounts by which they can log onto RASFF Window and download the newest notifications. Only notifications concerning their country that the ECCP made available to them can be downloaded.

B. Email-based procedure

In case the third country concerned is not using RASFF Window or in case the notification is very urgent, the ECCP can generate an email from the RASFF database containing the notification's PDF file(s) and send it to the contact point assigned in that country. Failing such contact point, the ECCP can request the EC Delegation in the country to forward the notification to the appropriate authority.

7. CLOSING AN ALERT NOTIFICATION

Alert notifications, involving a risk identified as serious, merit to be monitored for follow-up information that is either expected or requested explicitly. The flagging of countries for follow-up indicates from which countries follow-up is expected. Follow-up flags are set according to the rules given in WI 4.1. When follow-up information is received, the ECCP evaluates whether the follow-up flag may be closed out, if no further follow-up information is expected from that country. When all follow-up flags are closed out, the alert notification receives the “closed” status.

8. WEEKLY REVIEW OF RASFF NOTIFICATIONS

At the start of a new working week, the ECCP runs a weekly report of the previous week and verifies the notifications that were distributed the previous week. If necessary, small changes are made in the RASFF database to ensure compliance with data dictionaries and/or to clarify certain elements in the notification. Flagged countries and requests to NCPs are verified as well and additional requests may be made to NCPs in the course of this review. After finalisation, the report is distributed to the NCPs via CIRCABC. Email reminders are sent for questions that the ECCP asked members of the network which have remained unanswered for four weeks. Weekly and daily tables give information on the recurrence of hazards and operators in the notifications and whether a serious risk was identified. These elements serve as an input to the decision to trigger reinforced checks in TRACES for POAO (see REC guidance).

RASFF SOP 7:
Distribution of RASFF Notifications received from the ECCP

1. SCOPE

This SOP describes how the NCPs receive the notifications from the ECCP and gives advice on how to distribute them to the relevant competent authorities within their jurisdiction.

2. RECEPTION OF THE NOTIFICATIONS

(1) The NCP is informed directly by way of email of any alert notifications and urgent follow-up notifications. The notifications containing all details are available in iRASFF or in RASFF Window. Each CP should have at least one user ID and password to both applications. See WI 7.1 for further details on the operation of RASFF Window and iRASFF.

(2) The ECCP sends daily, weekly and monthly overviews of original notifications and of follow-up notifications to the functional mailbox dedicated to the RASFF that the NCP has communicated to the ECCP.

3. FILTERING NOTIFICATIONS

(1) The NCP can filter the notifications according to their seriousness and national relevance and dispatch the notifications in their entirety and/or a summary (translated into the national language(s) or not) of notifications received to the relevant competent authorities in the country for their assessment of what action needs to be taken.

(2) The current version of iRASFF (1.x) supports this filtering function albeit with a limited functionality: the NCP (MS validator role in iRASFF) can "flag" notifications appearing in the "notifications waiting for distribution" list to border, food or feed users. Users belonging to the flagged group will find the notification in their "notifications flagged for follow-up or for attention" list, with a flag for follow-up or for attention according to the flag set by the ECCP.

4. DISTRIBUTING NOTIFICATIONS

(1) Depending on the structure of the food and feed control authorities, the NCP can either:

- directly send notifications for appropriate follow up to national/regional competent authorities and contact persons;
- send notifications needing follow-up to contact points identified in each of the relevant food and feed control authorities (see also SOP 1).

(2) The NCP should ensure that the notification is received by the relevant national/regional competent authorities and/or risk assessment bodies, depending on the matter.

(3) A functional mailbox set up to receive messages concerning RASFF notifications should be able to receive emails of considerable size (at least 5 MB) and should be monitored during office hours. As proof of receipt, a read receipt can be sent (see also RASFF WI 5.1).

(4) Rather than distribution by email, the following tools are recommended, in order of preference and effectiveness:

- intranet or dedicated application to distribute notifications and/or instructions;
- iRASFF or RASFF Window for the transmission of the notifications, sending additional instructions by email;
- email only if iRASFF or RASFF Window are not available;
- fax in case iRASFF, RASFF Window, intranet or email are not available;
- telephone in case sending the information in written form is not possible.

RASFF SOP 8:Assessing a notification received from the ECCP

1. SCOPE

The scope of this SOP is guidance for the assessment of a RASFF notification received from the ECCP by the NCP, in order to decide what kind of action will be taken and what kind of follow-up information needs to be sent in response to the notification.

2. ASSESSMENT OF THE NOTIFICATION

(1) The NCP will carry out an assessment of each RASFF notification it has been flagged for.

This assessment will require, as appropriate, a review of:

(a) the nature of the hazard;

(b) the type of food, food contact material or feed involved;

(c) the associated risk with particular regard to potential implications for consumers;

(d) the origin of the product: country, name and address of manufacturer (in the absence of manufacturer: dispatcher) of processed product and/or raw material used;

(e) the distribution status: possible distribution of the product to the country directly or indirectly from another country known to have received the product;

(f) details of sampling and analysis carried out, including sampling and analytical method, analytical result and analytical measurement uncertainty for the original sample taken and any counter sample, counter analysis, referee sample and referee analysis;

(g) the measures taken.

If the assessment of the notification is not a part of the tasks of the NCP, the NCP's assessment will be limited to points (a) and (b) above. This first assessment will allow the NCP to determine to which competent authority or experts to relay the notification.

(2) If the notification contains insufficient information for a full assessment of the notification or for efficient action to be taken (e.g. incorrect address of a recipient), the NCP will ask for further information

(a) by way of a follow-up notification or

(b) bilaterally to the NCP concerned (see SOP 4) or

(c) by making contact with the business operator(s) concerned by the notification in their territory.

3. FOLLOW-UP ACTIONS

(1) When rapid action is required, the NCP will ensure that the notification is received by the relevant competent authority within the country without undue delay.

(2) Where the notification was made relating to a foodborne outbreak, the NCP may consider requesting relevant epidemiological and/or environmental data in order to enable the necessary follow-up action in their country.

(3) The NCP should require the competent authority acting upon the notification to provide to it reports from the outcome of investigations or measures taken on the basis of the notification, and should collate such information and transmit it to the ECCP by way of follow-up to the notification.

RASFF SOP 9:
Archiving and consulting RASFF notifications and related information

1. SCOPE

This SOP sets out guidance on the minimum information that needs to be available in the RASFF archive and gives some advice on good practice to maintain and access the archived information.

2. GUIDELINES FOR EFFICIENT ARCHIVING

(1) It is recommended that the ECCP and NCPs develop and maintain procedures for registering and archiving RASFF notifications and related data and ensure that the proper tools to carry out this task optimally are available.

(2) The arrangements described in this SOP should be seen as an achievable minimum. A member country may use its own database system containing supplementary information and designed to operate in their particular surveillance system and/or in part rely on the ECCP's notifications archive on iRASFF and RASFF Window for implementing the arrangements described below.

(3) Members of the network are advised to:

- create a file on every notification for which your country was flagged for follow-up or for attention;
- keep a record - e.g. in a spreadsheet or a database - of information about the assessment and action taken concerning the notifications sent or received.

3. INFORMATION WHICH SHOULD BE MAINTAINED ON FILE

Country creating a notification

- documents and reports leading to the creation of the notification
- date of creation of the notification
- EU notification reference number after EC validation of the notification
- information about the product concerned and hazard(s) found
- country of origin of the product and documents related to the traceability and origin of the product
- chronology of decisions taken and actions carried out in relation to the notification

Country providing follow-up to a notification

- date of follow-up notification

- EU notification reference number of the notification
- chronology of decisions taken and actions carried out in relation to the notification

4. DATABASES

- The RASFF Window application can be a useful tool to look up notifications and follow-up through the search tool provided. Also the iRASFF application can be used.

- The data from RASFF Window or iRASFF can be extracted to feed into the CP's database application.

5. ACCESS TO THE ARCHIVE

The following points are given as an example of how the requirements of Art. 52(2) of Regulation 178/2002 can be implemented when keeping an archive of RASFF-related information:

- All staff officially appointed to work in food and feed control authorities of member countries of the RASFF can have access to the documents.

- Only designated staff of the RASFF contact point should be allowed to :
  - enter the required information,
  - delete information,
  - update existing information in the archive, existing tables or databases.
- Other staff of the authorities dealing with RASFF can only consult the information.

- All the above persons should be made aware that, in accordance with Art. 52 of Regulation 178/2002, not all information in RASFF is made public and that certain information covered by professional secrecy needs to be protected from disclosure. Aspects of transparency and confidentiality are presented in SOP 10.

- It is advised to keep the archived information for a minimum of five years.

- An intranet application is most suitable to communicate the RASFF information efficiently, integrating requests for action and information by the CP with the responses by the inspectors and linking this information to the RASFF notification.

RASFF SOP 10:
Confidentiality rules for RASFF

General Food Law, Article 52
Confidentiality rules for the rapid alert system
1. Information, available to the members of the network, relating to a risk to human health posed by food and feed shall in general be available to the public in accordance with the information principle provided for in Article 10. In general, the public shall have access to information on product identification, the nature of the risk and the measure taken.
However, the members of the network shall take steps to ensure that members of their staff are required not to disclose information obtained for the purposes of this Section which by its nature is covered by professional secrecy in duly justified cases, except for information which must be made public, if circumstances so require, in order to protect human health.
2. Protection of professional secrecy shall not prevent the dissemination to the competent authorities of information relevant to the effectiveness of market surveillance and enforcement activities in the field of food and feed. The authorities receiving information covered by professional secrecy shall ensure its protection in conformity with paragraph 1.

General Food Law, Article 10
Public information
Without prejudice to the applicable provisions of Community and national law on access to documents, where there are reasonable grounds to suspect that a food or feed may present a risk for human or animal health, then, depending on the nature, seriousness and extent of that risk, public authorities shall take appropriate steps to inform the general public of the nature of the risk to health, identifying to the fullest extent possible the food or feed, or type of food or feed, the risk that it may present, and the measures which are taken or about to be taken to prevent, reduce or eliminate that risk.

1. SCOPE

This SOP describes what kind of information from the RASFF is made public and the circumstances in which it is made public.

2. TRANSPARENCY OF RASFF INFORMATION

(1) In accordance with Article 52(1) of Regulation 178/2002, the Commission makes available summary information of all alert, information and border rejection notifications, providing information on the type of product, the hazards identified, the analytical results if available, the country of origin of the products, the countries to which the product was distributed, the notifying country, the basis of the notification, the measures taken and the distribution status.

(2) In accordance with Article 10 of Regulation 178/2002, where a product which has been notified may present a risk to the consumer, depending on the nature, seriousness and extent of the risk, competent authorities should ensure to make public all information needed for the consumer to identify the product. The decision to make this information public should be notified in RASFF as well as where the information can be found.

(3) Information is often made public in relation to RASFF notifications, e.g. on food recalls, press releases or public health warnings in a RASFF member

country, informing consumers on the findings and where appropriate on the need to return the product(s) involved in a RASFF notification. The ECCP has prepared the “RASFF Consumers Portal” to link the RASFF notifications to this kind of information that is published on the web. The NCPs are requested to add the hyperlinks to such information in their RASFF notifications. The responsibility for the information given belongs with the authority, organisation or business operator that provided it.

(4) It is advised that member countries have adequate procedures in place to ensure that the professional operators mentioned in the notification are immediately provided with all information they require to take action in order to eliminate the risks notified and to enable them to provide additional information to the competent authority or, where applicable, to safeguard their right to appeal against the decision taken by the competent authority.

(5) An annual report on the notifications transmitted through the RASFF will be prepared and published by the Commission for each year's functioning of the system.

3. CONFIDENTIALITY OF RASFF INFORMATION

(1) Members of the network may publish or refer to the summary information provided by the Commission in its publicly accessible "RASFF Portal" database but can make more information public if there is a need to in order to protect human or animal health, in accordance with Article 10 of Regulation EC No 178/2002.

This need could arise when a serious risk has been detected in relation to a food, food contact material or feed present on the market that has or can be bought by the consumer, particularly if a professional operator refuses to inform consumers on its own initiative or refuses to co-operate with the competent authorities in order to effectively withdraw the products from sale or recall the products from the consumer.

(2) In accordance with Article 52 of Regulation 178/2002, competent authorities shall not disclose any information included in a RASFF notification that is covered by professional secrecy in duly justified cases. Only if required by circumstances to protect human health, to be considered on a case-by case basis, can such information or part of it be made public.

Notwithstanding the fact that competent authorities shall make available the information necessary to protect human or animal health, it is advised not to forward complete notifications to private persons or business operators, unless they are directly concerned by the notification. In the latter case the authorities should still ensure that commercially sensitive information / documents or parts of them, which are not needed for the operator to act or which are covered by professional secrecy, are removed from the copy of the notification that is handed over. Prices should in any case be deleted from the documents.

(3) Information covered by professional secrecy may include:

(a) Information covered in Article 7(3) of Regulation (EC) No 882/2004

(b) Commercial documents such as clients or recipients lists, inventories, bills and invoices, own-checks reports etc.

(c) Documents that are part of the intellectual property of a company such as recipes, process charts, pictures of processing equipment etc.

(d) Other specifically identified information, duly justified as to why it is covered by professional secrecy.

(4) In case a citizen requests a RASFF notification or a document exchanged in the context of a RASFF notification, access to documents rules[28] will apply.

[28] For the ECCP, Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents, *OJ L 145, 31.5.2001, p. 43–48,* applies.