EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Crisis preparedness in food, animals and plants
Food hygiene, feed and fraud

Standard operating procedures of the Alert and Cooperation Network (ACN)

version 3.2

Abbreviations and definitions used in the SOPs and WI

AAC	Administrative Assistance and Cooperation
AAC-type notification	Notification following the AAC procedure: all notifications in the ACN except RASFF notifications
ACN	Alert and Cooperation Network, governing AAC, RASFF and specialised networks
ADI	Acceptable Daily Intake
ARfD	Acute Reference Dose
AWCP	Animal Welfare (Network) Contact Point
AWN	Animal Welfare Network
BMDL	Benchmark Dose Limit
CFU	Colony Forming Units
CHED	Common Health Entry Document
CMR	Carcinogenic, Mutagenic or Reproduction-toxic
CP	Contact Point
DPO	Data Protection Officer
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
FCM	Food Contact Material
FFCP	Contact point of a member of the EU (Agri-Food) Fraud Network
FFN	EU (Agri-Food) Fraud Network as defined in Commission Implementing Regulation (EU) 2019/1715 (the IMSOC Regulation)
GFL	General Food Law: Regulation (EC) No 178/2002

HBGV	Health-Based Guidance Value
INFOSAN	International Food Safety Authorities Network
iRASFF	The electronic and interactive notification platform of the ACN
GM(O)	Genetically Modified (Organism)
ML	Maximum Level of contaminants of food as defined in Commission Regulation (EC) No 2023/0915and of undesirable substances in feed as defined in Directive 2002/32/EC
MOE	Margin Of Exposure
MRL	Maximum Residue Level (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
NC	Non-compliance
NCP	National Contact Point: the designated contact point representing the network member in the RASFF
NOAEL	No Observed Adverse Effect Level
OCR	Official Controls Regulation, i.e. Regulation (EU) 2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products
PACP	Pet Animals (Network) Contact Point
PAN	Pet Animals Network
PCR	Polymerase Chain Reaction
PDF	Portable Document Format: electronic document format used by Adobe Acrobat
PHN	Plant Health Network
RACE	Rapid Assessment of Contaminant Exposure
RASFF	Rapid Alert System for Food and Feed
RASFF notification	Notification in the ACN following the RASFF procedure on findings in the scope of RASFF
REG	Risk Evaluation Glossary

RPA	Reference Point for Action as provided for in Articles 18 and 19 of Regulation (EC) No 470/2009
RTE	Ready-to-eat
(DG) SANTE	Directorate General for Health and Food Safety
SAAS	SANTE Authorization System
SCP	Single Contact Point
SN	Specialised Network: a network, different than AAC/RASFF, defined in the ACN and in iRASFF that works on a specific (specialised) competence and has designated its own contact points
SNCP	Specialised Network Contact Point, see "specialised network"
SOP	Standard Operating Procedure
TDI	Tolerable Daily Intake
TRACES	TRAde Control and Expert System
TSEs	Transmissible Spongiform Encephalopathies
WI	Working Instruction: annex to a SOP with detailed practical information needed for the functioning of the RASFF network
UI	User Interface
UL	tolerable upper intake level

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Introduction and scope of the ACN SOPs

1. LEGAL FRAMEWORK

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 derived from feed.

Article 4(2) of Council Regulation (Euratom) 2016/52 stipulates that "Any case of non-compliance with the applicable maximum permitted levels shall be notified through the Rapid Alert System for Food and Feed (RASFF)"[3].

Article 102 of Regulation (EU) 2017/625[4] (hereinafter, 'the Official Controls Regulation') established the network of liaison bodies for the purpose of the AAC.

Commission Implementing Regulation (EU) 2019/1715 laying down rules for the functioning of the information management system for official controls and its system components ('the IMSOC Regulation') defines the procedures for RASFF and AAC.[5]

Guidance and procedures having importance for the ACN:

- 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.[6]

2. PURPOSE OF THE SOPS

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

- types of notifications and criteria for notifying

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[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] Council Regulation (Euratom) 2016/52 of 15 January 2016 laying down maximum permitted levels of radioactive contamination of food and feed following a nuclear accident or any other case of radiological emergency, and repealing Regulation (Euratom) No 3954/87 and Commission Regulations (Euratom) No 944/89 and (Euratom) No 770/ 90, *OJ L13,20.1.2016, p. 2-11*

[4] Regulation (EU) 2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, *OJ L 95, 7.4.2017, p. 1–142*

[5] *OJ L 261, 14.10.2019, p. 37–96*

[6] To be found at: https://ec.europa.eu/food/system/files_lv?file=2016-10/gfl_req_guidance_rev_8_en.pdf, at pp. 10-11.

- 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 non-member countries and business operators
- transparency and confidentiality of the information exchanged

The ACN 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 ACN working group meeting prior to incorporation into the SOPs. The ECCP coordinates the versioning of the SOPs and makes the updated ACN SOPs public on the ACN web pages of DG SANTE.

3. SOP 1: SCP TASKS

This SOP provides guidance regarding the relevant requirements laid down in the IMSOC 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 competent authorities to ensure that there is effective communication between the network and the competent authorities.

4. SOP 2: TYPES OF NOTIFICATIONS WITHIN THE ACN - CRITERIA TO DETERMINE WHAT NOTIFICATION TO MAKE AND WHAT NOTIFICATIONS ARE MANDATORY

The scope of RASFF, as laid down in Article 50 of General Food Law Regulation, supplemented with Article 29 of the Feed Hygiene 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.

The scope of AAC concerns instances of possible non-compliance with the rules referred to in Article 1(2) of Regulation (EU) 2017/625 that do not present a risk within the meaning of Article 50 of Regulation (EC) No 178/2002 and Article 29 of Regulation (EC) No 183/2005. This scope is also covered in the PHN but applied to plant health issues and to the AWN, applied to animal welfare issues.

The scope of FFN covers notifications concerning suspected intentional action by businesses or individuals for the purpose of deceiving purchasers and gaining undue advantage therefrom, in violation of the rules referred to in Article 1(2) of Regulation (EU) 2017/625. The PAN covers both the scope of the FFN and of the AAC, but applied to pet animal issues.

Notifications of the ACN are transparent to its members. This means that, regardless in which network they are operational, users of iRASFF have access to the notification if their organisation is granted access. For notifications in the FFN and PAN however, access is limited to the network in which the notification is created to allow investigating a (suspected) fraud.

This SOP provides guidance regarding the type of notification that should be made and how the different networks joint together in the ACN (RASFF, AAC, FFN, PHN, PAN and AWN) can collaborate using iRASFF.

5. SOP 3: PREPARING AN ORIGINAL NOTIFICATION

This SOP provides guidance on preparing an original iRASFF notification including collecting information, using notification templates, language, handling of documents and role of the SCP.

6. SOP 4: PREPARING A FOLLOW-UP NOTIFICATION

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

7. SOP 5: TRANSMITTING A NOTIFICATION USING THE RASFF PROCEDURE AND THE AAC PROCEDURE

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

8. SOP 6: ECCP TASKS

This SOP describes the ECCP tasks in the system as it receives RASFF notifications from the SCP, verifies them and distributes them to the SCPs, but also concerning its monitoring of AAC- and fraud-type notifications. It also clarifies the procedures for the withdrawal and closure of a notification, the distribution of RASFF notifications to non-member countries and the weekly review by the ECCP.

9. SOP 7: DISTRIBUTION OF RASFF NOTIFICATIONS RECEIVED FROM THE ECCP (RASFF PROCEDURE) OR FROM A LIAISON BODY (AAC PROCEDURE)

This SOP provides advice on how notifications received from the ECCP (RASFF procedure) or from a liaison body (AAC procedure) should be distributed by the SCPs or liaison bodies to the relevant competent authorities within the same member country.

10. SOP 8: ASSESSING A NOTIFICATION RECEIVED FROM THE ECCP (RASFF PROCEDURE) OR FROM A LIAISON BODY (AAC PROCEDURE)

This SOP enumerates what elements of the notification need to be assessed by the SCP or liaison body 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 the investigation and action taken by those authorities should be fed back into iRASFF in the form of follow-up notifications.

11. SOP 9: CONSULTING IRASFF NOTIFICATIONS; ARRANGEMENTS FOR PERSONAL DATA PROTECTION

In this SOP, advice on good practice for consulting iRASFF notifications is provided. The SOP also describes the arrangements put in place to ensure that iRASFF is fully in line with the personal data protection rules.

12. SOP 10: CONFIDENTIALITY RULES FOR iRASFF

This SOP explains how the requirements of Article 52 of the GFL and of Article 8 of the OCR can be respected. Advice is also given on how to respect the requirement for non-disclosure of information covered by professional secrecy.

ACN SOP 1: SCP tasks

Governing rules (IMSOC Regulation):

(13) 'single contact point' means a contact point composed of the RASFF and AAC contact points in each Member State, whether or not physically located in the same administrative unit;

Article 4

Components, networks and contact points

1. Each component shall have a network of which the Commission shall be part.

2. Network members shall each designate at least one contact point and communicate that designation and its contact details to the Commission contact point. They shall inform the Commission contact point immediately of any changes in this respect.

3. The Commission contact point shall maintain and keep up to date a list of contact points and make it available to all network members.

Article 12

Liaison bodies responsible for the exchange of certain types of information

Member States shall indicate which of the liaison bodies designated in accordance with Article 103(1) of Regulation (EU) 2017/625 are responsible for exchanging information on fraud notifications.

Article 13

Single contact point

1. The single contact point in each Member State shall be responsible for:

(a) setting up effective arrangements for the smooth exchange of relevant information with all relevant competent authorities within its jurisdiction, allowing the immediate transmission of notifications, requests or responses to the competent authorities for appropriate action, and maintaining the notifications, requests or responses in good order;

(b) determining its roles and responsibilities and those of the relevant competent authorities within its jurisdiction as regards preparing and transmitting notifications, requests and responses, and assessing and distributing notifications, requests and responses from other members of the alert and cooperation network.

2. Member States may include their fraud network contact point in their single contact point.

3. Communication within the RASFF network shall take place through the single contact point.

Article 14

Duties of the members of the alert and cooperation network

1. Members of the alert and cooperation network shall ensure the efficient functioning of their networks within their jurisdiction.

2. Each designated alert and cooperation network contact point shall communicate to the Commission contact point detailed information regarding the persons operating it and their contact details. For that purpose, it shall use the contact point information template provided by the Commission.

3. RASFF network contact points shall ensure that an on-duty officer is available for emergency communications on a 24/7 basis.

1. SCOPE

This SOP lays down 'best practice' to facilitate the network members' fulfilment of their obligations under the IMSOC Regulation, namely the efficient functioning of the ACN and its sub-networks, the effective communication between their single contact points, responsible for the ACN, on the one hand and between the SCP and the competent authorities on the other hand.

2. BEST PRACTICES FOR THE MEMBERS OF THE NETWORK

(1) The single contact point (SCP) should be established in the structure of national competent authorities as a single unit or composed out of persons from different units or sections but identifiable and directly contactable.

(2) It is advisable that a single functional mailbox be assigned to the SCP, to ensure that all its members are informed.

(3) The SCP represents the AAC/RASFF network in iRASFF, which is the “backbone” network of the ACN, and for AAC covers all the competences as given by the OCR. However, issues covered by specialised networks, will circulate as much as possible within these networks. Currently, the FFN, the PHN, the PAN and the AWN are specialised networks within the ACN.

(4) If there are contact points for specialised networks (the latter are referred to as "liaison bodies" in the legislation, even if these networks are not identified as specialised networks in iRASFF), then the SCP ensures to be in direct communication with these contact points (CPs).

Although the Agri-Food Fraud contact point (FFCP) should remain separately identifiable, member countries should ensure that coordination between SCP and FFCP is possible at all times. The FFCP may be represented in the SCP of its member country.

(5) The SCP should ensure that:

(a) its communication network with its CPs and all relevant competent authorities is fully operational, allowing immediate transmission of a notification, request or response to the competent authorities for appropriate action;

(b) it is fully aware of the roles and responsibilities of its CPs and those of the relevant competent authorities as regards the preparation and transmission of notifications, requests or responses, as well as the assessment and distribution of notifications, requests or responses received from other members of the ACN.

(6) The procedure for making available and updating the contact points' information, as required by Article 14(2) of the IMSOC Regulation, is

provided in WI 1.1. This WI is applicable to every person belonging to the SCP and to the contact points of the specialised networks.

(7) If persons belonging to the SCP are placed in more than one organisation within the competent authorities responsible for the enforcement of law in the scope of the OCR to enhance the efficiency of the information flow: e.g. persons responsible for food and persons responsible for feed issues, the SCP should inform the ECCP of this organisation and of these persons' contact details using the procedure in WI 1.1.

Contacts for the purpose of the ACN among member countries and with the ECCP should occur through the SCP, except for the specialised CPs (liaison bodies). Specialised CPs within the same network but belonging to different network members may directly contact each other, the ECCP or other services in the Commission. Nevertheless, if such communication involves an ACN notification in iRASFF and several networks are concerned, the SCPs concerned and the ECCP should always be put in copy of the conversation.

It is possible that, in addition to its role as SCP, the SCP is also the contact point for a competent authority in a specific area.

(8) “Internal” contact points can be identified in certain areas inside a network member that do not transmit notifications directly to other network members. Details of such contact points do not need to be sent to the ECCP. The SCP might however delegate certain tasks to them. Even though these internal CPs are not part of the SCP, while referring to the SCP, some information on best practices included in the ACN SOPs may apply to these internal CPs as well. These internal CPs 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 or other agri-food business operators;

– a competent authority, unit or expert for the purpose of providing a response to a particular request;

– border posts for reinforced checking at the border.

(c) the timely provision of information needed for the creation of an original or a follow-up notification in the iRASFF system.

The SCP should verify the correct execution of these delegated tasks.

(9) Member countries may consider setting up clearly identified ACN units / ACN contact persons in regional and/or local levels, to ensure effective communication between the SCP at the national level and the regional/local level.

(10) The SCP ensures and checks the operational readiness of an on-duty officer reachable outside office hours for RASFF emergency communications on a 24 hours/7 service. The details of these on-duty arrangements are given in WI 1.2.

(11) It is critical, for the SCP as well as for the specialised network CPs, 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, AAC, and the specialised networks is carried out.

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

(13) For the purpose of providing staff of competent authorities the right access to iRASFF, according to their duties, the SCP ensures that organisations needing access to iRASFF are identified in SAAS, as well as local administrators for SAAS that will assign and monitor user access to iRASFF. Local administrator accounts in SAAS should be regularly reviewed by the SCP, and at least twice yearly.

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

- 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 or providing response to a request: 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 regarding 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 and correctly applying the rules regarding personal data protection: see SOP 9;

- publishing information about RASFF notifications, recalls or identified risks while ensuring an appropriate level of protection of sensitive data: see SOP 10;
- analysing hazards notified to the ACN, identifying trends as an input for setting priorities in official controls.

ACN SOP 2: Types of notifications within the ACN - criteria to determine what notification to make and what notifications are mandatory

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.

Article 2 of the IMSOC Regulation with definitions:

(2) 'network' means a group of members having access to a specific component;

(3) 'network member' means a Member State's competent authority, the Commission, an EU agency, a third country's competent authority or an international organisation that has access to at least one component;

(4) 'contact point' means the contact point designated by the network member to represent it;

(14) 'non-compliance notification' means a notification in iRASFF of a non-compliance with the rules referred to in Article 1(2) of Regulation (EU) 2017/625 that does not represent a risk within the meaning of Article 50 of Regulation (EC) No 178/2002 and Article 29 of Regulation (EC) No 183/2005;

(15) 'alert notification' means a notification in iRASFF of a serious direct or indirect risk deriving from food, food contact material or feed within the meaning of Article 50 of Regulation (EC) No 178/2002 and Article 29 of Regulation (EC) No 183/2005 that requires or might require rapid action by another RASFF network member;

(16) 'information notification' means a notification in iRASFF of a direct or indirect risk deriving from food, food contact material or feed according to Article 50 of Regulation (EC) No 178/2002 and Article 29 of Regulation (EC) No 183/2005 that does not require rapid action by another RASFF network member;

(17) 'information notification for follow-up' means an information notification related to a product that is or may be placed on the market of another RASFF network member's country;

(18) 'information notification for attention' means an information notification related to a product that:

(i) either is present only in the notifying network member's country; or

(ii) has not been placed on the market; or

(iii) is no longer on the market;

(19) 'news notification' means a notification in iRASFF concerning a risk deriving from food, food contact material or feed within the meaning of Article 50 of Regulation (EC) No 178/2002 and Article 29 of Regulation (EC) No 183/2005 that has an informal source, contains unverified information or concerns as yet an unidentified product;

(20) 'border rejection notification' means a notification in iRASFF of a rejection of a batch, container or cargo of food, food contact material or feed due to a risk as referred to in point (c) of the first subparagraph of Article 50(3) of Regulation (EC) No 178/2002 and Article 29 of Regulation (EC) No 183/2005;

(21) 'fraud notification' means a non-compliance notification in iRASFF concerning suspected intentional action by businesses or individuals for the purpose of deceiving purchasers and gaining undue advantage therefrom, in violation of the rules referred to in Article 1(2) of Regulation (EU) 2017/625;

1. SCOPE

This SOP provides guidance as to the types of notifications that can be made within the ACN and when their usage is appropriate or required.

2. SCOPE OF AAC

The AAC procedure (Articles 102-108) applies to all controls within the scope of the Official Controls Regulation. The information concerns possible instances of non-compliance. The procedure may be precisely triggered to establish whether a non-compliance exists (Art. 104 "Assistance on request") when assistance is required from another member country to do so. It may also be triggered to ensure that compliance is enforced in another member country or to ensure that penalties associated with non-compliance can be imposed.

In the context of Article 106, it is possible to use the AAC procedure for the member country of destination to inform the member country of dispatch for the latter to investigate the matter and take the necessary measures. However, if the member country of destination finds a serious risk within the scope of RASFF it is required to use the RASFF procedure. In addition, it is appropriate to escalate the notification to RASFF when a non-compliance affecting human health triggers a withdrawal from the market, even if a serious risk is not identified. In general, the RASFF procedure should apply any time the finding is related to a health risk within the scope of RASFF.

Fraud notifications follow the AAC procedure but cannot be escalated to RASFF because they are exclusive to FFN members. PHN or AWN non-compliance notifications are also not escalated to RASFF because they belong to a different network and the subject matter is not in the scope of RASFF.

3. 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 and AAC

RASFF and AAC have different main objectives: while the RASFF's main 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 effective enforcement within the scope of the OCR in cases which have a cross-border dimension/impact**.

Cooperation within the framework of administrative assistance (AAC) 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 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. In case a health risk in the scope of RASFF is found and a RASFF notification is made, the RASFF notification offers identical features as a non-compliance notification in the AAC procedure for the purpose of administrative assistance.

Fraud notifications

Fraud notifications are a particular type of NC notifications reported in iRASFF, in the FFN and in the PAN. Their confidential nature implies that collaboration is only possible within

the network (FFN or PAN) that the notification is issued. Therefore, if there are health risks or other type of non-compliances identified, the issuing of a RASFF or NC notification (as appropriate) should be considered. A RASFF notification is mandatory if a serious health risk might be involved ("potentially serious" or "serious" risk decision). In such case, the RASFF notification shall not give any details of the fraud investigation and will only contain the information necessary to mitigate the risk and enable rapid action. If a RASFF or NC notification is created following from the same incident/investigation of a fraud notification, it should refer to that fraud notification.

In case a serious health risk or important non-compliances other than the potential fraud under investigation are already apparent at the time of notification, the SCP should consider starting a RASFF or NC notification respectively, in cooperation with/ coordination by the FFCP or PACP in order to share these issues with the other members involved. The FFCP/PACP should then add sensitive fraud investigation details as a **fraud follow-up** or ask specific questions in a **fraud conversation**, thereby sharing such fraud details in the RASFF or NC notification directly but **available to the FFN/PAN only**. Conversely, elements such as product identification and traceability, analytical results and hazards, measures taken etc. that are essential for a non-compliance or RASFF notification should preferably only be added as AAC/RASFF follow-up, to avoid any issue with consistency or visibility of the information.

The following headers outline whether RASFF should be used and when use of RASFF is required by law.

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/FCM 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 the Official Controls Regulation.

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 countries' competent authorities to exchange information necessary to take rapid action in case of risk, an evaluation of the risk should therefore be systematically carried out before a decision to send a RASFF notification is made.

[7] To be found at: GPSD and GFL (europa.eu) .

The assessment whether 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 members of the network 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 – through the organoleptic characteristics of the product - 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;

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 common entry document, health certificate or certified analytical report for which no risk could be related to the documentary irregularities, e.g. in case of fraud;

[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.

[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 (EU) 2015/2283 on novel foods, *OJ L 327, 11.12.2015, p. 1-22*.

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 serious direct or indirect risk **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 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). It would however not appear to be relevant or useful to report company own-checks on incoming raw materials if there is a process in place that in normal circumstances will eliminate the risk.

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.(EU) No. 2019/1871[12] 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 (detailed information in WI 2.2);

d) food containing (potentially) mutagenic or carcinogenic substances (Regulation 2008/1272[13] category 1A, 1B) or substances toxic for reproduction (Regulation 2008/1272 category 1A, 1B) 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

[10] Article 2(15) of the IMSOC Regulation.
[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] |*OJ L289, 8.11.2019, p. 41-46*
[13] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, OJ L 353, 31.12.2008, p. 1–1355

in national legislation unless a particular risk assessment allows defining a higher alert threshold;

e) food containing (potentially) mutagenic or carcinogenic substances (Regulation 2008/1272 category 1A, 1B) or substances toxic for reproduction (Regulation 2008/1272 category 1A, 1B) for which no legal limit is set but for which the safety margin comparing exposure to an appropriate health-based guidance value is considered too narrow (MOE/BMDL approach);

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 present a health hazard to the consumer in foods that are not meant to undergo a treatment before consumption sufficient to kill parasites;

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 (more detailed information in WI 2.2);

[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.

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 specific groups such as infant formulae, food for special medical purposes etc., that does not meet the required compositional criteria for its intended use;

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

[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.*

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) feed 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 animal disease, or human disease by persisting in the food chain;

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

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

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

h) presence of prohibited materials according to Annex III to Regulation (EC) No. 767/2009[22];

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

j) presence 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];

k) 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;

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[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*.
[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*

l) 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)

In addition to cases where a risk requires or might require rapid action across borders, the RASFF system enables member countries 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 2 of the IMSOC 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)**

Based on the guidance above, members of the network are required to decide whether a notification created in iRASFF should follow the AAC or the RASFF procedure. The prime consideration should be what is the main purpose for notifying, taking into account the different objectives for both systems: if the focus is on enabling the taking of remedial action, by other network members or non-members, to eliminate a (possible) health risk or to inform consumers then RASFF should be used. If however the focus is on requiring assistance to investigate a (potential) non-compliance or to enforce compliance, then the AAC should be used. Network members should always consider though which other network members to inform of an NC notification, even if they are not directly involved or required to assist, if such information could be useful to them.

As long as a notification marked as "RASFF" is not validated by the ECCP, it is not considered a confirmed RASFF notification, and it can be decided to reclassify the notification into the AAC procedure. The RASFF notification is final once validated by the

[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.

ECCP. At this stage, it is shared with all network members, and it cannot return to the AAC procedure.

4. RISK EVALUATION AND RISK DECISION

Whereas previously the "term" risk was to be understood as a risk in the scope of RASFF, with the integration of the ACN it can be any risk associated with food, feed or any agri-food product and regulated or managed by the OCR. These include human, plant or animal health risks as well as animal welfare or environmental risks. In iRASFF, only one area of impact can be chosen, which should be the most relevant one.

Unless the seriousness of the risk at hand is straightforward, the risk evaluation on which the notification classification 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 considered during verification to decide upon the seriousness of the risk (risk decision). The available risk decisions are: "no risk", "potential risk", "not serious", "potentially serious", "serious".

A "no risk" decision means that a risk in the chosen area of impact can be ruled out. A RASFF notification should never come with a "no risk" decision.

A potential risk is a risk decision given when no serious risk is suspected but a risk cannot be ruled out. Nevertheless, there is insufficient information to decide upon a ("not serious") risk.

Examples of potential risk:

- Novel food (ingredients) or (unauthorised) substances for which no risk was demonstrated but of which the safety was also not proven
- Substance benchmark levels exceeded or good manufacturing/hygiene/agriculture practice not respected without any further aggravation factor for the risk
- Substances that have CMR potential (CLP Regulation class 2)

"Not serious" is the outcome of a risk evaluation, demonstrating that a serious risk does not exist or is very unlikely. Or there is no evidence of a (serious) risk but measures designed to ensure product safety were not or insufficiently taken or demonstrated. Risk mitigation remains however desirable to ensure a high level of health protection.

Examples of not serious risk:

- Absence of or improper health certificate
- Salmonella in raw materials intended for animal feed
- Dioxins at levels just above ML in feed additives or feed premixtures
- Infestation with moulds
- Food additive non-compliances (some present no risk)
- Non-CMR substances that do not present an acute adverse health effect, but may present a chronic one, taking into account overall consumer exposure

- Pathogenic micro-organisms in food products requiring thorough cooking, unless they might have produced heat-stable toxins or unless there exists a food safety criterion (e.g. Regulation 2073/2005)

A "potentially serious" risk decision concerns an identified risk, but for which, at the time of notifying, it is not possible, for lack of evidence or consensus, to decide that the risk is serious, but a serious risk cannot be ruled out.

Examples of potentially serious risk:

- CMR substances or substances suspected of having CMR properties, for which there is no HBGV, BMDL or NOAEL available to evaluate the risk (CLP Regulation class 1 substance)
- Norovirus in live oysters, detected through PCR method
- Substances or nutrients such as vitamins, for which a UL is exceeded unless a specific risk evaluation rules out a serious risk
- New plant pests pending pest risk analysis (PHN)

A "serious risk" decision is made when evidence is available that demonstrates that the finding can significantly impact the consumers' health, whether acutely or chronically. A serious risk can also be identified for plant or animal health as well as for animal welfare or the environment, as an outcome of a preliminary or detailed risk assessment.

Examples of serious risk:

- Food safety criterion exceeded for pathogenic micro-organism
- Confirmed presence of foreign bodies that may cause physical harm
- Any substance in a concentration that leads to significant acute adverse effects in consumers upon exposure (including allergens)
- Substances that have a significant physiological effect that may be dangerous if taken in too high dose or by certain population groups
- Any substance, of which chronic exposure may lead to serious effects if the margin of exposure is too low
- CMR (carcinogenic, mutagenic or toxic for reproduction) substances or substances suspected of having CMR properties, for which there is a HBGV, BMDL or NOAEL available and a risk evaluation identifies an unacceptable risk to the consumer
- Salmonella in dog chew
- Aflatoxins above the ML in feed for milk-producing animals
- dioxins above the ML in feed materials
- Exceedance of an MRL for a pesticide residue for which a risk evaluation by Primo model results in an estimated short term intake above ARfD
- Confirmed presence of a Union quarantine pest (PHN)

In the case of a food or feed risk, the risk evaluation should be performed based on the hypothesis that the product is available to the consumer and that exposure occurs, even if the product notified is not actually available to the consumer**.** If the product is not a consumer product but a raw material or intermediate product, then the risk evaluation should factor in any processing step eliminating the hazard or reducing exposure, e.g. through a critical control point in a HACCP plan. Thereby the finding of e.g. a pathogenic micro-organism in a raw material at a manufacturer may result in a "no risk" decision if there is a

controlled eliminating processing step and cross-contamination to other products cannot occur. Processing, storage or transport steps may reduce the exposure and therefore the risk but may potentially also increase it (e.g. mycotoxins level rising during storage).

Information about the risk evaluation and the risk decision are recorded in the risk section of the notification. The actual risk is reflected in the notification classification, which also takes into account the possible distribution of the product on the market (distribution status, 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 SCP should however always verify if the risk evaluation is valid for the notification concerned. The risk evaluation should include references to the information on which it is based. The risk evaluation can include data from analytical reports. For chemical contaminants, EFSA has worked out an online tool (RACE, Rapid Assessment of Contaminant Exposure) that calculates the exposure and compares it to available health-based guidance values for a quick evaluation of the risk. It allows comparing exposure for consumers belonging to different consumer groups or countries. More info is available in the EFSA webinar or the EFSA report concerning the RACE tool.

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.

As an instrument for guidance and consistency, the ECCP has compiled a repository of risk evaluations in the RASFF network, based on previous notifications: the risk evaluations glossary (REG).

ACN SOP 3 – Preparing an original notification

Article 15

Information exchanged in iRASFF

1. Information exchanges between alert and cooperation network contact points for the purposes of Article 50 of Regulation (EC) No 178/2002 and Title IV of Regulation (EU) 2017/625 shall be made in iRASFF only and in the form of notifications, requests and responses.

2. The alert and cooperation network contact points shall complete the relevant fields of a notification to enable clear identification of the product, risk(s), instances of non-compliance and suspected fraud concerned, provide traceability information where possible and identify contact points responsible for any follow-up to a notification or response to a request.

3. Notifications may be transmitted in the form of original or follow-up notifications.

4. Requests and responses shall indicate the alert and cooperation network contact point(s) to which the request or response is addressed.

1. SCOPE

This SOP provides guidance on how an original iRASFF notification should be prepared including sources of information, what templates to use, what documents to collect etc. For specialised networks e.g. the FFN, the "SCP" should be read as "FFCP" etc. For a specific competence e.g. on animal health, for which no specialised network is set up, the SCP may delegate certain responsibilities to a liaison body for this competence.

2. GUIDANCE FOR PREPARING A NOTIFICATION

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

(2) The SCP may contact other network members in order to collect information required for the notification but should not delay the notification because of unsatisfactory or lack of reply. It is recommended to use the built-in conversation module in iRASFF to make any requests for information once the notification is shared with other network members.

(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, for the AAC/RASFF network, the "offline" template should be used (downloadable from Teams/SharePoint). The SCP must ensure that all essential information is entered in the notification. Practical advice on using 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 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 or shared with other members be filled as far as possible in English, especially fields such as hazard, name and description of the product, risk evaluation, 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 RASFF 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 is always filled and that a decision is made as to what risk the notification presents. If it concerns a hazard or hazards for which no guidance is available in SOP 2 or if the risk decision requires explanation, summary information should be entered in the "Motivate risk decision" box and, if necessary, documents attached to demonstrate the risk decision made.

(6) The notifying member should always inform about the measures it has taken with regard to the product(s) concerned or explain why it has not (yet) taken any measures. If the measures taken restrict the placing on the market of the product, it should be made clear to what effect and which products are exactly concerned.

(7) Official (e.g. analytical reports) and commercial (e.g. delivery note, invoice) documents are very helpful for other network members and should in principle be attached to the notification. Efforts should be made to ensure that the legibility of the documents is sufficient. 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, personal data) should be blackened in the documents. 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. **The addition of such documents nevertheless does not discharge the SCP from filling in the proper fields in the structure of the**

notification template. This is particularly important for notifications that have the potential to grow out to a complex collection of data and documents.

(8) Particular attention should be given to providing information on the origin of the product. This includes foremost the country of origin and the consignor, but more precise information can be crucial for the country of origin, such as consignment/lot number(s), article code(s), certificates or invoices etc. In the case of a non-member country of origin, operator approval or registration numbers, information on health or phytosanitary certificate(s), border check(s) etc.

(9) When appropriate and whenever possible, a separate recipients list using the template (downloadable from Teams/SharePoint) provided by the ECCP should be attached for each country the notified product has been distributed to. Recipient lists should be as detailed and complete to facilitate action in a recipient country.

(10) For notifications reporting on unauthorised GM food or feed, the GMO-annex, completed by the laboratory that performed the analysis, should be added to the notification. For notifications reporting on shigatoxin-producing or enteropathogenic *Escherichia* coli, the STEC-annex should be filled in and added to the notification. Both templates are downloadable from Teams/SharePoint.

(11) Wherever possible, copies of laboratory reports should be obtained and these can be transmitted along with the notification (or if necessary as follow-up) 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.

(12) All attached documents should be digital wherever possible or scanned copies of original if a digital copy is unavailable. Copies of poor quality (too heavily compressed, low resolution or pale) should be avoided.

(13) 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 for ACN notifications in the IMSOC Regulation, exact details of the product including name, batch details, durability date, pack size and packaging description (where appropriate) 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 iRASFF. For a NC notification, the information should be sufficient to enable a good understanding of the possible non-compliance and any actions that should be undertaken to investigate and remediate it.

(14) Where some information is not available immediately, such as full distribution details, the known information should be presented in the

notification with an additional note (possibly in the form of a conversation) indicating what further information is to follow.

(15) Before validating the notification, the SCP should make final checks to ensure the accuracy and completeness of the document, in particular that all the information is coherent (e.g. that information in the notification form corresponds with the attached documents as regards weights, batch numbers, delivery dates etc.); that 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 RASFF notifications, provided that the missing information is supplemented as soon as possible by means of a follow-up notification.

(16) **E-commerce**

The registration (and authorisation) requirements for agri-food business operators apply to e-businesses in the same way as to stationary businesses. iRASFF should be used to notify **online offered products** which raise health concern or which are suspected to be subject of non-compliances or fraud (no health concern) in the same way as for products which are traded via conventional routes. It is possible to report the notification as "e-commerce related". In this case, information about "Internet search performed" (for this product) and sampling by "online purchase" can be added. Also, operator types "e-platform/e-marketplace" and "e-trader" have been created for which several fields allow to provide additional information like URL, website owner, address and email of website owner, and screenshots can be added.

To this end, members of the network

- should notify online offered products which raise health concern in RASFF, according to Article 50 of Regulation (EC) No. 178/2002,
- should send follow-ups to existing RASFF notifications if new online-related information becomes available,
- should report non-compliance to the hosting marketplace and inform other members and the ECCP about any difficulties in communicating with cross-border operating e-platforms.

Sellers might offer products to EU consumers from outside the jurisdiction of the network members. In case of non-compliance, the network members may rely on the administrative assistance of non-member country authorities[27] in order to cease the offer and delivery to EU consumers. In case the non-compliant offer constitutes a risk to public health, it should be notified in RASFF.

[27] Not supported through the rules on administrative assistance in the OCR nor in iRASFF

3. ROLE OF THE SCP

Before validating the notification, the SCP should ensure that the proper risk decision is entered as well as the proper notification classification (into alert, information for attention, information for follow-up, border rejection, non-compliance or news). It should share the notification with the countries/members involved in the notification for attention or for follow-up (if it wants that country/member to react) and decide whether the notification should be escalated to the ECCP (see SOP 5) as a RASFF notification. The ECCP verifies the risk decision and classification of a RASFF notification and consults the notifying SCP with the aim of reaching agreement if its risk decision differs from the one proposed by the notifying SCP and that would lead to a different classification.

ACN SOP 4: Preparing a follow-up notification

Article 22

Follow-up notifications

1. Where an alert and cooperation network member has additional information relating to an original notification, the contact point(s) concerned shall immediately transmit a follow-up notification to that network.

2. Where a contact point referred to in paragraph 1 has requested follow-up information relating to an original notification, the alert and cooperation network shall be provided with such information to the extent possible and without undue delay.

3. Where a RASFF network member takes action on receipt of an original notification in accordance with Article 50(5) of Regulation (EC) No 178/2002, its contact point shall immediately transmit a detailed follow-up notification to the alert and cooperation network.

4. Where the action referred to in paragraph 3 consists of detaining a product and returning to a dispatcher in the country of another RASFF network member:

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

(b) the other network member shall provide information in a follow-up notification on the action taken on the returned product.

5. By way of derogation from paragraph 1, where a follow-up notification changes the classification of an original notification to an alert or an information notification, the alert and cooperation network member shall submit it to the Commission contact point for verification and transmission to the alert and cooperation network contact points within the delays laid down in Article 17 or Article 18.

1. SCOPE

According to Article 2(23) of the IMSOC Regulation, a 'follow-up notification' is a notification in iRASFF 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. Through the legal basis of the IMSOC Regulation, the guidance regarding follow-up notifications applies to notifications following the AAC procedure (all notifications except RASFF) in addition to the RASFF procedure. Requests and responses (inside a conversation) can be considered a part of the follow-up notification in the AAC procedure. Follow-up notifications to a RASFF notification however will only be considered follow-up to the RASFF (part of the) notification if they are accessible to all members of the network.

2. WHEN TO ISSUE A FOLLOW-UP NOTIFICATION

(1) A follow-up notification is particularly useful for other members of the network handling the notification to add information from the outcome of their investigation or about measures taken. This is the case if the product was distributed to or originated from another member country. If information in the original notification was incomplete or incorrect, it is advised to be completed or corrected by the country that has gathered that information (e.g. after a request made in a conversation).

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 through the conversation module and monitored by the ECCP. Details of this system are set down in WI 4.1. but currently only apply to RASFF notifications. AAC and fraud notifications' flagging occurs exclusively through the conversation module.

(2) In application of Article 22(2) of the IMSOC Regulation, when an SCP has been requested by the ECCP or by another contact point to provide information in the form of a response to a request in a conversation or as a follow-up to a notification, the SCP concerned should reply without undue delay in order not to delay the necessary action following the notification. If the information is unavailable, the SCP 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[28] in the context of a recall or withdrawal, the requesting member of the network may be asked to provide a justification of its request in case it concerns an information or non-compliance 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 non-member countries). If the

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

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 a RASFF notification by a member country in order to inform the members of the network and in accordance with Article 22(3) of the IMSOC 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 non-member countries or international organisations. If the ECCP receives follow-up information from business operators or from business operator associations, it will first consult the SCPs 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. For notifications in RASFF/AAC, if the original notification is not available in iRASFF, the offline notification template (downloadable from Teams/SharePoint) 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 notifications, 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 in iRASFF using the AAC procedure, meaning that in case of in a RASFF notification, escalation of the follow-up notification is not always needed. Nevertheless, the SCP should always consider carefully if the information contained in the follow-up notification should not be escalated.

The AAC procedure in iRASFF must include flagging another member for follow-up or for attention using a conversation to make sure that the information or request is made known to the other party (see SOP 5 for more information). If structured information or documents are to be added, then a follow-up notification should be created in addition to the conversation. If the information is of an unstructured nature (contrary to e.g. traceability, sampling or measures data) or requires reply/response coordination, then a conversation may be sufficient.

ACN SOP 5: Transmitting a notification using the "RASFF" procedure and the "AAC" procedure

1. SCOPE

This SOP provides guidance about what steps need to be taken from when an iRASFF notification is completed to when the notification is received by the ECCP, including the applicable time-limits. It also clarifies specific steps taken for an NC notification and how it differs from a RASFF notification.

2. TIME-LIMITS WITHIN WHICH A NOTIFICATION IS TRANSMITTED IN THE ACN, AS SPECIFIED IN THE IMSOC 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 (IMSOC Regulation Art. 17)
- non-compliance notifications, information notifications, border rejections and fraud notifications without undue delay (IMSOC Regulation Art. 16, 18, 20 and 21).

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

- immediately whenever the network member has any additional information of relevance to other members of the network (IMSOC Regulation Art. 22(1))
- immediately when action is taken following a RASFF notification (IMSOC Regulation Art. 22(3))
- without undue delay upon request of another network member (IMSOC Regulation Art. 22(2))

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

3. VALIDATING THE NOTIFICATION

Before transmitting or sharing the notification, the SCP should verify and validate the notification to ensure its compliance with regard to the criteria for notification. In particular, the SCP 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?

A. the RASFF procedure

RASFF notifications can only be transmitted through iRASFF although it is possible to create a draft notification from a rejected CHED through importing from TRACES (NT) with the

“notify RASFF” feature. Email is only used if iRASFF 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 SCP. It is possible that there is no direct transmission from originator to SCP 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 (national and regional level), the iRASFF notification is transmitted to the SCP via iRASFF.

(2) iRASFF ensures a safe and reliable transmission of the notifications. In case a notification is not validated by the ECCP within the set time or the SCP has doubts about its correct transmission in iRASFF, the SCP should enquire with the ECCP. In case iRASFF is not available and the notification is sent using email, the SCP 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 if necessary. 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) 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.

(5) After validation, the SCP should indicate which members should provide follow-up to the notification and which other members are concerned, through a conversation in iRASFF in which members are added as “participants”, flagged for follow-up or for attention. After this, the SCP immediately transmits the notification to the ECCP via iRASFF (*escalate* function) or via e-mail (for urgent notifications if iRASFF is unavailable).

(6) Outside office hours, the transmission of an alert notification or follow-up to an alert notification presenting a serious health risk and flagging one or more other network members for follow-up should be accompanied by a phone call

to the ECCP's emergency RASFF phone number. Whenever transmission is not possible through iRASFF, email is used and the out-of-office procedure is activated. When transmission in written form is exceptionally not immediately possible, essential 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 presenting a serious risk and flagging their country for follow-up, 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 SCP. This list is published on Teams/SharePoint and updated at least monthly. SCPs should inform the ECCP immediately of any change in the emergency contact information.

B. the AAC procedure

NC notifications are only to be introduced in iRASFF. The general requirements regarding quality and completeness of the information provided are the same as for RASFF notifications (see also SOP 3). NC notifications require a validation at the national level in iRASFF. This validation is not required to be carried out by the SCP and can be done by a liaison body. That liaison body will then have to be accorded validator role in iRASFF at the national level. In order to avoid a potential clash between multiple liaison bodies configured for the same network member in which case one liaison body would have full access to notifications made by another liaison body, liaison bodies can be configured instead on the regional level. In such a configuration however, a liaison body cannot share a notification directly with a liaison body of another network member but will have to submit to the SCP and require the SCP to validate and share the notification with the other network member. This is obviously not the case for the specialised networks, where the liaison bodies are specifically identified in their own network. This means that notifications at national level of a specialised network can only be validated by a validator belonging to that network.

The AAC procedure is characterised by the possibility to share a notification, after validation at the national level, between network members. There is no involvement of the ECCP in this procedure, although the ECCP has read-only access to shared notifications for monitoring purposes. The notifying member shares the notification with identified network members. For each network member with whom the notification is shared, a flag is set in the conversation sharing the notification. A flag "for attention" means that no specific request for information or action is made. A flag "for follow-up" indicates that the network member is requested for particular information or action concerning this notification. The precise requests are formulated as messages in the conversation. Responses or holding replies are also posted as messages in the conversation. More information on working with conversations in iRASFF is given in the iRASFF user manual.

5. CLASSIFICATION

Before validating an original notification, the SCP (or liaison body if appropriate) classifies the notification in accordance with the definitions given in the IMSOC Regulation, Article 2 (see WI 5.2. "guidance for the classification of a notification") as RASFF (RASFF procedure) or as a "non-compliance notification" or “fraud notification” (AAC procedure). Notifications in the specialised networks can be of specific types, not defined in the IMSOC Regulation. If the SCP 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 IMSOC Regulation and the criteria laid down in this SOP.

6. WHEN TO FLAG A COUNTRY?

Before transmitting or sharing a notification, the notifying member indicates which other network members are concerned and are expected to react, through a conversation. These network members are then flagged for follow-up or for attention in the conversation, depending on whether there is a specific request for them. The ECCP can additionally flag members in the notification e.g. when distributing a RASFF notification. When e.g. 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 any time at a later stage. More guidance on a harmonised flagging of network members in the context of RASFF is given in WI 4.1.

ACN SOP 6: ECCP tasks

Article 24

Verification and publication of notifications

1. The Commission contact point's verification of notifications shall cover:

(a) the completeness and legibility of the notification;

(b) the correctness of the legal basis supporting the notification; however an incorrect legal basis shall not prevent transmission of the notification if a risk has been identified;

(c) whether the notification falls within the scope of the RASFF network;

(d) whether the essential information in the notification is provided in a language that the alert and cooperation network contact point will easily understand;

(e) compliance with this Regulation;

(f) possible recurrences of the same operator and/or hazard and/or country of origin.

2. By way of derogation from paragraph 1, verification of non-compliance, fraud and border rejection notifications shall cover points (b), (c) and (e) of that paragraph.

3. Once the Commission contact point has verified a notification in accordance with paragraph 1 or 2, it may publish a summary of alert, information, border rejection and non-compliance notifications, with information on the classification and status of the notification, the product and risk(s) identified, the country of origin, the countries in which the product was distributed, the notifying network member, the basis for the notification and the measures taken.

1. SCOPE

This SOP describes how the ECCP verifies the iRASFF notifications and what actions it may take following this verification.

2. RECEPTION OF iRASFF NOTIFICATIONS

The iRASFF notification becomes available to the ECCP either through:

a) a conversation flagging the ECCP (automatically) for attention. The ECCP will verify the notification.

b) a conversation flagging the ECCP for follow-up. The ECCP will verify the notification and provide reply to the request in the conversation.

c) SCP escalating the notification to the ECCP as a RASFF notification. 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 SCP immediately, by declining the escalation of the notification and giving the reasons therefore. The ECCP will then verify the notification's subject, risk decision and classification and will give priority to alert notifications and their follow-up. Should the ECCP not agree with the given risk decision based on the information provided, and that would lead to a different classification, it will contact the SCP immediately (using the conversation module in iRASFF) 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 24 of the IMSOC 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 the IMSOC Regulation and these SOPs.

(2) The ECCP may provide feedback about its verification to the SCP 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 RASFF NOTIFICATION

The ECCP will check the recurrence of hazards and operators identified in a RASFF 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 and that particular product category 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 a RASFF notification is followed.

A. Email- based procedure

The ECCP encodes essential information from the notification in the RASFF (Microsoft Access) database in English, supplemented with information resulting from its verification. The ECCP will verify the countries flagged by the SCP in the notification and will ensure that the proper countries are flagged for follow-up and for attention in the database as well as in the iRASFF notification. A daily table of notifications is sent to all SCPs 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. If iRASFF is unavailable, the ECCP compiles PDF versions of the iRASFF notifications and compiled with all attached documents, At the end of the day, in case of inavailability of iRASFF, SCPs will receive a “daily zip” file in Teams with all notifications in PDF format. 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 a notification email to all SCPs. This email will normally not contain the notification details in PDF format unless iRASFF is unavailable.

B. iRASFF-based procedure

(1) The ECCP receives RASFF notifications escalated by the SCP in its task list as well as through a notification mail generated by iRASFF. Considering that not yet all functions of the system described under heading A are taken over by iRASFF, the ECCP will continue to encode in the RASFF database. However, preparation of PDF file as described in system “A” is only done when required if iRASFF is offline (backup function) or to inform a non-member country not subscribed to RASFF Window. Further development of iRASFF will allow to progressively abandon system "A" in favour of iRASFF.

(2) If the notification is considered incomplete, the ECCP can request additional information in iRASFF through a conversation, after which the SCP can complete the notification by escalating a follow-up notification. The ECCP can delay validating the notification if it does not agree with certain elements in the notification that it may request the SCP to modify first. The ECCP can also decline escalation 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 performs these changes as a follow-up to the notification, which ensures full transparency of what information was changed, added or removed.

(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 *notify* function in iRASFF. Flagged countries receive an email about the notification and are flagged in daily and weekly overview table for follow-up or for attention.

C. TRACES-based procedure

(1) TRACES NT provides an option to insert a draft notification in iRASFF on the basis of a rejected CHED. The SCP should take every care to ensure that the resulting RASFF notification is as complete as possible and contains minimally the essential information that every RASFF notification should contain: identifying hazards found, product, batch and operators concerned. If such information is lacking it should not validate or escalate the notification in iRASFF.

▼B

Article 25

Notification withdrawal and amendments

1. Where the action to be taken appears to be based on unfounded information or the notification was transmitted erroneously, any alert and cooperation network contact point may ask:

▼M1

(a) a notifying contact point to withdraw a non-compliance, fraud or follow-up notification;

▼B

(b) the Commission contact point, with the agreement from the notifying contact point, to withdraw an alert, information, border rejection or news notification.

2. Any alert and cooperation network contact point may request amendments to a notification with the agreement of the notifying contact point.

3. A follow-up notification shall not be considered an amendment to a notification and may therefore be transmitted without the agreement of any other network member, unless such follow-up notification changes the classification of the notification.

5. WITHDRAWAL OF AN iRASFF NOTIFICATION

(1) In accordance with Article 25(1) of the IMSOC Regulation, any member of the network can ask for withdrawal of a RASFF notification, for one of 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.

Supplementary information derived from additional investigations revealing that the notification does not present a health risk in the scope of RASFF is not a valid reason to withdraw the notification. In such case the notification may be closed instead of withdrawn, unless such information demonstrates that errors were committed in the findings or conclusions of the original

notification, or that the original notification did not meet the relevant criteria for a RASFF notification.

(2) With the request for withdrawal of a RASFF notification, 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) Non-compliance notifications or fraud notifications may be withdrawn by the notifying member at any time, but it is strongly recommended that the notifying member provides information on the reason for withdrawal.

(4) 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.

(5) 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.

(6) If it concerns withdrawal of an original RASFF notification, the summary of the follow-up notification containing the reason for the withdrawal is made available through RASFF Window. The follow-up notification is then also made available to any non-member country concerned by the notification. Only the ECCP can withdraw an EC validated RASFF notification by changing the notification status to "withdrawn". In iRASFF, the “withdrawn” status currently only exists for original notifications.

(7) Immediately following the notification withdrawal, SCPs should ensure that concerned business operators are notified of the notification withdrawal if it has any possible effect or consequence for them.

Article 27

Exchange of information with third countries

1. Where an alert, information or border rejection notification concerns a product originating in or distributed to a third country that does not have access to iRASFF or TRACES, the Commission shall inform that third country without undue delay.

▼M1

2. Where a non-compliance or fraud notification concerns a product originating in or distributed to a third country that does not have access to iRASFF or TRACES, the Commission may inform that third country.

6. DISTRIBUTION OF RASFF NOTIFICATIONS TO NON-MEMBER COUNTRIES

(1) iRASFF does not yet include a facility to make available a notification to a non-member country. The distribution of the RASFF notifications depends on a system involving iRASFF 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 shares the necessary information with concerned non-members, to enable them to investigate and take action. 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). The procedure involves the RASFF database (emails to non-member countries' EC Delegations), iRASFF (notification sharing) and RASFF Window (front end UI for non-members).

(3) In iRASFF, the ECCP makes summaries of follow-up notifications of relevance to the non-member country and makes specific files attached to the notification available to the non-member country(ies) to facilitate its/their investigations. If necessary, the ECCP will edit unnecessary information or information which is commercially sensitive or is covered by professional secrecy out of the files before sharing them. To this end, the ECCP uploads any redacted files to the notification to iRASFF, resulting in both the original file (not shared with non-members) and the redacted file (shared with non-members) being present in the notification.

(4) If the country and the EC Delegation in the country are not subscribed to RASFF Window, the PDF files of the original notification and selected follow-ups that contain information of importance to the country in question are sent by email to the country in question or its EC Delegation. Where there

is information which is commercially sensitive or is covered by professional secrecy, it is removed as far as possible.

A. RASFF Window-based procedure

After ECCP validation of the notification, the details are synchronised with RASFF Window and will be available to non-member users that have login credentials for RASFF Window. There also the files and documents previously shared by ECCP can be downloaded. Based on selecting the country as origin, recipient or location of an operator, the users belonging to that non-member country will be automatically notified by email. The ECCP may also manually notify them in iRASFF if necessary.

The non-member SCP controls who has access to RASFF Window in its organisation. The SCP can be a contact point assigned by the non-member country itself or for some countries, the EC Delegation in the country in question. The authorised users can log onto RASFF Window and download the newest notifications. Only notifications concerning their country can be downloaded[29].

The SCP has the responsibility to inform the appropriate competent authorities in their countries about new original and follow-up notifications received. By replying to the notification emails, the SCPs have the possibility to provide feedback on their investigations and measures taken as well as to request information or actions by member countries. If appropriate, the ECCP transmits such feedback through the RASFF network as a follow-up notification.

B. Email-based procedure

In case the non-member country concerned is not using RASFF Window or in case RASFF Window is unavailable, the ECCP can send an email containing the notification's PDF file(s) (if necessary or appropriate) and send it to the SCP assigned for that country. Failing such SCP, the ECCP can request the EC Delegation in the country to forward the notification to the appropriate authority. The non-member country can provide feedback to the SANTE RASFF mailbox, which the ECCP can transmit as follow-up notification as per the procedure described under A.

[29] Access is given if a country is entered as country of origin or recipient country or if an operator is located in that country. It is important that the country is entered in the traceability section and not in a free text field.

Article 26

Closure of a notification and storage period of personal data

1. A notification is automatically closed in iRASFF if:

(a) no follow-up requests are pending; or

(b) all requests have received a response; or

(c) no response to the last request is provided within 6 months of its transmission.

2. Personal data from closed notifications shall be stored for no longer than 10 years.

7. CLOSING A RASFF NOTIFICATION

Alert notifications in particular, 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 RASFF notification receives the "closed" status.

8. CLOSING AN AAC- TYPE NOTIFICATION

For a notification following the AAC procedure, there is no such coordination by the ECCP. An AAC-type notification is considered closed when all follow-up flags, set in the various conversations inside the notification, are closed.

9. WEEKLY REVIEW OF IRASFF NOTIFICATIONS

At the start of a new working week, the ECCP runs a weekly report of the previous week and verifies the RASFF 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 RASFF notification. Flagged countries and requests to SCPs are verified as well and additional requests may be made to SCPs in the course of this review. 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 what risk decision was made by the ECCP (which may differ from the one in iRASFF, insofar it does not affect the notification's classification).

NC notifications are subject to a less detailed screening. After finalisation, the report is distributed to the SCPs via Teams/SharePoint. A similar report on fraud notifications and other ACN notifications which had been identified as possibly concerning fraud is made available to the FFN on iRASFF.

The Commission (DG AGRI) weekly screens the three components (EU Alerts, INEU, INTC) of OFIS (Organic Farming Information System). and informs DG SANTE about OFIS cases that might need RASFF follow-up. DG SANTE carries out an assessment and if notification to RASFF is required, DG SANTE informs the RASFF SCP. The ECCP screens iRASFF for organic products and informs DG AGRI on a weekly basis.

ACN SOP 7:
Distribution of iRASFF notifications received from the ECCP (RASFF procedure) or from a liaison body (AAC procedure)

1. SCOPE

This SOP describes how the SCPs receive the notifications from the ECCP (RASFF procedure) or how a liaison body receives the notifications from other liaison bodies (AAC procedure) and gives advice on how to distribute them to the relevant competent authorities within their jurisdiction.

2. RECEPTION OF THE NOTIFICATIONS

(1) A RASFF- or AAC-type notification containing all details is made available in iRASFF. Depending on the status of the notification, it will be available to the user or not. A RASFF notification validated by ECCP is available to all users. An AAC-type notification is made available to other liaison bodies by sharing the notification through a conversation.

(2) The ECCP informs all SCPs directly by way of email of any RASFF alert notifications and urgent follow-up RASFF notifications.

(3) Each CP or liaison body should have at least one user ID and password to iRASFF. See WI 7.1 for further details.

(4) Notifications for which the member of the network is flagged (for follow-up or for attention) are made available in its dashboard and an automated mail is sent from iRASFF.

(5) The ECCP sends daily overviews of original RASFF notifications and of follow-up RASFF notifications to the functional mailbox of the SCP. Weekly overviews of RASFF notifications and of NC notifications are made available via Teams/SharePoint. The weekly overview of fraud notifications and other ACN notifications which had been identified as possibly concerning fraud is shared on iRASFF in the FFN.

3. FILTERING NOTIFICATIONS

(1) The SCP 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 / liaison bodies in the country for their assessment of what action needs to be taken. For specialised networks this function is carried out by the SNCP.

(2) The current version of iRASFF (4.x) supports the SCP in coordinating the "flagged" notifications appearing in the "notifications for follow-up" list to its iRASFF users. The users will find these notifications in the "notifications for follow-up" list, to which they have to react to with a response or with additional information or follow-up notification. The SCP has the option to add guidance or instructions in the form of parent conversations, provided that the liaison bodies have been configured at the regional level in the application.

4. DISTRIBUTING NOTIFICATIONS

(1) Depending on the structure of the competent authorities and the nature of the notification (AAC or RASFF procedure), the SCP 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). It is recommended that these contact points are identical to the liaison bodies that may have been set up for the AAC procedure.

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

(3) As mentioned under 3(2), the SCP can make notifications directly available in iRASFF through the "notifications for follow-up" list provided that the liaison bodies or contact points are configured on the regional level. If all contact points are configured at the national level there will be only one dashboard at the national level shared by the different competent authorities, which could lead to confusion or mistakes.

(4) The SCP should set up a functional mailbox to receive messages concerning iRASFF notifications, able to receive emails of considerable size (at least 5 MB) and should monitor it during office hours (see also WI 5.1).

(5) The following tools are recommended, in order of preference and effectiveness, taking into account a possible temporary inavailability of iRASFF (business continuity):

- iRASFF, adding instructions through conversations linked in the notification;
- intranet or dedicated application to distribute instructions together with iRASFF to download notifications;
- intranet or email instructions combined with downloading information from RASFF Window if iRASFF is unavailable;
- email only if iRASFF or RASFF Window are not available;
- telephone in case sending the information in written form is not possible.

ACN SOP 8: Assessing a notification received from the ECCP (RASFF procedure) or from a liaison body (AAC procedure)

1. SCOPE

The scope of this SOP is guidance for the assessment of a RASFF notification received from the ECCP (RASFF procedure) or from a liaison body (AAC procedure) by the SCP or liaison body, 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 SCP (or liaison body) will carry out an assessment of each notification it has been flagged for. Priority should in principle be given to RASFF notifications and in particular to alert notifications.

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

(a) the nature of the hazard or non-compliance;

(b) the type of product 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 type of check carried out: official control or company own-check

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

(g) details of sampling and analysis carried out, including sampling, laboratory (accredited?) and analytical method (accredited?), analytical result and analytical measurement uncertainty for the original sample taken and any counter sample, counter analysis, referee sample and referee analysis; It is important to check for any such (intended, ongoing or finalised) counter samples/analyses that may invalidate (some of) the hazard/non-compliance findings under (a) under the condition that they are representative of the same quantity of product as the original analysis.

(h) the measures taken.

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

experts to relay the notification. 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 SCP (or liaison body) will ask for further information:

(a) by requesting another contact point or liaison body through a conversation inside the notification or

(b) by requiring the competent authority to contact the business operator(s) concerned by the notification in their territory.

3. FOLLOW-UP ACTIONS

(1) When rapid action is required (RASFF alert), the SCP 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 SCP may consider requesting relevant epidemiological and/or environmental data in order to enable the necessary follow-up action in their country.

(3) For a RASFF notification if flagged for follow-up, the SCP 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, should collate such information and transmit it to the ECCP by way of follow-up to the notification.

(4) For an AAC-type notification, the SCP should require the competent authority acting upon the notification to provide a (holding) response to the request(s) made in the notification within ten working days (OCR Articles 104, 105 and 106) unless a longer deadline was set by the requester.

ACN SOP 9:
Consulting iRASFF notifications; arrangements for personal data protection

1. SCOPE

This SOP sets out guidance on what information can be exported/extracted from iRASFF and gives some advice on good practice on what to do with that information. The SOP also describes the arrangements put in place to ensure that iRASFF is fully in line with the personal data protection rules.

2. INFORMATION THAT CAN BE EXPORTED FROM iRASFF

Information from iRASFF can be extracted through the IMSOC analytics tool or be exported from an individual iRASFF notification:

The print to PDF facility is available to print the whole notification to PDF (including file attachments!) or to print the notification based on one particular follow-up notification. It should be noted that always all notification fields available to the user will be printed to PDF. This means that a notification printed at the same time by persons belonging to different network members or to different levels (regional or national) within a network member may contain different information depending on the status of the follow-up notification(s) integrated in the original notification. This also goes for the "print to PDF" facility for conversations. Obviously, only the conversations available to the user can be printed to PDF.

An XML export is available to export data in fields of the original notification available to the user to XML. An XML schema can be obtained from the ECCP if required.

3. GUIDANCE REGARDING INFORMATION EXPORTED FROM iRASFF

The following points are given as an example of how the requirements of Art. 52(2) of the GFL and of Article 8 of the OCR can be implemented when saving and consulting iRASFF-extracted information outside of iRASFF:

- Only staff officially appointed in authorities of member countries of the ACN can have access to the documents, if required for their official tasks.

- The above persons should be made aware that not all information in iRASFF 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.

4. DATABASES

- For RASFF notifications, the RASFF Window application can be a useful tool to look up notifications and follow-up through the search tool provided. It provides some search options that are not available on iRASFF.

- The data from RASFF Window or iRASFF can be extracted to feed into the CP's database applications. Contrary to iRASFF, from RASFF Window, data can be extracted from a search result (list of notifications). This is not possible for a RASFF Window notification detail, for which users need to resort to the Qliksense tool.

5. PERSONAL DATA PROTECTION ARRANGEMENTS

The IMSOC personal data processing is registered with the European Commission Data Protection Officer's register. For details on the nature of the data and their storage, the IMSOC notification to the register (hereinafter called "IMSOC DPO notification") is referred to.

The IMSOC DPO notification stipulates that the responsibility for ensuring data protection on personal data processed is shared between the Commission and the members of the network, where the Commission is responsible for the technical adequacy and security and for the processing of personal data of the iRASFF users and the members of the network for individuals' personal data (e.g. of business operators or authorised representatives, laboratory operators, inspectors, other officials of competent authorities, described as “data subjects”) that is given in the iRASFF notifications. This is called "joint controllership".

Members of the network are advised to keep the entering of personal data to the necessary minimum and to limit such information as much as possible to the fields that are foreseen to contain such information.

Users of the iRASFF and RASFF Window applications are informed about their rights through the privacy statement published in these applications. Members of the network need to ensure that the individuals, whose data are recorded in iRASFF, are informed on the personal data processed, the nature of the processing, as well as on their rights to access and rectify data concerning them. They should do so the latest immediately after the information is transmitted to the ECCP, by way of a specific privacy statement.

ACN SOP 10:
Confidentiality rules for iRASFF

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.

Official Controls Regulation, Article 8

Confidentiality obligations of the competent authorities

1.Competent authorities shall ensure that, subject to paragraph 3, information acquired when performing their duties in the context of official controls and other official activities is not disclosed to third parties where, under national or Union legislation, that information is, by its nature, covered by professional secrecy.

For that purpose, Member States shall ensure that appropriate confidentiality obligations are established for staff and other individuals employed during official controls and other official activities.

2.Paragraph 1 shall also apply to organic control authorities, delegated bodies and natural persons to which specific official control tasks have been delegated and to official laboratories.

3.Unless there is an overriding public interest in the disclosure of information covered by professional secrecy as referred to in paragraph 1, and without prejudice to situations where disclosure is required by Union or national legislation, such information shall include information whose disclosure would undermine:

(a)the purpose of inspections, investigations or audits;

(b)the protection of commercial interests of an operator or any other natural or legal person; or

(c)the protection of court proceedings and legal advice.

4.The competent authorities, when determining whether there is an overriding public interest in the disclosure of information covered by professional secrecy as referred to in paragraph 1, shall take into account inter alia the possible risks to human, animal or plant health, or to the environment, and the nature, severity and extent of such risks.

5.The confidentiality obligations provided for in this Article shall not prevent the competent authorities from publishing or making otherwise available to the public information about the outcome of official controls regarding individual operators, provided, without prejudice to situations where disclosure is required by Union or national legislation, that the following conditions are met:

(a)the operator concerned is given the opportunity to comment on the information that the competent authority intends to publish or make otherwise available to the public, prior to its publication or release, taking into account the urgency of the situation; and
(b)the information which is published or made otherwise available to the public takes into account the comments expressed by the operator concerned or is published or released together with such comments.

IMSOC Regulation, Article 24
3. Once the Commission contact point has verified a notification in accordance with paragraph 1 or 2, it may publish a summary of alert, information, border rejection and non-compliance notifications, with information on the classification and status of the notification, the product and risk(s) identified, the country of origin, the countries in which the product was distributed, the notifying network member, the basis for the notification and the measures taken.
4. The Commission shall publish an annual report on the notifications transmitted in iRASFF.

1. SCOPE

This SOP describes what kind of information from iRASFF is made public and the circumstances in which it is made public. It further clarifies what information is to remain confidential and what that entails.

2. TRANSPARENCY OF iRASFF INFORMATION

(1) In application of Article 52(1) of the GFL and Article 24(3) of the IMSOC Regulation, 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, through its "RASFF Window" application.

(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 iRASFF 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 made its RASFF Window application suitable to link the RASFF notifications to this kind of information that is published on the web, in particular as regards the "Consumers" page giving a view per member country of RASFF. The SCPs 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) Members of the network have the duty and responsibility to decide what information they will make public and to verify the accuracy thereof while taking into account the requirements of the OCR Article 8(5). For RASFF

notifications, the information they add in certain fields in iRASFF will become available in RASFF Window after ECCP validation. Members of the network can verify this in the public part of RASFF Window.

(5) 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 or non-compliances 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.

(6) An annual report on the notifications transmitted through iRASFF is prepared and published by the Commission for each year's functioning of the system.

3. CONFIDENTIALITY OF iRASFF INFORMATION

(1) Members of the network may publish or refer to the summary information provided in the publicly accessible part of its "RASFF Window" application 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 the GFL or if there is an overriding public interest in accordance with Article 8 of the OCR.

This need could for example 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 the GFL and with Article 8 of the OCR, competent authorities shall not disclose any information included in an iRASFF 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 any information necessary to protect human or animal health or welfare or the environment, 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 before making them available to a business operator. The same applies to any personal data that is not necessary for the business operator to act.

(3) Information covered by professional secrecy may include:

(a) Information covered in Article 8(3) of the Official Controls Regulation

(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 an iRASFF notification or a document exchanged in the context of an iRASFF notification, access to documents rules[30] will apply.

[30] 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.